

METABASIS THERAPEUTICS INC

Form 10-Q

August 07, 2009

[Table of Contents](#)

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 10-Q**

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

**For the quarterly period ended June 30, 2009.**

**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 000-50785**

**METABASIS THERAPEUTICS, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of

incorporation or organization)

**11119 North Torrey Pines Road,**

**La Jolla, CA**

(Address of principal executive offices)

**33-0753322**

(I.R.S. Employer

Identification No.)

**92037**

(Zip code)

**(858) 587-2770**

(Registrant's telephone number, including area code)

## Edgar Filing: METABASIS THERAPEUTICS INC - Form 10-Q

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 submit and post such files). ☐ Yes ☐ No ☐

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

The number of outstanding shares of the registrant's common stock, par value \$0.001 per share, as of August 4, 2009 was 35,157,359.

**Table of Contents**

**METABASIS THERAPEUTICS, INC.**

**FORM 10-Q**

**FOR THE QUARTERLY PERIOD ENDED June 30, 2009**

**TABLE OF CONTENTS**

<u>PART I FINANCIAL INFORMATION</u>	2
<u>Item 1. Financial Statements</u>	2
<u>Balance Sheets at June 30, 2009 (Unaudited) and December 31, 2008</u>	2
<u>Statements of Operations for the three and six months ended June 30, 2009 and 2008 (Unaudited)</u>	3
<u>Statements of Cash Flows for the six months ended June 30, 2009 and 2008 (Unaudited)</u>	4
<u>Notes to Financial Statements (Unaudited)</u>	5
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	13
<u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u>	19
<u>Item 4. Controls and Procedures</u>	19
<u>PART II OTHER INFORMATION</u>	21
<u>Item 1. Legal Proceedings</u>	21
<u>Item 1A. Risk Factors</u>	21
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	36
<u>Item 3. Defaults Upon Senior Securities</u>	37
<u>Item 4. Submission of Matters to a Vote of Security Holders</u>	37
<u>Item 5. Other Information</u>	37
<u>Item 6. Exhibits</u>	38
<u>SIGNATURES</u>	

**Table of Contents****PART I FINANCIAL INFORMATION****Item 1. Financial Statements****Metabasis Therapeutics, Inc.****Balance Sheets****(In thousands, except par value data)**

	<b>June 30, 2009 (Unaudited)</b>	<b>December 31, 2008</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 6,632	\$ 12,599
Securities available-for-sale		9,000
Prepays and other current assets	446	1,091
Total current assets	7,078	22,690
Property and equipment, net	2,908	4,779
Other assets	160	273
Total assets	\$ 10,146	\$ 27,742
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 1,023	\$ 93
Accrued compensation	740	2,439
Accrued liabilities	485	1,798
Deferred revenue, current portion	4,883	5,652
Current portion of long-term debt	216	3,890
Current portion of capital lease obligations	40	26
Total current liabilities	7,387	13,898
Deferred revenue, net of current portion		2,499
Deferred rent	3,200	3,079
Long-term debt		4,658
Capital lease obligations, net of current portion		27
Other long-term liabilities		200
Total liabilities	10,587	24,361
Stockholders' equity:		
Preferred stock, \$0.001 par value; 5,000 shares authorized at June 30, 2009 and December 31, 2008, no shares issued or outstanding		
Common stock, \$0.001 par value; 100,000 shares authorized at June 30, 2009 and December 31, 2008; 35,157 shares issued and outstanding at June 30, 2009 and December 31, 2008	35	35
Additional paid-in capital	197,031	195,640
Accumulated deficit	(197,507)	(192,326)
Accumulated other comprehensive income		32
Total stockholders' (deficit) equity	(441)	3,381
Total liabilities and stockholders' equity	\$ 10,146	\$ 27,742

*See accompanying notes.*



**Table of Contents****Metabasis Therapeutics, Inc.****Statements of Operations****(In thousands, except per share data)****(Unaudited)**

	<b>Three Months Ended June 30,</b>		<b>Six Months Ended June 30,</b>	
	<b>2009</b>	<b>2008</b>	<b>2009</b>	<b>2008</b>
Revenues:				
License fees	\$ 2,953	\$ 173	\$ 4,042	\$ 590
Sponsored research	759	514	1,559	1,039
Other	6,000		6,000	
Total revenues	9,712	687	11,601	1,629
Operating expenses:				
Research and development	3,424	9,667	10,840	19,412
General and administrative	2,879	2,569	5,402	5,088
Total operating expenses	6,303	12,236	16,242	24,500
Income (loss) from operations	3,409	(11,549)	(4,641)	(22,871)
Other income (expense):				
Interest income	2	245	40	643
Interest expense	(558)	(238)	(787)	(414)
Miscellaneous income	207		207	
Total other (expense) income	(349)	7	(540)	229
Net income (loss)	\$ 3,060	\$ (11,542)	\$ (5,181)	\$ (22,642)
Basic and diluted net income (loss) per share	\$ 0.09	\$ (0.34)	\$ (0.15)	\$ (0.70)
Shares used to compute basic and diluted net income (loss) per share				
Basic	35,152	34,244	35,152	32,501
Diluted	35,157	34,244	35,152	32,501

*See accompanying notes.*

**Table of Contents****Metabasis Therapeutics, Inc.****Statements of Cash Flows****(In thousands)****(Unaudited)**

	<b>Six Months Ended June 30,</b>	
	<b>2009</b>	<b>2008</b>
<b>Operating activities</b>		
Net loss	\$ (5,181)	\$ (22,642)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	1,389	1,967
Depreciation and amortization	1,102	1,037
Deferred rent	121	254
Amortization of discount and premium on securities available-for-sale	(32)	(334)
Loss on disposal or abandonment of assets	769	20
Realized gain on securities available-for-sale		(7)
Change in operating assets and liabilities:		
Other current assets	645	(58)
Other assets	113	52
Deferred revenue	(3,268)	(740)
Accounts payable	930	(276)
Accrued compensation and other liabilities	(3,012)	(2,684)
Net cash flows used in operating activities	(6,424)	(23,411)
<b>Investing activities</b>		
Purchases of securities available-for-sale		(14,111)
Sales/maturities of securities available-for-sale	9,000	23,992
Purchases of property and equipment		(427)
Net cash flows provided by investing activities	9,000	9,454
<b>Financing activities</b>		
Issuance of common stock, net	2	9,670
Principal payments on debt and capital lease obligations	(8,545)	(1,056)
Proceeds received from debt		5,000
Net cash flows (used in) provided by financing activities	(8,543)	13,614
Decrease in cash and cash equivalents	(5,967)	(343)
Cash and cash equivalents at beginning of year	12,599	14,141
Cash and cash equivalents at end of period	\$ 6,632	\$ 13,798
<b>Supplemental schedule of noncash investing and financing activities:</b>		
Unrealized loss on securities available-for-sale	\$ (32)	\$ (54)
Accrued debt issuance costs	\$	\$ 202

*See accompanying notes.*





**Table of Contents**

**Metabasis Therapeutics, Inc.**

**Notes to Financial Statements**

**(Unaudited)**

**1. Basis of Presentation**

The accompanying unaudited financial statements have been prepared in accordance with U.S. generally accepted accounting principles ( GAAP ) and with the rules and regulations of the Securities and Exchange Commission ( SEC ) related to a quarterly report on Form 10-Q. Accordingly, they do not include all of the information and disclosures required by GAAP for complete financial statements. The balance sheet at December 31, 2008 has been derived from the audited financial statements at that date but does not include all information and footnotes required by GAAP for complete financial statements. The interim financial statements reflect all adjustments which, in the opinion of management, are necessary for a fair presentation of the financial condition and results of operations for the periods presented. Except as otherwise disclosed, all such adjustments are of a normal recurring nature.

Operating results for the three and six months ended June 30, 2009 are not necessarily indicative of the results that may be expected for the year ending December 31, 2009. For further information, see the financial statements and notes thereto for the year ended December 31, 2008 included in our annual report on Form 10-K filed with the SEC.

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 as well as disclosures of contingent assets and liabilities at the date of the financial statements. Estimates also affect the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

The terms Company and we and our are used in this report to refer to Metabasis Therapeutics, Inc.

**2. Going Concern**

As of June 30, 2009 the Company's accumulated deficit totaled \$197.5 million. In July 2009, the Company entered into an agreement with a third party to sell its laboratory and office equipment under which the Company is entitled to receive a minimum of \$1.5 million in proceeds through October 2009 as the assets are sold, subject to reduction in the event of earlier termination of the agreement. In addition, in July 2009 the Company terminated its lease for its corporate headquarters (see Note 11), thereby reducing its future cash operating needs. Based on the current operating plan, after considering the impact of these recent transactions, and together with the cash available at June 30, 2009, the Company expects its existing working capital to fund the current operating plan through December 2009. Excluding the \$1.5 million in proceeds from the agreement to sell its laboratory and office equipment, the Company expects its existing working capital to fund the current operating plan through September 2009. The Company intends to obtain additional resources through the licensing or selling of some, or all, of its product pipeline and potentially through other strategic alternatives, which may include the sale of some or all of its assets or an equity financing. In the event the Company is unsuccessful in the near-term in its efforts to secure additional resources, such as from the proceeds from the sale of its equipment or otherwise, it will be required to cease operations entirely. These conditions raise substantial doubt about the Company's ability to continue as a going concern. The accompanying financial statements have been prepared on a going concern basis that contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The financial statements do not include adjustments to reflect the possible future effects on the recoverability and classification of recorded assets or the amounts of liabilities that might be necessary should the Company be unable to continue as a going concern.

**3. Debt**

In March 2008, the Company entered into a Loan and Security Agreement ( Agreement ) with Oxford Corporation ( Oxford ), pursuant to which Oxford provided the Company with a three-year, \$5.0 million term loan accruing interest at an annual rate of 9.83%. The Company paid a facility fee of \$50,000 upon signing of the term sheet and is required to pay an additional fee of \$200,000, at the earlier of a prepayment of the loan in full or the end of the three year term. In addition, the Company obtained equipment loans with Oxford accruing interest at annual rates ranging from 8.0% to 12.85%. The loans were collateralized by the general assets of the Company, excluding intellectual property.

## Edgar Filing: METABASIS THERAPEUTICS INC - Form 10-Q

On May 26, 2009, the Company was notified by Oxford that the material adverse change and insolvency events of default under the terms of the Agreement had occurred, which required full payment by the Company of all amounts due to Oxford, totaling \$7.2 million. On May 26, 2009, the Company paid Oxford the outstanding principal and interest due, totaling \$6.8 million. On May 28, 2009, the Company and Oxford amended the Agreement to release the Company from any obligation to pay the prepayment penalty of \$236,000 under the Agreement, and providing new terms for the remittance to Oxford of the remaining loan balance of \$200,000. The new terms require payment of the remaining \$200,000 in full, including accrued interest at a rate of 14.83%, on June 1, 2010, provided that pro-rata portions of the remaining \$200,000 plus accrued interest will become due earlier upon the occurrence of certain Company funding events. On June 11, 2009, the Company paid Oxford all outstanding amounts due under the amended Agreement.

**Table of Contents**

In accordance with Emerging Issues Task Force ( EITF ) No. 02-4, *Determining Whether a Debtor's Modification or Exchange of Debt Instruments is within the Scope of FASB Statement ( SFAS ) No. 15*, we determined that the amendment of the Agreement on May 28, 2009 met the criteria of a troubled debt restructuring requiring the impact of the modifications to the Agreement to be accounted for in accordance with SFAS No. 15. After giving effect to the prepayment of the principal and interest on the outstanding loan amounts, the debt obligation totaled \$436,000 (consisting of the \$200,000 final payment and the prepayment penalty) payable at a rate of 9.83% annually immediately prior to the restructuring. The restructured loan totaled \$200,000 in principal payable at an annual rate of 14.83% and provided for the release of the prepayment penalty of \$236,000. We evaluated the revised terms under the amended Agreement and determined that the effective borrowing rate on the restructured debt was less than the effective borrowing rate on the debt immediately prior to the amendment. In accordance with SFAS No. 15, the Company recognized a gain of \$207,000 for the three and six months ended June 30, 2009, representing the excess of the carrying amount of the debt prior to the restructuring over the future cash payable under the terms of the restructured debt.

**4. Comprehensive Loss**

Statement of Financial Accounting Standard ( SFAS ) No. 130, *Reporting Comprehensive Income*, requires that all components of comprehensive income (loss), including net income (loss), be reported in the financial statements in the period in which they are recognized. Comprehensive income (loss) is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources. The Company's comprehensive income (loss) is as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2009	2008	2009	2008
Net income (loss)	\$ 3,060	\$ (11,542)	\$ (5,181)	\$ (22,642)
Unrealized loss on available-for-sale investments		(57)	(32)	(54)
Comprehensive income (loss)	\$ 3,060	\$ (11,599)	\$ (5,213)	\$ (22,696)

**Table of Contents****5. Net Loss Per Share**

The Company calculates net income (loss) per share in accordance with SFAS No. 128, *Earnings Per Share*. Basic earnings per share (EPS) is calculated by dividing the net income (loss) by the weighted average number of common shares outstanding for the period, without consideration for common stock equivalents. Diluted EPS is computed by dividing the net income (loss) by the weighted average number of common share equivalents outstanding for the period determined using the treasury-stock method. For purposes of this calculation, common stock subject to repurchase by the Company, options and warrants are considered to be common stock equivalents and are only included in the calculation of diluted EPS when their effect is dilutive. The total number of shares issuable upon exercise of stock options and warrants excluded from the calculation of diluted EPS since they are anti-dilutive were 6,734,213 and 7,381,142 for the three months ended June 30, 2009 and 2008, respectively, and 7,205,710 and 7,168,734 for the six months ended June 30, 2009 and 2008, respectively. There are 5,000 shares issuable upon the exercise of options that are dilutive for the three months ended June 30, 2009 as included below.

	Three Months Ended June 30, 20092008 (in thousands, except per share data)		Six Months Ended June 30, 20092008 (in thousands, except per share data)	
Actual:				
Numerator:				
Net income (loss)	\$ 3,060	\$ (11,542)	\$ (5,181)	\$ (22,642)
Denominator:				
Weighted average common shares:				
Basic	35,152	34,244	35,152	32,501
Diluted	35,157	34,244	35,152	32,501
Basic and diluted net income (loss) per share	\$ 0.09	\$ (0.34)	\$ (0.15)	\$ (0.70)

**6. Collaboration Agreements**

In connection with the Company's business strategy, the Company has entered into various collaboration agreements which provide collaboration partners access to certain know-how, technology and patent rights maintained by the Company in exchange for the rights to participate in the research and under certain terms development and/or co-promotion of products, if successfully developed through these arrangements. Terms of the various collaboration agreements entitle the Company to receive up-front license fees, milestone payments upon the achievement of certain product research and development objectives and royalties on future sales, if any, of commercial products resulting from the collaboration.

In the first quarter of 2009, the Company implemented EITF No. 07-01, *Accounting for Collaborative Arrangements*, which prescribes that certain transactions between collaborators be recorded in the income statement on either a gross or net basis, depending on the characteristics of the collaboration relationship, and provides for enhanced disclosure of collaborative relationships. In accordance with EITF No. 07-01, the Company evaluated its collaborative agreements for proper income statement classification based on the nature of the underlying activity. If payments from collaborative partners are not within the scope of other authoritative accounting literature, the income statement classification for the payments is based on a reasonable, rational analogy to authoritative accounting literature that is applied in a consistent manner. Amounts due from collaborative partners related to research and development activities are generally reflected as sponsored research revenues if the proceeds are provided for research services performed or license fee revenues if the proceeds are provided for rights and access to certain know-how, technology and patent rights maintained by the Company. The adoption of EITF No. 07-01 did not affect the Company's financial position or results of operations, however it resulted in enhanced disclosures for its collaboration activities.

*Roche*

The Company maintains a Research Collaboration and License Agreement with Hoffmann-La Roche Inc., F. Hoffmann-La Roche Ltd. and Roche Palo Alto LLC (collectively, Roche). The collaboration operates as an agreement rather than a joint venture or other legal entity. The Company's HepDirect liver-targeted technology is applied to proprietary Roche compounds to develop second-generation nucleoside analog drug candidates for treating hepatitis C virus. The Company provides a non-exclusive worldwide license to its proprietary know-how and technology to Roche through contracted research and development services during the research phase of this collaboration. By June 2009 a development

## Edgar Filing: METABASIS THERAPEUTICS INC - Form 10-Q

candidate was identified and Roche has assumed all development responsibility. The Company will be eligible to receive up to \$191.0 million in additional payments upon achievement of predetermined preclinical and clinical development events as well as regulatory and commercialization events. Roche will retain full commercial rights for any marketed products resulting from the collaboration and will pay the Company a royalty on net sales of such products.

The Company received a non-refundable upfront payment of \$10.0 million from Roche in August 2008, of which \$8.3 million will be recognized as license fee revenue and \$1.7 million will be recognized as sponsored research revenue. The Company recognizes

**Table of Contents**

the upfront, nonrefundable fee over the period the related services are provided. Amounts received for sponsored research funding for a specific number of full-time researchers are recognized as revenue as the services are provided.

As a result of the Company's restructuring in May 2009 (see note 8), Roche did not extend the research term beyond the first year and the Company accelerated the recognition of the unamortized license fee through the end of the one-year research period in August 2009. On June 1, 2009, the Company entered into a letter agreement with Roche, which provided for the early payment by Roche of a \$2.0 million milestone payment to the Company, on or before June 1, 2009. Pursuant to the letter agreement, the payment of this milestone was accelerated in exchange for certain know-how that the Company is obligated to provide to Roche within 30 days of receipt of the payment. All other terms of the Collaboration Agreement are unchanged and remain in effect. The Company will recognize the \$2.0 million of milestone revenue once all know-how has been transferred. The Company recognized the following revenues and costs related to this collaboration (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2009	2008	2009	2008
License fee revenue	\$ 2,902	\$	\$ 3,939	\$
Sponsored research revenue	425		850	
	\$ 3,327	\$	\$ 4,789	\$
Research and development costs	\$ 182	\$	464	

Deferred revenue of approximately \$4.9 million is reflected on the balance sheet as of June 30, 2009 relating to this collaboration.

*Merck*

The Company maintains a collaboration agreement with Merck & Co. ( Merck ), to research, develop and commercialize novel small molecule therapeutics with the potential to treat type 2 diabetes, and potentially other metabolic diseases, by activating an enzyme in the liver called AMP-activated Protein Kinase. The collaboration operates as an agreement rather than a joint venture or other legal entity. The Company is providing research and preclinical services on jointly identified compounds for the potential treatment of type 2 diabetes and potentially other metabolic diseases. Merck is solely responsible for conducting and funding all development work for compounds resulting from this collaboration. The Company maintains an option to co-promote any such product in the United States.

As part of this collaboration, Merck paid an initial non-refundable license fee of \$5.0 million in July 2005 and provided research support funding of approximately \$6.3 million over the three-year research term. The three-year research term is subject to renewal for one additional year upon the parties' mutual agreement. In April 2008, the research term was extended for an additional year, through June 2009. The Company received \$1.5 million over the course of the one year extension to support the research efforts. Under the original collaboration agreement, Merck was also obligated to pay milestone payments if specified preclinical and clinical development and regulatory events occur and pay royalties on sales of any product resulting from this collaboration. If all preclinical and clinical milestones were achieved on multiple indications, and including the \$5.0 million initial, non-refundable license fee and the minimum \$7.8 million in research support funding, the Company would have been entitled to payments totaling up to \$75.8 million, plus royalties.

On June 9, 2009 the Company and Merck amended the License and Collaboration Agreement providing for a one-time, non refundable payment by Merck of \$6.0 million to the Company to satisfy all potential future milestone and royalty payments payable by Merck. All other material terms of the Collaboration Agreement are unchanged and remain in effect. The research period under this collaboration ended on June 30, 2009 and the Company maintains no further material performance obligations to Merck in connection with the License and Collaboration Agreement and therefore recognized the \$6.0 million payment upon receipt in June 2009.

**Table of Contents**

The Company recognizes the upfront, nonrefundable fee over the period the related services are provided. Amounts received for sponsored research funding are recognized as revenues as the services are performed. The Company recognized the following revenues and costs related to this collaboration (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2009	2008	2009	2008
License fee revenue	\$ 51	\$ 173	\$ 103	\$ 590
Sponsored research revenue	334	514	709	1,039
Other	6,000		6,000	
	\$ 6,385	\$ 687	\$ 6,812	\$ 1,629
Research and development costs	\$ 338	\$ 610	860	1,285

There are no deferred revenues as of June 30, 2009 relating to this agreement.

**7. Offer to Exchange Stock Options**

On January 29, 2009, the Company completed an Offer to Exchange certain outstanding options to purchase shares of the Company's common stock, that were originally granted under the Company's Amended and Restated Equity Incentive Plan and that had an exercise price that is equal to or greater than \$1.50 per share, for replacement options to purchase shares of the Company's common stock (the Offer). Eligible option holders included employees and scientific advisory board members. Subject to the participant's continued service with the Company, 25% of the shares underlying the replacement options vest six months after the date the replacement options were granted and the remaining 75% of the shares vest in equal monthly installments beginning on the date of grant of the replacement options so that the replacement options will be vested in full three years from the grant date of the replacement options.

Upon expiration of the Offer, the Company accepted elections to replace eligible stock options to purchase 1,831,887 shares of common stock, representing 64.3% of the shares subject to options that were eligible to be exchanged in the Offer. As a result, options to purchase 1,831,887 shares of common stock were immediately granted to the participants at an exercise price of \$1.00 per share, in accordance with the terms of the Offer. The closing sales price of the Company's common stock on January 29, 2009 was \$0.47 per share.

In accordance with SFAS No. 123R, the Company accounted for the Offer as a short-term inducement and recognized none and \$83,000 of additional compensation expense during the three and six months ended June 30, 2009, representing the incremental fair value for those options that were exchanged for new options.

**8. Corporate Restructurings**

In November 2008, the Company committed to a restructuring plan that resulted in the reduction of approximately 30% of the Company's workforce. The restructuring was a result of a strategic realignment of the Company to preserve cash and reduce on-going operating expenses. Employees directly affected by the restructuring plan received notification and were provided with severance payments, retention bonuses, where applicable, continued benefits for a specified period of time and outplacement assistance. The Company completed this restructuring plan in March 2009.

In accordance with SFAS No. 146, *Accounting for Costs Associated with Exit or Disposal Activities*, the Company reversed \$0.1 million of charges in the three months ended June 30, 2009 for unused benefits. The Company recognized \$0.1 million for the six months ended June 30, 2009 related to the November 2008 restructuring, all of which were recorded in research and development expense. Since November 2008, the Company incurred restructuring charges of approximately \$1.5 million related to the November 2008 restructuring, of which \$1.2 million were recorded in research and development expense and \$0.3 million were recorded in general and administrative expense. All charges were primarily associated with personnel-related termination costs. The Company did not incur any expense related to contractual or lease obligation or other exit costs. The Company does not anticipate incurring any additional charges related to this restructuring.

## Edgar Filing: METABASIS THERAPEUTICS INC - Form 10-Q

On January 15, 2009, the Company committed to another restructuring plan that resulted in the further reduction of approximately 43% of the Company's workforce. In connection with this restructuring plan, the Company narrowed its research and development activities to focus on its clinical-stage product candidate, MB07811 for the treatment of hyperlipidemia, as well as on advancing its glucagon antagonist program and its second-generation TRß agonist program. Employees directly affected by this restructuring plan received notification and were provided with severance payments, retention bonuses, where applicable, continued benefits for a specified period of time and outplacement assistance. The Company incurred none and \$0.3 million during the three and



## Table of Contents

six months ended June 30, 2009 of impairment charges primarily related to scientific equipment and other assets which were abandoned or disposed of. The Company expects to complete the restructuring plan in the third quarter of 2009.

In accordance with SFAS No. 146, the Company recorded charges of none and \$1.5 million for the three and six months ended June 30, 2009 related to the January 2009 restructuring, of which \$1.3 million and \$0.2 million were recorded in research and development expense and general and administrative expense for the six months ended June 30, 2009, respectively. The Company does not anticipate incurring any additional charges related to this restructuring. All charges were primarily associated with personnel-related termination costs. The Company did not incur any expense related to contractual or lease obligation or other exit costs.

On May 26, 2009, the Company committed to a third restructuring plan that resulted in the reduction of 45 employees, or approximately 85% of the Company's workforce. This restructuring is intended to further preserve cash and reduce ongoing operating expenses, providing the Board of Directors additional time to evaluate strategic alternatives. All research and development activities were discontinued. The seven remaining employees, primarily consisting of the current officers of the Company, will continue to pursue the monetization of its product pipeline and equipment while assisting the Board of Directors in the evaluation of its other strategic alternatives. Employees directly affected by the restructuring plan have received notification. The Company did not incur any material costs related to severance or other personnel related benefits. However, in connection with the cessation of all research and development activities under the restructuring, the Company expects to incur certain contract termination costs (primarily associated with the termination of the Company's facility lease in July 2009), \$0.5 million in impairment charges primarily related to scientific equipment and other assets previously utilized in its research and clinical development activities and \$0.2 million in certain other costs associated with the reduction of the use of its facilities. The Company recorded charges of \$0.2 million for the three months ended June 30, 2009 related to the May 2009 restructuring.

The severance-related charge that the Company expects to incur in connection with the January 2009 restructuring is subject to a number of assumptions, and actual results may materially differ. The increase in the actual amount of restructuring charges incurred of \$1.5 million compared to the originally anticipated amount of \$1.4 million was due to employees remaining with the Company longer than originally planned. The contract termination costs that the Company expects to incur in connection with the May 2009 restructuring is subject to a number of assumptions, and actual results may materially differ. The Company entered into a lease termination agreement with its landlord in July 2009 which will result in material contract termination charges to be recognized in the third quarter of 2009 (refer to Note 11). The Company may also incur other material charges not currently contemplated due to events that may occur as a result of, or associated with, the restructuring plan.

	<b>Employee Severance and Related Benefits</b> (in thousands)
Accrual balance at December 31, 2007	\$
Accruals	1,483
Payments	(901)
Accrual balance as of December 31, 2008	\$ 582
Accruals	1,559
Payments	(2,105)
Accrual balance as of June 20, 2009	\$ 36

The following details the restructuring charges incurred inclusive of severance and related benefits and other costs (in thousands):

	<b>Three Months Ended June 30,</b>		<b>Six Months Ended June 30,</b>	
	<b>2009</b>	<b>2008</b>	<b>2009</b>	<b>2008</b>
Research and development	\$ 43	\$	\$ 1,465	\$

## Edgar Filing: METABASIS THERAPEUTICS INC - Form 10-Q

General and administrative	103	303
	\$ 146	\$ 1,768

**Table of Contents****9. Impairment and Disposal of Long-Lived Assets**

In accordance with SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*, if indicators of impairment exist, the Company assesses the recoverability of the affected long-lived assets by determining whether the carrying value of such assets can be recovered through undiscounted future operating cash flows. An impairment loss is recognized when the carrying amount of the long-lived asset is not recoverable and exceeds its fair value. The impairment charge is recorded as a reduction to the carrying value of the related asset and to operating expense. In the instance where a long-lived asset is to be abandoned it is disposed of when it ceases to be used. The Company revises its estimates for depreciation based on the plan of disposal or when the Company ceases to use such assets.

In connection with the Company's corporate restructuring during the first quarter of 2009, the Company began the process of disposing and/or discontinuing the use of various lab equipment, office equipment and furniture resulting in none and \$0.3 million of impairment charges within research and development expenses for the three and six months ended June 30, 2009.

In connection with the Company's corporate restructuring during the second quarter of 2009, the Company began the process of discontinuing the use of various lab equipment, office equipment and furniture resulting in \$0.5 million of impairment charges of which \$0.4 million and \$0.1 million are recorded within research and development expenses and general and administrative expenses, respectively, for the three and six months ended June 30, 2009. As prescribed by SFAS No. 144, impairment losses on long-lived assets to be held and used are reflected as a permanent write-down of the cost basis of the affected assets. The previously recorded depreciation on the impaired long-lived assets will be eliminated and a new life will be used to determine the depreciation of the revised cost basis of the assets.

The Company utilized quoted market prices to establish the fair value of these assets. These assets are considered a level 2 asset class as defined within SFAS No. 157, *Fair Value Measurements* (SFAS No. 157). The Company utilized quoted prices for similar items in active markets as determined by an independent third party (i.e. broker). Based on the Company's estimated future cash flows, a change in the estimated useful life of these assets was deemed to be seven months (through December 2009). Additionally, as all research and development activities have ceased in May 2009, all depreciation costs will be reflected as costs associated with general and administrative activities.

In July 2009, the Company's management entered into an agreement to terminate the lease for the use of its corporate offices (see Note 11). In connection with this agreement, the Company transferred all leasehold improvements and furniture to the landlord. In addition, the Company entered into an agreement with EquipNet to facilitate the sale of the Company's lab equipment and certain of its office equipment. Pursuant to the terms of the lease termination, the Company will cease to occupy its facilities on January 2, 2010. Pursuant to the terms of the agreement with EquipNet, the sale of the lab and office equipment is expected to be completed in November 2009. The carrying values of the assets as of June 30, 2009 are as follows (in thousands):

Laboratory and office equipments	\$ 1,873
Furniture and fixtures	107
Leasehold improvements	928
	\$ 2,908

**10. Accounting Pronouncements**

In April 2009, the FASB issued FASB Staff Position (FSP) Financial Accounting Standard (FAS) No. 157-4, *Determining Whether a Market Is Not Active and a Transaction Is Not Distressed*. FSP FAS No. 157-4 provides guidelines for making fair value measurements more consistent with the principles presented in SFAS No. 157. FSP FAS No. 157-4 provides additional authoritative guidance in determining whether a market is active or inactive, and whether a transaction is distressed, is applicable to all assets and liabilities (i.e. financial and nonfinancial) and will require enhanced disclosures. This standard is effective for periods ending after June 15, 2009. The adoption of FSP FAS No. 157-4 did not have a material impact on the Company's financial statements.

In April 2009, the FASB issued FSP FAS No. 115-2, FAS No. 124-2 and EITF No. 99-20-2, *Recognition and Presentation of Other-Than-Temporary Impairments*. FSP FAS No. 115-2, FAS No. 124-2, and EITF No. 99-20-2 provides additional guidance to provide greater clarity about the credit and noncredit component of an other-than-temporary impairment event and to more effectively communicate when an other-than-temporary impairment event has occurred. This FSP applies to debt securities. This standard is effective for periods ending after June 15, 2009. The adoption of these standards did not have a material impact on the Company's financial statements.

## Edgar Filing: METABASIS THERAPEUTICS INC - Form 10-Q

In April 2009, the FASB issued FSP FAS No. 107-1 and Accounting Principals Board ( APB ) No. 28-1, *Interim Disclosures about Fair Value of Financial Instruments*. FSP FAS No. 107-1 and APB No. 28-1 amends FASB Statement No. 107, *Disclosures about Fair Value of Financial Instruments*, to require disclosures about fair value of financial instruments in interim as well as in annual financial statements. This FSP also amends APB Opinion No. 28, *Interim Financial Reporting*, to require those disclosures in all interim financial statements. This standard is effective for periods ending after June 15, 2009. The adoption of these standards did not have a material impact on the Company's financial statements.

## **Table of Contents**

In June 2008, the FASB ratified the consensus reached by the EITF on EITF No. 07-5, *Determining Whether and Instrument (or Embedded Feature) is Indexed to an Entity's Own Stock*, ( EITF No. 07-5 ). EITF No. 07-5 provides guidance for determining whether an equity-linked financial instrument, or embedded feature, is indexed to an entity's own stock and was effective January 1, 2009. The adoption of EITF No. 07-5 did not have a material impact on the Company's financial statements.

### **11. Subsequent Events**

In connection with preparation of the financial statements and in accordance with the recently issued Statement of Financial Accounting Standards No. 165, *Subsequent Events*, the Company evaluated subsequent events after the balance sheet date of June 30, 2009 through August 7, 2009.

On July 21, 2009, the Company entered into an Agreement for Termination of Lease and Voluntary Surrender of Premises (the Termination Agreement ) with ARE-SD Region No. 24, LLC ( Owner ) to terminate the Lease Agreement, dated December 21, 2004, by and between the Company and Owner, as amended pursuant to a First Amendment to Lease Agreement dated May 16, 2006 (the Lease Agreement ). The Lease Agreement governed the terms and conditions for the use of the facilities the Company occupies as its corporate offices. Under the Lease Agreement the Company was obligated to make future payments to the Owner for a base monthly rent and operating expenses totaling \$25.7 million between August 2009 and October 2015.

Pursuant to the terms of the Termination Agreement, the Lease Agreement terminated effective July 21, 2009 (the Termination Date ) and the Owner granted the Company a license for continued use of the facilities ( License ). The License will automatically expire on the earlier to occur of: (i) January 2, 2010 or (ii) upon receipt of a 30 day notice of termination from the Owner to the Company. In consideration of the early termination of the Lease Agreement, the Company has agreed to the following: (i) to pay the Owner a fee of \$2.5 million on the Termination Date, (ii) pay up to an additional \$1.5 million to be paid as 35% of the gross revenues earned by the Company from licenses, collaboration arrangements or sales of the Company's existing pipeline of therapeutic programs entered into or effected during the period commencing July 1, 2009 and ending September 30, 2010, provided that the proceeds from these revenue generating events have been received by the Company, (iii) to grant the Owner a warrant to purchase 1.0 million shares of the Company's common stock at \$0.41 per share, and (iv) to surrender and forfeit the \$152,356 security deposit to the Owner. The Termination Agreement excuses both the Company and the Owner from any further material obligations with respect to the Lease Agreement as of the Termination Date. An estimate relating to the impact to the financial statements cannot be made at the time this report is issued.

In July 2009, the Company entered into an agreement with EquipNet, Inc. whereby EquipNet will sell the Company's laboratory and office equipments. EquipNet will receive a pre-determined commission for proceeds generated through the sale of these assets. Amounts are payable to the Company in periodic installments through October 2009 for the first \$1.5 million of proceeds. All proceeds in excess of \$1.5 million due to the Company will be paid as earned. An estimate relating to the impact to the financial statements cannot be made at the time this report is issued.

## **Table of Contents**

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

*You should read the following discussion and analysis together with our unaudited financial statements and the notes to those statements included elsewhere in this quarterly report on Form 10-Q, as well as our audited financial statements and notes to those statements as of and for the year ended December 31, 2008 included in our annual report on Form 10-K filed with the Securities and Exchange Commission on June 30, 2009. This discussion contains forward-looking statements that involve risks and uncertainties. As a result of many factors, such as those set forth under "Risk Factors" and elsewhere in this quarterly report on Form 10-Q and in our other filings with the Securities and Exchange Commission, our actual results may differ materially from those anticipated in these forward-looking statements. Readers are cautioned not to place undue reliance on forward-looking statements. The forward-looking statements speak only as of the date on which they are made, and we undertake no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they are made.*

#### **Overview**

We are a biopharmaceutical company that has established a pipeline of novel drugs for metabolic diseases using our proprietary technology and our knowledge of processes and pathways within the liver that are useful for liver-selective drug targeting and treatment of metabolic diseases. Our product pipeline includes product candidates and advanced discovery programs for the treatment of metabolic and liver diseases such as diabetes, hyperlipidemia, hepatitis and primary liver cancer.

We currently have four product candidates at the clinical stage of development. These product candidates include our metabolic disease proprietary product candidates, MB07811 and MB07803, which have been developed as potential treatments for hyperlipidemia, and type 2 diabetes, respectively, and our liver disease proprietary product candidates, pradefovir and MB07133, which have been developed as potential treatments for hepatitis B and primary liver cancer, respectively. In addition, we have compounds generated from various advanced research programs, such as our glucagon antagonist program. At this time, we do not intend to independently develop any of the assets within our product pipeline.

#### *Recent Events and Management Plans*

In May 2009, we announced a plan to restructure our organization which followed the initiation of two separate restructuring plans that we announced in January 2009 and November 2008. The three restructuring plans resulted in an approximate 95% reduction of our workforce with seven employees ultimately remaining. As part of the May 2009 restructuring plan, we terminated all of our research and development activities.

Also in May 2009, we were notified by Oxford Corporation, or Oxford, that the material adverse change and insolvency events of default under the terms of the Loan and Security Agreement, or the Agreement, had occurred, which required full payment by us of all amounts due to Oxford, totaling \$7.2 million. In May 2009, we paid Oxford the outstanding principal and interest due under the Agreement, totaling \$6.8 million. Also in May 2009, we and Oxford amended the Agreement to release us from any obligation to pay the prepayment penalty of \$236,000 under the Agreement, and provide new terms for the remittance to Oxford of the remaining loan balance of \$200,000. The new terms required payment of the remaining \$200,000 in full, including accrued interest at a rate of 14.83%, on June 1, 2010, provided that pro-rata portions of the remaining \$200,000 plus accrued interest become due earlier upon the occurrence of certain events. In June 2009, in connection with our receipt of certain proceeds from Hoffmann-La Roche Inc., F. Hoffmann-La Roche Ltd. and Roche Palo Alto LLC, or collectively Roche, and Merck & Co., or Merck, we paid Oxford all remaining outstanding amounts due under the amended Agreement.

We maintain a Research Collaboration and License Agreement with Roche. Under the agreement, our HepDirect liver-targeted technology is applied to proprietary Roche compounds to develop second-generation nucleoside analog drug candidates for treating hepatitis C virus. We provided contracted research and development services during the research phase of this collaboration which ends in August 2009. By June 2009, a development candidate was identified and Roche assumed development responsibility. We will be eligible to receive up to \$191.0 million in additional payments upon achievement of predetermined preclinical and clinical development events as well as regulatory and commercialization events and Roche will retain full commercial rights for any marketed products resulting from the collaboration and will pay us a royalty on net sales of such products.

In June 2009, we entered into a letter agreement with Roche, which provided for the early payment by Roche of a \$2.0 million milestone payment to us, on June 1, 2009. Pursuant to the letter agreement, the payment of this milestone was accelerated in exchange for certain know-how that we are obligated to provide to Roche within 30 days of receipt of the payment. We received this milestone payment in June 2009. All other terms of the License and Collaboration Agreement are unchanged and remain in effect.

We maintain a collaboration agreement with Merck to research, develop and commercialize novel small molecule therapeutics with the potential to treat type 2 diabetes, and potentially other metabolic diseases, by activating an enzyme in the liver called AMP-activated Protein Kinase. We

## Edgar Filing: METABASIS THERAPEUTICS INC - Form 10-Q

provided research and preclinical services on jointly identified compounds for the potential treatment of type 2 diabetes and other metabolic diseases which ended in June 2009. Merck is solely responsible for conducting and funding all development work for compounds resulting from this collaboration. We maintain an option to co-promote any such product in the United States.

## **Table of Contents**

On June 9, 2009, we and Merck amended the collaboration agreement to provide for a one-time, non refundable payment by Merck of \$6.0 million to us to satisfy all potential future milestone and royalty payments payable by Merck under the collaboration agreement. We received this \$6.0 million payment in June 2009. All other material terms of the collaboration agreement are unchanged and remain in effect. The research period under this collaboration ended in June 2009 and we maintain no further material performance obligations to Merck in connection with the collaboration agreement.

In July 2009, we entered into an Agreement for Termination of Lease and Voluntary Surrender of Premises, or Termination Agreement, with ARE-SD Region No. 24, LLC, or Owner, to terminate the Lease Agreement, dated December 21, 2004, by and between us and Owner, as amended. The Lease Agreement governed the terms and conditions for the use of the facilities we occupy as our corporate offices. Under the Lease Agreement we were obligated to make future payments to the Owner for a base monthly rent and operating expenses totaling \$25.7 million between August 2009 and October 2015.

Pursuant to the terms of the Termination Agreement, the Lease Agreement terminated effective July 21, 2009 and the Owner granted us a license for the continued use of the facilities. The license will automatically expire on the earlier to occur of: (i) January 2, 2010 or (ii) upon receipt of a 30 day notice of termination from the Owner to us. In consideration of the early termination of the Lease Agreement, we agreed to the following: (i) to pay the Owner a fee of \$2.5 on July 21, 2009, (ii) pay up to an additional \$1.5 million to be paid as 35% of the gross revenues earned by us from licenses, collaboration arrangements or sales of our existing pipeline of therapeutic programs entered into or effected during the period commencing July 1, 2009 and ending September 30, 2010, provided that the proceeds from these revenue generating events have been received by us, (iii) to grant the Owner a warrant to purchase 1.0 million shares of our common stock at \$0.41 per share, and (iv) to surrender and forfeit the \$152,356 security deposit to the Owner. The Termination Agreement excuses both us and the Owner from any further material obligations with respect to the Lease Agreement as of July 21, 2009.

In July 2009, we entered into an agreement with EquipNet, Inc., or EquipNet, whereby EquipNet will sell our laboratory and office equipment. EquipNet will receive a pre-determined commission for proceeds generated from the sale of these assets. Amounts are payable to us from EquipNet in periodic installments through October 2009 for the first \$1.5 million of proceeds. All proceeds in excess of \$1.5 million due to the Company will be paid as earned.

Based on the current operating plan, after considering the impact of these recent transactions, together with the cash available at June 30, 2009, our working capital will fund the current operating plan through December 2009. Excluding the \$1.5 million in proceeds from our agreement to sell our lab and office equipment, our working capital will fund the current operating plan through September 2009. We intend to obtain additional resources through the licensing or selling of our product pipeline and potentially through other strategic alternatives which may include the sale of some or all of our assets or an equity financing. In the event we are unsuccessful in the near-term in our efforts to secure additional resources, such as the \$1.5 million in proceeds from the sale of our equipment or otherwise, we will be required to cease operations entirely.

In connection with our fiscal year end 2008 financial statement audit, our independent registered public accounting firm expressed substantial doubt about our ability to continue as a going concern given our recurring net losses, negative cash flows from operations and our working capital not being sufficient to fund our operations beyond December 31, 2009.

## **Research and Development**

Through May 2009, our research and development expenses consist primarily of salaries, stock-based compensation and other expenses for research and development personnel, costs associated with the development and clinical trials of our product candidates, facility costs, supplies and materials, costs for consultants and related contract research and depreciation. We charge all research and development expenses to operations as they are incurred. In June, our research and development expenses consist primarily of impairment charges and various restructuring costs.

## **General and Administrative**

General and administrative expenses consist primarily of salaries, stock-based compensation and other related costs for personnel in executive, finance, accounting, business development, information systems, legal and human resource functions. Other costs include facility costs not otherwise included in research and development expenses, depreciation and professional fees for legal and accounting services.

## **Other Income (Expense)**

Other income, net includes interest earned on our cash, cash equivalents and securities available-for-sale, net of interest expense.



**Critical Accounting Policies**

Our discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles, or GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and related disclosure of contingent assets and liabilities. We review our estimates on an on-going basis. We base our

## **Table of Contents**

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. Actual results may differ from these estimates under different assumptions or conditions. We believe the following accounting policies to be critical to the judgments and estimates used in the preparation of our financial statements.

*Revenue Recognition.* Our revenue recognition policies are in accordance with Securities and Exchange Commission Staff Accounting Bulletin, or SAB, No. 104, *Revenue Recognition*, and Emerging Issues Task Force, or EITF, Issue 00-21, *Revenue Arrangements with Multiple Deliverables*. Our agreements generally contain multiple elements, including access to our proprietary HepDirect technology and research and development services. Payments under our collaborations are generally made in the form of up-front license fees, milestone payments and downstream royalties. All fees are nonrefundable. Revenue from milestones is recognized when earned, provided that:

the milestone event is substantive and its achievability was not reasonably assured at the inception of the agreement, and

collaborator funding, if any, of our performance obligations after the milestone achievement will continue at a level comparable to before the milestone achievement.

If both of these criteria are not met, the milestone payment is recognized over the remaining minimum period of our performance obligations under the agreement. Up-front, nonrefundable fees under our collaborations are recognized over the period the related services are provided. Nonrefundable upfront fees not associated with our future performance are recognized when received. Amounts received for sponsored research funding are recognized as revenues as the services are performed. Amounts received for sponsored research funding for a specific number of full-time researchers are recognized as revenue as the services are provided, as long as the amounts received are not refundable regardless of the results of the research project.

*Stock-Based Compensation.* We grant equity based awards under three stockholder-approved share-based compensation plans. We may grant options and restricted stock awards to employees, directors and consultants under our Amended and Restated 2001 Equity Incentive Plan. We also grant awards to non-employee directors under our 2004 Non-Employee Directors' Stock Option Plan. All of our employees are eligible to participate in our 2004 Employee Stock Purchase Plan which provides a means for employees to purchase common stock at a discount through payroll deductions. The benefits provided under all of these plans are subject to the provisions of Statement of Financial Accounting Standard, or SFAS, No. 123R which we adopted effective January 1, 2006. As of June 30, 2009, we had approximately \$1.9 million of unrecognized compensation expense which we expect to recognize over a weighted average period of 2.3 years.

We estimate the fair value of stock options granted using the Black-Scholes Merton, or Black-Scholes, option valuation model. This fair value is then amortized over the requisite service periods of the awards. The Black-Scholes option valuation model requires the input of subjective assumptions, including the option's expected life and price volatility of the underlying stock. As stock-based compensation expense is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures. SFAS No. 123R requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Forfeitures were estimated based on historical experience. We may elect to use different assumptions under the Black-Scholes option valuation model in the future, which could materially affect our net loss and net loss per share.

*Restructuring Charges.* In accounting for restructuring charges we consider the primary elements to our restructuring plans: one-time termination benefits and the discontinued use or abandonment of any assets. We recognize the fair value of one-time termination benefits when we have taken actions or have the appropriate approval for taking action, and when a liability is incurred (when the plan has been communicated to employees). If employees are required to render service beyond a 60-day minimum retention period, the fair value of the obligation is determined on the date of the communication to the employee and recognized over the service period. We recognize charges for the abandonment of assets in the period we cease to use the assets. We recognize the cumulative effect of any changes to the plan subsequent to the communication date and cease-use date in the period of the change.

## **Table of Contents**

**Asset Impairment.** In accounting for the impairment or disposal of long-lived assets we assess the recoverability of the affected long-lived assets by determining whether the carrying value of such assets can be recovered through undiscounted future operating cash flows. If impairment is indicated, we measure the amount of such impairment by comparing the carrying value of the asset to the estimated fair value of the related asset, which is generally determined based on the present value of the expected future cash flows. In the instance where a long-lived asset is to be abandoned it is disposed of when it ceases to be used. We revise our estimates for depreciation based on the plan of disposal or when we cease to use such assets.

### **Recently Issued Accounting Pronouncements**

In April 2009, the Financial Accounting Standards Board, or FASB, issued FASB Staff Position, or FSP, Financial Accounting Standard, or FAS, No. 157-4, *Determining Whether a Market Is Not Active and a Transaction Is Not Distressed*. FSP FAS No. 157-4 provides guidelines for making fair value measurements more consistent with the principles presented in SFAS No. 157. FSP FAS No. 157-4 provides additional authoritative guidance in determining whether a market is active or inactive, and whether a transaction is distressed, is applicable to all assets and liabilities (i.e. financial and nonfinancial) and will require enhanced disclosures. This standard is effective for periods ending after June 15, 2009. The adoption of FSP FAS No. 157-4 did not have a material impact on our financial statements.

In April 2009, the FASB issued FSP FAS No. 115-2, FAS No. 124-2 and EITF No. 99-20-2, *Recognition and Presentation of Other-Than-Temporary Impairments*. FSP FAS No. 115-2, FAS No. 124-2, and EITF No. 99-20-2 provides additional guidance to provide greater clarity about the credit and noncredit component of an other-than-temporary impairment event and to more effectively communicate when an other-than-temporary impairment event has occurred. This FSP applies to debt securities. This standard is effective for periods ending after June 15, 2009. The adoption of these standards did not have a material impact on our financial statements.

In April 2009, the FASB issued FSP FAS No. 107-1 and Accounting Principals Board, or APB, No. 28-1, *Interim Disclosures about Fair Value of Financial Instruments*. FSP FAS No. 107-1 and APB No. 28-1 amends FASB Statement No. 107, *Disclosures about Fair Value of Financial Instruments*, to require disclosures about fair value of financial instruments in interim as well as in annual financial statements. This FSP also amends APB Opinion No. 28, *Interim Financial Reporting*, to require those disclosures in all interim financial statements. This standard is effective for periods ending after June 15, 2009. The adoption of these standards did not have a material impact on our financial statements.

In June 2008, the FASB ratified the consensus reached by the EITF on EITF No. 07-5, *Determining Whether and Instrument (or Embedded Feature) is Indexed to an Entity's Own Stock*, or EITF No. 07-5. EITF No. 07-5 provides guidance for determining whether an equity-linked financial instrument, or embedded feature, is indexed to an entity's own stock and was effective January 1, 2009. The adoption of EITF No. 07-5 did not have a material impact on our financial statements.

### **Results of Operations**

#### *Comparison of the Three Months Ended June 30, 2009 and 2008*

**Revenues.** Revenues were \$9.7 million for the three months ended June 30, 2009, compared with \$0.7 million for the three months ended June 30, 2008. The \$9.0 million increase was mainly due to a \$6.0 million one-time, non-refundable payment received from Merck in settlement of all potential future amounts payable by Merck in the form of milestone or royalty payments under our AMPK collaboration agreement. The remaining \$3.0 million increase primarily relates to license and research revenues of \$3.3 million from our HCV collaboration with Roche entered into in August 2008, offset by a decrease of \$0.3 million in license and research revenues from our AMPK collaboration with Merck as the research period naturally ended in the second quarter of 2009.

**Research and Development Expenses.** Research and development expenses were \$3.4 million for the three months ended June 30, 2009, compared with \$9.7 million for the three months ended June 30, 2008. The \$6.3 million decrease was mainly due to a decrease of \$3.8 million in payroll and related benefits as a result of lower headcount, a decrease of \$1.5 million in clinical, pre-clinical and development expenses for the MB07811, MB07803 MB07133 and other research programs and a decrease of \$0.5 million in non-cash stock-based compensation. In connection with the restructuring in May 2009, all research and development activities were discontinued. As a result, all facilities and other formerly allocated overhead costs subsequently became fully absorbed by the general and administrative function resulting in a decrease of \$0.7 million in depreciation and occupancy costs. These decreases were partially offset by a \$0.4 million in restructuring costs and costs associated with the disposal and/or discontinued use of various long-lived assets. We do not expect to incur any additional research and development costs in the near-term.

**General and Administrative Expenses.** General and administrative expenses were \$2.9 million for the three months ended June 30, 2009, compared with \$2.6 million for the three months ended June 30, 2008. In connection with the restructuring in May 2009, all research and

## Edgar Filing: METABASIS THERAPEUTICS INC - Form 10-Q

development activities were discontinued. As a result, all facilities and other formerly allocated overhead costs subsequently became fully absorbed by the general and administrative function resulting in an approximate \$0.7 million increase in costs reflected in general and administrative expenses. In addition, we incurred \$0.2 million in severance related restructuring costs

## **Table of Contents**

and impairment charges for the second quarter of 2009. These increases were offset by a decrease of \$0.5 million in payroll and related benefits and professional services.

*Other Income (Expense).* Net interest expense was \$0.3 million for the three months ended June 30, 2009, compared to net interest income of \$7,000 for the three months ended June 30, 2008. The \$0.3 million change was primarily a result of increased interest expense associated with the settlement of our former debt obligations with Oxford and decreased interest income as a result of lower cash balances in the first quarter of 2009 as compared to the first quarter of 2008. These impacts were partially offset by a \$0.2 million gain recognized from the restructuring of our debt obligation with Oxford.

### *Comparison of the Six Months Ended June 30, 2009 and 2008*

*Revenues.* Revenues were \$11.6 million for the six months ended June 30, 2009, compared with \$1.6 million for the six months ended June 30, 2008. The \$10.0 million increase was mainly due to a \$6.0 million one-time, non-refundable payment received from Merck in settlement of all potential future amounts payable by Merck in the form of milestone or royalty payments under our AMPK collaboration agreement. The remaining \$4.0 million increase primarily relates to license and research revenues of \$4.8 million from our HCV collaboration with Roche entered into in August 2008, offset by a decrease of \$0.8 million in license and research revenues from our AMPK collaboration with Merck as the research period naturally ended in the second quarter of 2009.

*Research and Development Expenses.* Research and development expenses were \$10.8 million for the six months ended June 30, 2009, compared with \$19.4 million for the six months ended June 30, 2008. The \$8.6 million decrease was mainly due to a decrease of \$6.1 million in payroll and related benefits as a result of lower headcount, a decrease of \$2.8 million in clinical, preclinical and development expenses for the MB07811, MB07803 MB07133 and other research programs and a decrease of \$0.6 million in non-cash stock-based compensation. In addition, we experienced a decrease of \$1.0 million in depreciation and occupancy costs, primarily as a result of a change in the allocation of these costs. In connection with the restructuring in May 2009, all research and development activities were discontinued. As a result, all facilities and other formerly allocated overhead costs subsequently became fully absorbed by the general and administrative function. These decreased costs were partially offset by a \$1.5 million increase in costs associated with severance benefits provided in connection with the January 2009 restructuring and \$0.7 million in costs associated with the disposal and/or discontinued use of various long-lived assets. We do not expect to incur any additional research and development costs in the near-term.

*General and Administrative Expenses.* General and administrative expenses were \$5.4 million for the six months ended June 30, 2009, compared with \$5.1 million for the six months ended June 30, 2008. In connection with the restructuring in May 2009, all research and development activities were discontinued. As a result, all facilities and other formerly allocated overhead costs subsequently became fully absorbed by the general and administrative function resulting in an approximate \$0.7 million increase in costs reflected in general and administrative expenses. In addition, we incurred \$0.2 million in costs associated with severance benefits provided in connection with the January 2009 restructuring and \$0.1 million in costs associated with the disposal and/or discontinued use of various long-lived assets. These increases were offset by a \$0.7 million decrease in payroll and related benefits, and professional services.

*Other Income (Expense).* Net interest expense was \$0.5 million for the six months ended June 30, 2009, compared to net interest income of \$0.2 million for the six months ended June 30, 2008. The \$0.7 million change was primarily a result of increased interest expense associated with the settlement of our former debt obligations with Oxford and decreased interest income as a result of lower cash balances in the first half of 2009 as compared to the first quarter of 2008. These impacts were partially offset by a \$0.2 million gain recognized from the restructuring of our debt obligation with Oxford.

## Table of Contents

### Liquidity and Capital Resources

Since our inception, we have funded our operations primarily with \$55.8 million in net proceeds from equity financings prior to becoming a public company and \$117.4 million in aggregate net proceeds from our initial public offering in June 2004, a private placement of common stock and warrants in October 2005, a registered direct offering of common stock in March 2006 and our warrant exchange and concurrent private placement in April 2008.

As of June 30, 2009, we had \$6.6 million in cash and cash equivalents as compared to cash, cash equivalents and securities available-for-sale of \$21.6 million as of December 31, 2008, a decrease of \$15.0 million. The decrease is primarily a result of net cash used in operations of \$6.4 million and \$8.6 million of aggregate payments made during the first half of 2009 and in final settlement of our debt facilities.

In July 2009, we entered into an Agreement for Termination of Lease and Voluntary Surrender of Premises, or Termination Agreement, with ARE-SD Region No. 24, LLC, or Owner, to terminate the Lease Agreement, dated December 21, 2004, by and between us and Owner, as amended. The Lease Agreement governed the terms and conditions for the use of the facilities we occupy as our corporate offices. Under the Lease Agreement we were obligated to make future payments to the Owner for a base monthly rent and operating expenses totaling \$25.7 million between August 2009 and October 2015.

Pursuant to the terms of the Termination Agreement, the Lease Agreement terminated effective July 21, 2009 and the Owner granted us a license for the continued use of the facilities. The license will automatically expire on the earlier to occur of: (i) January 2, 2010 or (ii) upon receipt of a 30 day notice of termination from the Owner to us. In consideration of the early termination of the Lease Agreement, we agreed to the following: (i) to pay the Owner a fee of \$2,483,529 on July 21, 2009, (ii) pay an additional \$1.5 million to be paid as 35% of the gross revenues earned by us from licenses, collaboration arrangements or sales of our existing pipeline of therapeutic programs entered into or effected during the period commencing July 1, 2009 and ending September 30, 2010, provided that the proceeds from these revenue generating events have been received by us, (iii) to grant the Owner a warrant to purchase 1,000,000 shares of our common stock at \$0.41 per share, and (iv) to surrender and forfeit the \$152,356 security deposit to the Owner. The Termination Agreement excuses both us and the Owner from any further material obligations with respect to the Lease Agreement as of July 21, 2009. In connection with the termination of the Lease Agreement, we expect to incur up to \$200,000 of costs associated with the decontamination of the facilities and will incur additional costs for relocating our corporate offices to a new location, which has yet to be identified.

In July 2009, we entered into an agreement with EquipNet, whereby EquipNet will sell our laboratory and office equipment. EquipNet will receive a pre-determined commission for proceeds generated from the sale of these assets. Amounts are payable to us from EquipNet in periodic installments through October 2009 for the first \$1.5 million of proceeds. All proceeds in excess of \$1.5 million due to the Company will be paid as earned.

Based on the current operating plan, after considering the impact of these recent transactions, together with the cash available at June 30, 2009, our working capital will fund the current operating plan through December 2009. Excluding any proceeds from our agreement to sell our laboratory and office equipment, our working capital will fund the current operating plan through September 2009. We intend to obtain additional resources through the licensing or selling of our product pipeline and potentially through other strategic alternatives which may include the sale of some or all of our assets or an equity financing. In the event we are unsuccessful in the near-term in our efforts to secure additional resources, such as the proceeds from the sale of our laboratory and office equipment, we will be required to cease operations entirely. If we raise additional funds by issuing equity securities, our stockholders will experience dilution of their ownership interests. If we raise additional funds by issuing debt or other senior securities, then the rights, preferences and privileges of our existing common stock may be junior to any rights, preferences or privileges that may be established in connection with any such issuances.

The following summarizes our long-term contractual obligations as of June 30, 2009 (in thousands):

	Total	Payments Due by Period			
		Less than 1 Year	1 to 3 Years	4 to 5 Years	After 5 Years
Operating leases	\$ 20,888	\$ 3,051	\$ 6,372	\$ 6,749	\$ 4,716
Long-term debt	216	27	62	72	55
Interest on long-term debt	60	16	26	15	3
Capital leases	40	25	15		
Interest on capital leases	4	3	1		

Edgar Filing: METABASIS THERAPEUTICS INC - Form 10-Q

Total	\$ 21,208	\$ 3,122	\$ 6,476	\$ 6,836	\$ 4,774
-------	-----------	----------	----------	----------	----------

---

## **Table of Contents**

We maintain employment agreements with our executive officers and certain other key employees that, under certain circumstances, provide for the continuation of salary and certain other benefits if these individuals are terminated under specified circumstances. These agreements generally expire upon termination for cause or when we have met our obligations under these agreements. As of June 30, 2009, \$0.4 million in severance and other separation benefit costs were accrued in connection with the separation of our former chief executive officer.

We have no material contractual obligations that are not fully recorded on our balance sheets or disclosed in the notes to our financial statements. We have no off-balance sheet arrangements as defined in Securities and Exchange Commission Regulation S-K 303(a)(4)(ii).

## **FORWARD-LOOKING STATEMENTS**

This quarterly report on Form 10-Q contains forward-looking statements that are based on our management's beliefs and assumptions and on information currently available to our management. Forward-looking statements include information concerning our possible or assumed future results of operations, business strategies, financing plans, competitive position, industry environment, potential growth opportunities, the effects of future regulation and the effects of competition. Forward-looking statements include all statements that are not historical facts and can be identified by terms such as anticipates, believes, could, estimates, expects, intends, may, plans, potential, predicts, projects, or similar expressions.

Forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements. We discuss these risks in greater detail in the section entitled "Risk Factors" and elsewhere in this quarterly report on Form 10-Q and in our other filings with the Securities and Exchange Commission, including our annual report on Form 10-K for the year ended December 31, 2008. Given these uncertainties, you should not place undue reliance on these forward-looking statements.

Also, forward-looking statements represent our management's beliefs and assumptions only as of the date of this quarterly report on Form 10-Q. Our actual future results may be materially different from what we expect. Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

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

Our exposure to market risk for changes in interest rates relates primarily to the increase or decrease in the amount of interest income we can earn on our investment portfolio. Our risk associated with fluctuating interest income is limited to our investments in interest rate sensitive financial instruments. Under our current policies, we do not use interest rate derivative instruments to manage this exposure to interest rate changes. We seek to ensure the safety and preservation of our invested principal by limiting default risk, market risk, and reinvestment risk. We mitigate default risk by investing in short-term investment grade securities such as treasury-backed money market funds, corporate bonds and commercial paper. Due to the current market conditions, we no longer invest in asset-backed securities. In accordance with our investment policy, we do not invest in auction rate securities. While changes in our interest rates may affect the fair value of our investment portfolio, any gains or losses are not recognized in our statement of operations until the investment is sold or if a reduction in fair value is determined to be a permanent impairment.

We do not have any foreign currency or other derivative financial instruments.

## **Item 4. Controls and Procedures**

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Securities and Exchange Act of 1934, as amended, reports is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms, and that such information is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable and not absolute assurance of achieving the desired control objectives. In reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. In addition, the design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, a control may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.



## Edgar Filing: METABASIS THERAPEUTICS INC - Form 10-Q

As required by the Securities and Exchange Commission Rule 13a-15(b), we carried out an evaluation, under the supervision and with the participation of our management, including our chief executive officer and chief financial officer, of the effectiveness of

**Table of Contents**

the design and operation of our disclosure controls and procedures as of the end of the period covered by this report. Based on the foregoing, our chief executive officer and chief financial officer concluded that our disclosure controls and procedures were not effective at the reasonable assurance level as a result of the circumstances described below.

In May 2009, we terminated all of our employees with the exception of the officers of the Company and two other key individuals. Due to the inherent limitations of our Company from the date of the restructuring in May 2009, derived from the limited number of employees and requisite skill sets, management concluded that there is a material weakness with respect to the segregation of duties that may not provide reasonable assurance regarding the reliability of internal controls over financial reporting and may not prevent or detect misstatements. These shortfalls are reasonably likely to materially affect our internal control over financial reporting until such time as we are able to remediate these issues. We intend to remediate the weaknesses associated with our disclosure controls and procedures by December 31, 2009.

---

**Table of Contents**

**PART II OTHER INFORMATION**

**Item 1. Legal Proceedings**

None.

**Item 1A. Risk Factors**

*You should consider carefully the following information about the risks described below, together with the other information contained in this quarterly report on Form 10-Q and in our other filings with the Securities and Exchange Commission, before you decide to buy or maintain an investment in our common stock. We believe the risks described below are the risks that are material to us as of the date of this quarterly report. If any of the following risks actually occur, our business, financial condition, results of operations and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our common stock could decline, and you may lose all or part of the money you paid to buy our common stock. The risks described below include certain revisions to the risks set forth in our annual report on Form 10-K for the fiscal year ended December 31, 2008.*

**Risks Related to our Finances and Capital Requirements**

***We will need substantial additional funds to continue operations, which we may not be able to raise on favorable terms, or at all.***

We expect that our existing working capital, together with expected proceeds from the sale of our equipment, will support our on-going planned operating expenses through December 2009. In the event we do not receive the expected proceeds from the sale of our equipment, we expect that our existing working capital will support our on-going planned operating expenses through September 2009. We intend to obtain additional resources through the licensing or selling of some, or all, of our product pipeline and potentially through other strategic alternatives which may include the sale of some or all of our assets to another company or an equity financing. In the event we are unsuccessful in the near-term in our efforts to secure additional resources, we will be required to cease operations entirely. If we raise additional funds by issuing equity securities, our stockholders will experience dilution of their ownership interests. If we raise additional funds by issuing debt or other senior securities, then the rights, preferences and privileges of our existing common stock may be junior to any rights, preferences or privileges that may be established in connection with any such issuances.

We cannot be certain that additional funding will be available on acceptable terms, or at all. If adequate funds are not available, we will be unable to continue our operations.

***We may need to liquidate the Company in a voluntary dissolution under Delaware law or to seek protection under the provisions of the U.S. Bankruptcy Code, and in that event, it is unlikely that stockholders would receive any value for their shares.***

We have incurred net operating losses every year since our inception. As of June 30, 2009, we had an accumulated deficit of approximately \$197.5 million. We are currently evaluating our strategic alternatives with respect to all aspects of our business. We cannot assure our stockholders that any actions that we take would raise or generate sufficient capital to fully address the uncertainties of our financial position. As a result, we may be unable to realize value from our assets and discharge our liabilities in the normal course of business. If we are unable to sale some or all of our product pipeline or consummate a strategic transaction, such as the sale of some or all of our assets to another company or an equity financing, we would likely need to liquidate the Company in a voluntary dissolution under Delaware law or to seek protection under the provisions of the U.S. Bankruptcy Code. In that event, we or a trustee appointed by the court may be required to liquidate our assets. In either of these events, we might realize significantly less value from our assets, than their carrying values on our financial statements, and our product pipeline. The funds resulting from the liquidation of our assets would be used first to satisfy obligations to creditors before any funds would be available to our stockholders, and any shortfall in the proceeds would directly reduce the amounts available for distribution, if any, to our creditors and to our stockholders. In the event we were required to liquidate under Delaware law or the federal bankruptcy laws, it is highly unlikely that stockholders would receive any value for their shares.

***Our independent registered public accounting firm has expressed substantial doubt about our ability to continue as a going concern.***

In its audit opinion issued in connection with our balance sheets as of December 31, 2008 and 2007 and our statements of operations, stockholder's equity and cash flows for the years ended December 31, 2008, 2007 and 2006, our independent registered public accounting firm has expressed substantial doubt about our ability to continue as a going concern given our recurring net losses, negative cash flows from operations and our working capital not being sufficient to fund our operations through December 31, 2009. The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities and

## Edgar Filing: METABASIS THERAPEUTICS INC - Form 10-Q

commitments in the normal course of business. The financial statements do not include any adjustments relating to reflect the possible future effects on the recoverability and classification of recorded assets or the amounts and classification of liabilities that might be necessary should we be unable to continue in existence.

---

## **Table of Contents**

Our independent registered public accounting firm's substantial doubt about our ability to continue as a going concern may negatively impact our ability to obtain financing. Their opinion may be perceived by our investors as a risk of insolvency and potentially impair our ability to enter into new debt facilities or equity financings.

***The recent changes in regulatory requirements for developing drugs for the treatment of metabolic disease have increased the cost of development of metabolic disease products and negatively impacted the economic potential of collaborative partnerships in the metabolic disease area, which may limit our ability to fund our near-term operational cash flow requirements through the licensing or sale of our assets.***

We are seeking to fund our on-going cash requirements by licensing or selling our product candidates, among other means. Payments under our collaborations are generally made in the form of up-front license fees, milestone payments and downstream royalties. The amounts of these payments are generally determined as a factor of the future estimated economic realizable return on the eventual commercialization of these products.

Our assets include product candidates and advanced discovery programs for the treatment of metabolic diseases. The clinical development, manufacturing and commercialization of our product candidates are subject to extensive regulation by the FDA and other regulatory agencies in the U.S. In the U.S., neither we, nor our collaborators, are permitted to market our product candidates until we or our collaborators receive approval of a New Drug Application, or NDA, from the FDA. The process of obtaining these approvals is expensive, takes many years, and can vary substantially based upon the type, complexity and novelty of the product candidates involved. Approval policies or regulations may change and may be influenced by the results of other similar or competitive products. For example, in February 2008 the FDA released draft guidance regarding clinical trials for product candidates treating diabetes that may result in more stringent requirements for the clinical testing and regulatory approval of such product candidates. These and any future guidance that may result from FDA advisory panel discussions may make it more expensive to develop and commercialize such product candidates. Certain large pharmaceutical and/or biotechnology companies may elect to terminate or not pursue development activities for diabetes products as a result of this draft guidance and possible increases in development costs and therefore may be unavailable as potential licensing partners. Similarly, product candidates for treating hyperlipidemia may be subject to guidance in the future that may limit the number of potential licensing partners.

The anticipated increases in the cost of development, complexity and time associated with expected additional regulatory requirements inherently increases the risk of delaying and/or not obtaining the FDA approvals necessary to develop, manufacture or commercialize products in metabolic diseases. Moreover, if any of our product candidates receive regulatory approval, the FDA or other foreign regulatory agencies may still impose significant restrictions on the indicated uses or marketing of the product candidates or impose on-going requirements for potentially costly post-approval studies. The increased costs associated with more stringent regulatory requirements may negatively impact the ability to license or sell our products. If we are unsuccessful in licensing or selling one or more of our assets in the near-term we may be required to cease operations.

***Turmoil in the credit markets and the financial services industry may negatively impact our business, results of operations and financial condition.***

Since our inception, we have funded our operations primarily with net proceeds from equity financings, our venture debt facility and strategic alliances and collaborative partnerships. We intend to fund our near-term and on-going cash requirements through equity financings or other means, including the licensing or selling of our assets. In the event we are not able to generate sufficient capital through equity financings or business development activities, we will be required to cease operations. The credit markets and the financial services industry are currently experiencing a period of unprecedented turmoil and upheaval characterized by the bankruptcy, failure, collapse or sale of various financial institutions and an unprecedented level of intervention from the U.S. federal government. While the ultimate outcome of these events cannot be predicted, they may have a material adverse effect on our ability to obtain the capital necessary to continue operations.

***We have a history of net losses, which we expect to continue for the foreseeable future, and we are unable to predict when we will become profitable, if ever.***

We have incurred net losses from our inception. As of June 30, 2009, we had an accumulated deficit of approximately \$197.5 million. While we are unable at this time to determine whether our net losses will increase or decrease in the future, we expect to continue to incur net losses during the next several years as we conduct operations. Because of the numerous risks and uncertainties associated with our product development efforts, we are unable to predict when we will become profitable, if ever.

***We currently lack a significant continuing revenue source and may not become or remain profitable.***

## Edgar Filing: METABASIS THERAPEUTICS INC - Form 10-Q

Our ability to become and remain profitable depends upon our ability to generate continuing revenues. To date, our product candidates and strategic collaborations have not generated any significant revenues, other than one-time or time-limited payments associated with our collaborations such as milestone payments and up-front fees. Our ability to generate significant continuing revenues depends on a number of factors, including:

successful completion of development activities for our product candidates,

achievement of regulatory approval for our product candidates, and

## **Table of Contents**

successful completion of our current and future business development activities.

We do not anticipate that we will generate significant continuing revenues for several years. If we are unable to eventually generate significant continuing revenues, we will not become or remain profitable, and we may be unable to continue our operations.

***We may not have sufficient authorized and available shares of common stock to raise additional funds by issuing securities.***

We had 53,007,415 authorized shares of common stock available for future issuance as of July 31, 2009. In the event we wish to raise additional funds through public or private equity offerings, we may be required to obtain stockholder approval to increase the number of authorized shares of our common stock in order to provide a sufficient number of shares for such an equity offering given recent market prices for our common stock. If we are unable to obtain stockholder approval to increase our authorized shares, then our ability to raise additional funds through public or private equity offerings may be limited due to our having insufficient authorized and available shares of common stock. If we are unable to raise additional funds through the issuance of securities and no alternative source of funds is available, we may be unable to continue our operations.

***Our quarterly operating results and stock price may fluctuate significantly.***

We expect our operating results to be subject to quarterly fluctuations. The revenues we generate, if any, and our operating results will be affected by numerous factors, including:

the establishment of licensing or other arrangements, and the timing of payments we may receive under these arrangements,

the development status of product candidates under existing collaboration agreements,

impact of restructuring costs, and

changes in the use assumptions in the application of SFAS No. 123R, *Share-Based Payment*, in future periods.

Quarterly fluctuations in our operating results may, in turn, cause the price of our stock to fluctuate substantially. We believe that quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

***Raising additional funds by issuing securities or through licensing arrangements may cause dilution to, or impair the rights of, existing stockholders, restrict our operations or require us to relinquish proprietary rights.***

We may raise additional funds through public or private equity offerings, licensing arrangements, debt financings, grants or our CEFF, if available. We currently do not have access to additional capital through the CEFF. We have an effective shelf registration statement on file with the Securities and Exchange Commission which allows us to issue shares of our common stock and warrants to purchase our common stock in the future for an aggregate initial offering price of up to \$75 million, subject to substantial limitations relating to the aggregate market value of our common stock held by non-affiliates. We have also filed a registration statement with the Securities and Exchange Commission covering the resale of shares issuable under the CEFF though to date, no shares have been issued under this resale registration statement. We may sell additional securities from time to time in one or more offerings in amounts, at prices and on terms that we will determine at the time of the offering. To the extent that we raise additional capital by issuing equity securities, pursuant to our effective shelf registration statements or otherwise, our existing stockholders' ownership will be diluted. If we raise additional capital by issuing debt or senior securities, then the rights, preferences and privileges of our existing common stock may be junior to any rights, preferences or privileges that may be established in connection with any such issuances.

Any debt financing we enter into may involve covenants that restrict our operations. These restrictive covenants may include limitations on additional borrowing, specific restrictions on the use of our assets as well as prohibitions on our ability to create liens, pay dividends, redeem our stock or make investments. In addition, if we raise additional funds through collaboration and licensing arrangements, it may be necessary to relinquish potentially valuable rights to our potential products or proprietary HepDirect technology, or grant licenses on terms that are not favorable to us.

## Edgar Filing: METABASIS THERAPEUTICS INC - Form 10-Q

Given the on-going financial crisis in the U.S. and other current negative macroeconomic indicators, such as the recession in the U.S. or other economic downturns in the global markets, our ability to issue securities or obtain debt financing in the future may not be available or attainable on favorable terms, if at all.

***Our CEFF may not be available to us if we elect to make a draw down, may require us to make additional blackout or other payments to an institutional investor and may result in dilution to our stockholders.***

We have entered into a CEFF with an institutional investor that entitles us to sell and obligates the investor to purchase, from time to time over a period of up to 36 months which commenced in December 2006, shares of our common stock at a discount of up to 10% for cash consideration up to an aggregate of \$50.0 million, or 6,046,701 shares, of common stock, subject to specified conditions and restrictions. Our current market capitalization does not meet the CEFF minimum threshold of \$53 million, and therefore, we do not currently have access to this capital.

The investor will not be obligated to purchase shares under the CEFF unless specified conditions are met, which include a minimum price for our common stock; a minimum amount of our market capitalization; the accuracy of representations and warranties



## **Table of Contents**

made to the investor; compliance with laws; and the effectiveness of a registration statement registering for resale the shares of common stock to be issued in connection with the CEFF. In addition, among other termination rights, the investor is permitted to terminate the CEFF by providing written notice to us within 10 business days after it obtains actual knowledge that an event has occurred resulting in a material and adverse effect on our business, operations, properties or financial condition (subject to specified exceptions, including conditions or events that are reasonably expected to occur in the ordinary course of our business). If we are unable to access funds through the CEFF, or if the investor terminates the CEFF, we may be unable to access capital on favorable terms, or at all.

We are entitled, in certain circumstances, to deliver a "blackout" notice to the investor to suspend the use of the prospectus covering the shares of common stock issued in connection with the CEFF and prohibit the investor from selling shares under that prospectus for a certain period of time. If we deliver a blackout notice in the 15 trading days following the settlement of a draw down, or if the registration statement covering the resale of the shares of common stock to be issued in connection with the CEFF is not effective in circumstances not permitted by our registration rights agreement with the investor, then we must make a payment to the investor, or issue the investor additional shares in lieu of this payment, calculated on the basis of a specified number of shares held by the investor immediately prior to the blackout period and the change in the market price of our common stock during the period in which the use of the resale registration statement is suspended. If the trading price of our common stock declines during a suspension of the resale registration statement, the blackout or other payment could be significant.

Should we sell shares to the investor under the CEFF, or issue shares in lieu of a blackout payment, it will have a dilutive effect on the holdings of our current stockholders.

### **Risks Related to the Securities Markets and Investment in our Common Stock**

*As of June 30, 2009 we failed to meet one of the Nasdaq Capital Market's continued listing requirements and our common stock could be delisted from the Nasdaq Capital Market, which could negatively impact the price of our common stock and our ability to access the capital markets.*

As of June 30, 2009, we maintained a stockholders' deficit of \$0.4 million which does not meet the minimum stockholders' equity requirement for continued listing on the Nasdaq Capital Market. In order to maintain our listing on the Nasdaq Capital Market, we will need to regain compliance with certain minimum listing standards that include, or may include, requirements related to our stockholders' equity, the market value of our listed or publicly-held securities, the number of publicly-held shares, our net income, a minimum bid price for our common stock, the number of stockholders, the number of market makers and compliance with certain corporate governance policies. Failing to regain compliance and maintain compliance with the standards in the future may result in the delisting of our common stock from the Nasdaq Capital Market. The delisting of our common stock would significantly affect the ability of investors to trade our securities and would negatively affect the value and liquidity of our common stock. In addition, the delisting of our common stock could materially adversely affect our ability to raise capital on terms acceptable to us, or at all. Delisting from the Nasdaq Capital Market could also have other negative results, including the potential loss of confidence by suppliers and employees and the loss of institutional investor interest.

*If our executive officers, directors and largest stockholders choose to act together, they may be able to control our operations and act in a manner that is not necessarily consistent with the interests of other stockholders.*

Our executive officers, directors and holders of 5% or more of our outstanding common stock, beneficially owned approximately 74% of our common stock as of June 30, 2009. As a result, these stockholders, acting together, are able to control all matters requiring approval by our stockholders, including the election of directors and the approval of mergers or other business combination transactions. The interests of this group of stockholders may not always coincide with our interests or the interests of other stockholders, and they may act in a manner that is not necessarily consistent with the interests of other stockholders.

*Market volatility may affect our stock price and the value of your investment.*

The market price of our common stock has been and is likely to continue to be volatile. In addition, the market price of our common stock may fluctuate significantly in response to a number of factors, most of which we cannot control, including:

changes in the regulatory status of our product candidates, including the status and results of development activities,

## Edgar Filing: METABASIS THERAPEUTICS INC - Form 10-Q

establishment of new license or asset acquisition agreements,

events affecting Roche or any future collaborators,

announcements of new products or technologies, commercial relationships or other events by us or our competitors,

regulatory developments in the U.S. and foreign countries,

fluctuations in stock market prices and trading volumes of similar companies,

variations in our quarterly operating results,

changes in securities analysts' estimates of our financial performance,

changes in accounting principles,

issuances of new equity securities by us, pursuant to our effective shelf registration statements or otherwise,

---

**Table of Contents**

sales of large blocks of our common stock, including sales by our executive officers, directors and significant stockholders,

additions or departures of key personnel,

discussion of us or our stock price by the financial and scientific press and in online investor communities, and

changes in industry and general market conditions, including the recent economic crisis.

***Our certificate of incorporation provides the ability to issue preferred stock without any further vote or action by our stockholders, and any such issuance may be dilutive to and impair the rights of holders of our common stock.***

Our board of directors has the authority to issue up to 5.0 million shares of preferred stock and to determine the price, rights, preferences and privileges and restrictions, including voting rights, of those shares without any further vote or action by our stockholders. The rights of the holders of common stock will be subject to, and may be harmed by, the rights of the holders of any shares of preferred stock that may be issued in the future. The issuance of preferred stock could also have a dilutive effect on our stockholders.

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

Provisions in our amended and restated certificate of incorporation and bylaws may delay or prevent an acquisition of us or a change in our management. These provisions include a classified board of directors, a prohibition on actions by written consent of our stockholders, and the ability of our board of directors to issue preferred stock without stockholder approval. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits stockholders owning in excess of 15% of our outstanding voting stock from merging or combining with us. Although we believe these provisions collectively provide for an opportunity to receive higher bids by requiring potential acquirers to negotiate with our board of directors, they would apply even if the offer may be considered beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management.

***We incur costs associated with regulatory compliance, and these costs could be significant.***

There are numerous regulatory requirements for public companies, including the provisions of the Sarbanes-Oxley Act of 2002 and rules adopted or proposed by the Securities and Exchange Commission and by the Nasdaq Stock Market. Section 404 requires management to report on, and our independent registered public accounting firm to attest to, our internal controls over financial reporting. These laws and regulations could make it more difficult or more costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these laws and regulations could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers. Compliance with these rules could also result in continued diversion of management's time and attention, which could be disruptive to normal business operations. If we do not satisfactorily or timely comply with these requirements, possible consequences could include sanction or investigation by regulatory authorities such as the Securities and Exchange Commission or the Nasdaq Stock Market; fines and penalties; incomplete or late filing of our periodic reports, including our annual report on Form 10-K; or civil or criminal liability. Our stock price and business could also be adversely affected.

***If we fail to maintain an effective system of internal controls, we may not be able to accurately report our financial results or prevent fraud and as a result, investors may be misled and lose confidence in our financial reporting and disclosures, and the price of our common stock may be negatively affected.***

The Sarbanes-Oxley Act of 2002 requires that we report annually on the effectiveness of our internal control over financial reporting. A significant deficiency means a deficiency or a combination of deficiencies, in internal control over financial reporting that is less severe than a material weakness yet important enough to merit attention by those responsible for oversight of the Company's financial reporting. A material weakness is a deficiency, or a combination of deficiencies in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis.

## Edgar Filing: METABASIS THERAPEUTICS INC - Form 10-Q

We have disclosed material weaknesses with our internal controls that we have yet to remediate. Although we intend to make improvements in our internal controls, if we discover other deficiencies or material weaknesses, it may adversely impact our ability to report accurately and in a timely manner our financial condition and results of operations in the future, which may cause investors to lose confidence in our financial reporting and may negatively affect the price of our common stock. Moreover, effective internal

## **Table of Contents**

controls are necessary to produce accurate, reliable financial reports and to prevent fraud. If we continue to have deficiencies in our internal controls over financial reporting, these deficiencies may negatively impact our business and operations.

### ***Future sales of our common stock may cause our stock price to decline.***

A large portion of our shares are held by a small number of persons and investment funds. In addition, these persons and funds hold warrants to purchase 2,363,556 shares of common stock that, if exercised, will result in these additional shares becoming available for sale. Moreover, several of our stockholders and warrant holders have rights, subject to some conditions, to require us to file registration statements covering the unregistered shares they currently hold or may acquire upon exercise of warrants, or to include these shares in registration statements that we may file for ourselves or other stockholders. Under the CEFF, an institutional investor is committed to purchase up to \$50 million or 6,046,471 shares of our common stock over a 36 month period which commenced in December 2006, subject to certain conditions. Our current market capitalization does not meet the CEFF minimum threshold of \$53 million, and therefore, we do not currently have access to this capital. Sales by these current and potential future stockholders or warrant holders of a substantial number of shares could significantly reduce the market price of our common stock.

### ***We are at risk of securities class action litigation due to our expected stock price volatility.***

In the past, stockholders have brought securities class action litigation against a company following a decline in the market price of its securities. This risk is especially acute for us because life science companies have experienced greater than average stock price volatility in recent years and, as a result, have been subject to, on average, a greater number of securities class action claims than companies in other industries. To date, we have not been subject to class action litigation. However, we may in the future be the target of this litigation. Securities litigation could result in substantial costs and divert our management's attention and resources, and could seriously harm our business.

## **Risks Related to our Business**

### ***We may not be able to license or sell our assets, MB07811, MB07803, our glucagon antagonist program, pradequivir and MB07133, on acceptable terms, if at all, which would impact the ability to generate stockholder value from these assets, and may require us to cease operations.***

Since we do not currently possess the resources necessary to independently develop and commercialize the potential product candidates that may be based upon our technologies, including MB07811, MB07803, our glucagon antagonist program, pradequivir and MB07133, we plan to license or sell these assets to a third-party to perform the development and assume the future commercialization of some or all of these assets. However, our discussions with potential collaborators may not lead to the establishment of new collaborations on acceptable terms or for significantly less value that may have been available if we were more financially stable, if at all, or it may take longer than expected to establish new collaborations, which would adversely affect our liquidity and requires us to cease operations entirely.

### ***If we fail to keep key management personnel, we may be unable to pursue the licensing and selling of our assets and/or other strategic transactions, as necessary, in order to continue operations.***

Our ability to pursue transactions to secure additional resources to fund the current and on-going operations of the Company depends on our continued ability to retain and motivate our current management personnel. The loss of the services of certain members of our management staff could delay or prevent the execution of these near-term objectives. We employ these individuals on an at-will basis and their employment can be terminated by us or them at any time, for any reason and with or without notice, subject to the terms of their severance agreements. Certain terms within our existing collaboration agreements require that we maintain a specified number of scientific personnel through the sponsored research period of the collaboration. The recent terminations of scientific personnel in connection with the various restructuring events could be viewed as a breach of these terms.

### ***Delays in the commencement or completion of clinical trials could result in increased costs to us and delay our ability to license or sell our assets.***

Delays in the commencement or completion of clinical trials could significantly impact product development costs. We do not know whether potential future clinical trials will begin on time or be completed on schedule, if at all. The commencement of clinical trials can be delayed for a variety of reasons, including, but not limited to, delays related to:

## Edgar Filing: METABASIS THERAPEUTICS INC - Form 10-Q

obtaining the necessary resources to fund the trial,

obtaining regulatory approval to commence a clinical trial,

reaching agreement on acceptable terms with prospective contract research organizations and clinical trial sites,

manufacturing sufficient quantities of a product candidate or other materials necessary to conduct the clinical trial,

obtaining institutional review board approval to conduct a clinical trial at a prospective site,

recruiting and enrolling patients to participate in a clinical trial, and

## **Table of Contents**

the failure of our collaborators to adequately resource our product candidates due to their focus on other programs or as a result of general market conditions.

In addition, once a clinical trial has begun, it may be suspended or terminated by us, our collaborators, the FDA or other regulatory authorities due to a number of factors, including:

failure to conduct the clinical trial in accordance with regulatory requirements or clinical protocols,

inspection of the clinical trial operations or clinical trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold,

unforeseen safety issues, or

lack of adequate funding to continue the clinical trial.

If we experience significant delays in the commencement or completion of clinical testing, product development costs may increase, we may lose any competitive advantage associated with early market entry and our ability to license or sell our assets. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate.

***We are currently dependent on our collaboration with Roche for the development and commercialization of product candidates related to that collaboration, and we may be dependent on future collaborators for the development of our current and future product candidates. Events involving our collaboration with Roche, or any future collaborations, could prevent us from developing and commercializing our product candidates and continuing operations.***

We maintain a collaboration with Roche. Our collaboration with Roche seeks to develop new products for treating hepatitis C. The research term of our collaboration with Roche continues through July 2009. We will be dependent on Roche for further development and commercialization of any resulting product candidates.

We have limited control over the amount and timing of resources that Roche or any future collaborators devote to our programs or potential product candidates. These collaborations with us may end or may be terminated or our collaborators may otherwise fail to conduct their collaborative activities successfully and in a timely manner. Further, our collaborators may not develop product candidates that arise out of our collaborative arrangements or devote sufficient resources to the development, manufacture, marketing or sale of these products. In the event that one of our collaborations is terminated, and we believe that the continued development or commercialization of a product candidate or drug compound covered by the collaboration is warranted, we may seek to obtain rights to develop and commercialize the product candidate or drug compound, if we do not already have those rights. We would then determine whether to continue the development or commercialization of the product candidate or drug compound independently or together with a new collaborator. We currently do not have sufficient resources to independently develop or commercialize any product candidate or drug compound, and if we cannot establish a new collaboration on acceptable terms, we would be forced to discontinue its development or commercialization. For example, at this time, we do not intend to independently develop any of our assets and intend to license or sell these product candidates.

Our present and future collaborators may fail to develop or effectively commercialize products or drug compounds if:

our product candidates do not meet the primary endpoints of any clinical trials conducted on them or exhibit undesirable side effects,

we are unable to obtain patent protection for the product candidates or our proprietary HepDirect technology we discover in our collaborations,

## Edgar Filing: METABASIS THERAPEUTICS INC - Form 10-Q

we are unable to manage multiple simultaneous product discovery and development collaborations,

our potential collaborators are less willing to expend their resources on our programs due to their focus on other programs or as a result of general market conditions,

our collaborators become competitors of ours or enter into agreements with our competitors,

we or our collaborators encounter regulatory hurdles that prevent commercialization of our product candidates,

we develop products and processes or enter into additional collaborations that conflict with the business objectives of our other collaborators,

consolidation in our target markets limits the number of potential collaborators, or

we are unable to negotiate additional collaboration agreements under terms satisfactory to us.

If we are unable to develop or commercialize our products as a result of the occurrence of any of these events, we may not be able to generate sufficient revenues to continue operations.



---

## **Table of Contents**

***Because our collaboration with Roche may involve Roche's proprietary compounds, if Roche terminates development of product candidates containing these compounds, we may not have the right to pursue development of these product candidates on our own.***

Our agreement with Roche to develop new products to treat hepatitis C infection may include the development of compounds owned or controlled by Roche. If our collaboration with Roche is terminated, we may not have any right to develop product candidates developed in connection with the collaboration.

***Conflicts may arise between us and any of our collaborators that could delay or prevent the development or commercialization of our product candidates.***

Conflicts may arise between our collaborators and us, such as conflicts concerning the interpretation of clinical data, the achievement of milestones or the ownership of intellectual property developed during the collaboration. If any conflicts arise with Roche or any future collaborators, they may act in their self-interest, which may be adverse to our best interests. Any such disagreement between us and a collaborator could result in one or more of the following, each of which could delay or prevent the development or commercialization of our product candidates, and in turn prevent us from generating sufficient revenues to achieve or maintain profitability:

unwillingness on the part of a collaborator to pay milestone payments or royalties we believe are due to us under our collaboration agreement,

uncertainty regarding ownership of intellectual property rights arising from our collaborative activities, which could prevent us from entering into additional collaborations or independently pursuing the development and/or commercialization of product candidates, or disagreements with our collaborators regarding the protection of intellectual property rights,

unwillingness on the part of a collaborator to keep us informed regarding the progress of its development and commercialization activities or to permit public disclosure of the results of those activities, or

slowing or cessation of a collaborator's development or commercialization efforts with respect to our product candidates.

***We rely on third parties in connection with the development of our product candidates. If these third parties do not successfully meet their obligations under our agreements, we may not be able to obtain regulatory approval for or commercialize our product candidates.***

At this time, we do not intend to independently develop any of our assets and intend to license or sell these product candidates. If successful in entering into future license agreements, we will be dependent upon our licensees for the further development and commercialization of these product candidates. We are dependent on Roche to conduct the development of resulting product candidates. If Roche or other third parties do not successfully meet their obligations under our agreements, or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to applicable protocols or for other reasons, clinical trials or other studies may be extended, delayed or terminated, and these product candidates may not receive regulatory approval or be successfully commercialized.

***We are dependent on the success of one or more of our current product candidates and we cannot be certain that any of them will receive regulatory approval or be commercialized.***

We have expended significant time, money and effort in the development of our assets, MB07811, MB07803, our glucagon antagonist program, pradefovir and MB07133. Early clinical trials conducted to date have provided initial evidence of safety and therapeutic effect with all of our product candidates. However, to date, no pivotal, adequate and well-controlled clinical trials designed to provide clinical and statistically significant proof of efficacy, or to provide sufficient evidence of safety to justify approval, have been completed with any of our product candidates. All of our product candidates will require additional development, including clinical trials as well as further preclinical studies to evaluate their toxicology, carcinogenicity and pharmacokinetics and optimize their formulation, and regulatory clearances before they can be commercialized. Positive results obtained during early development do not necessarily mean later development will succeed or that regulatory clearances will be obtained. Our product development efforts may not lead to commercial drugs, either because our product candidates fail to be safe and effective, our licensees discontinue development, or because we have inadequate financial or other resources to pursue our product candidates through the clinical development and approval processes. If any of our product candidates fail to demonstrate safety or efficacy at any

## Edgar Filing: METABASIS THERAPEUTICS INC - Form 10-Q

time or during any phase of development, we, or our licensees, would experience potentially significant delays in, or be required to abandon, development of the product candidate. For example, we terminated all research and development activities in May 2009 due to the lack of sufficient financial resources and collaboration partners to continue the development of these assets. If we are unsuccessful in obtaining sufficient resources to fund the continued development our product pipeline or license these assets to a third-party, these product candidates and research programs may never be developed or commercialized.

We do not anticipate that any of our current product candidates will be eligible to receive regulatory approval and begin commercialization for a number of years, if at all. Even if we were ultimately to receive regulatory approval for these product candidates, we and/or our potential future partners, as applicable, may be unable to commercialize them successfully for a variety of

## **Table of Contents**

reasons. These include, for example, the availability of alternative treatments, lack of cost effectiveness, restrictions of labeling in the use of products, the cost of manufacturing the product on a commercial scale and the effect of competition with other drugs. The success of our product candidates may also be limited by the prevalence and severity of any adverse side effects. If we fail to commercialize one or more of our current product candidates, we may be unable to generate sufficient revenues to attain or maintain profitability, and our reputation in our industry and the investment community may be damaged.

***If development of our product candidates does not produce favorable results, we and our collaborators, as applicable, may be unable to commercialize these products.***

To receive regulatory approval for the commercialization of our assets, MB07811, MB07803, our glucagon antagonist program, pradefovir and MB07133, or any other product candidates that we may develop, adequate and well-controlled clinical trials must be conducted to demonstrate safety and efficacy in humans to the satisfaction of the FDA in the U.S. and other regulatory agencies elsewhere in the world. In order to support marketing approval, these agencies typically require successful results in one or more Phase 3 clinical trials, which our current product candidates have not yet reached and may never reach. In addition, regulatory approval of our product candidates may be affected by adverse results in animal studies conducted during clinical development to, among other things, evaluate their toxicology, carcinogenicity and pharmacokinetics and optimize their formulation.

The development process is expensive, can take many years and has an uncertain outcome. Failure can occur at any stage of the process. We may experience numerous unforeseen events during, or as a result of, the development process that could delay or prevent commercialization of our current or future product candidates, including the following:

clinical trials may produce negative or inconclusive results,

animal studies conducted on product candidates during clinical development to, among other things, evaluate their toxicology and pharmacokinetics and optimize their formulation may produce unfavorable results,

patient recruitment and enrollment in clinical trials may be slower than we anticipate,

costs of development may be greater than we anticipate,

our product candidates may cause undesirable side effects that delay or preclude regulatory approval or limit their commercial use or market acceptance if approved,

collaborators who are responsible for development of our product candidates may not devote sufficient resources to these clinical trials or other studies of these candidates or conduct them in a timely manner, or

we may face delays in obtaining regulatory approvals to commence a clinical trial.

Success in early development does not mean that later development will be successful because, for example, product candidates in later-stage clinical trials may fail to demonstrate sufficient safety and efficacy despite having progressed through initial clinical testing.

Our clinical experience with our product candidates is limited, and to date our product candidates have been tested in less than the number of patients that will likely need to be studied to gain regulatory approval. The data collected from clinical trials with larger patient populations may not demonstrate sufficient safety and efficacy to support regulatory approval of these product candidates. In addition, the requirements for regulatory approval of our product candidates may change, making it more difficult for us to achieve such approval in a timely manner or at all. For example, in February 2008 the FDA released draft guidance regarding clinical trials for product candidates treating diabetes that may result in more stringent requirements for the clinical testing and regulatory approval of such product candidates. This and any future guidance that may

## Edgar Filing: METABASIS THERAPEUTICS INC - Form 10-Q

result from recent FDA advisory panel discussions may make it more expensive to develop and commercialize such product candidates. Such increased expense could make it more difficult to obtain favorable terms in the collaborative arrangements we require to maximize the value of our programs seeking to develop new product candidates for diabetes.

We are currently not developing any of our product candidates and intend to license or sell our assets. Therefore, in the future, any potential future collaborators will be responsible for establishing the targeted endpoints and goals for development of our product candidates. These targeted endpoints and goals may be inadequate to demonstrate the safety and efficacy levels required for regulatory approvals. Even if we believe data collected during the development of our product candidates are promising, such data may not be sufficient to support marketing approval by the FDA or other regulatory agencies abroad. Further, data generated during development can be interpreted in different ways, and the FDA or other foreign regulatory agencies may interpret such data in different ways than us or our partners. Our failure to adequately demonstrate the safety and efficacy of our product candidates would prevent our receipt of regulatory approval, and ultimately the commercialization of these product candidates.

***Our product candidates may cause undesirable side effects that could delay or prevent their regulatory approval or commercialization or have other significant adverse implications on our business.***

Prior to receiving regulatory approval, undesirable side effects observed in human clinical trials or in supportive animal studies with our product candidates could interrupt, delay or halt their development and could result in the denial of regulatory approval by the FDA or other regulatory authorities for any or all targeted indications or adversely affect the marketability of any such product

## **Table of Contents**

candidates that receive regulatory approval. In turn, this could eliminate or limit our ability to commercialize our product candidates and generate revenues from their sale.

Our product candidate may exhibit adverse effects in animal toxicology studies. Our product candidates could also exhibit adverse interactions with other drugs. The unique nature of our proprietary HepDirect technology may cause undesirable side effects in future clinical trials or supportive animal studies. In addition, our product candidates may have greater or lesser degrees of potential risk of undesirable side effects relative to other product candidates based on the nature of their molecular targets and the various physiological responses associated with those targets. For example, MB07811 is a product candidate designed to exploit the beneficial hepatic effects of thyroid hormone agonists while avoiding toxicities related to systemic exposure to these types of compounds. If MB07811 is not successful in this regard, it could be associated with undesirable side effects.

There are also risks associated with additional requirements the FDA may impose for marketing approval in a particular disease. For example, MB07803 is a product candidate to treat patients with type 2 diabetes. The FDA has recently issued guidance for companies developing anti-diabetic compounds that require companies to demonstrate that the product will not result in an unacceptable increased risk of cardiovascular effects. There is a risk that our product will not show an acceptable risk level and the FDA may require we study more patients for approval, following approval, or even prevent our product from receiving a marketing approval.

Our products may require a risk management program that could include but not be limited to patient and healthcare provider education, usage guidelines, appropriate promotional activities, a post-marketing observational study, and on-going safety and reporting mechanisms. Prescribing could be limited to physician specialists or physicians trained in the use of the product or prescribing could be limited to a more restrictive patient population. Any risk management program required for approval of our product candidates could potentially have an adverse impact on our business.

Undesirable side effects involving our product candidates may have other significant adverse implications on our business, for example:

we may be unable to obtain additional financing on acceptable terms, if at all,

our stock price could decline,

our collaborators may ultimately terminate development of our partnered products, may further decide not to develop backup product candidates and may terminate our agreements,

if these agreements were terminated we may determine not to further develop the affected product candidates due to resource constraints and may not be able to establish additional collaborations for their further development on acceptable terms, if at all,

if we were to later continue the development of these product candidates and receive regulatory approval, earlier findings may significantly limit their marketability and thus significantly lower our potential future revenues from their sale,

we may be subject to product liability or stockholder litigation, and

we may be unable to attract and retain key employees.

In addition, if any of our product candidates receive marketing approval and we or others later identify undesirable side effects caused by the product:

## Edgar Filing: METABASIS THERAPEUTICS INC - Form 10-Q

regulatory authorities may withdraw their approval of the product, or we or our partners may decide to cease marketing and sale of the product voluntarily,

we may be required to change the way the product is administered, conduct additional studies, change the labeling of the product, or change the product's manufacturing facilities, and

our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product or could substantially increase the costs and expenses of commercializing the product, which in turn could delay or prevent us from generating significant revenues from the sale of the product.

***Because some of our product candidates and research programs depend on our proprietary HepDirect technology, adverse events affecting our proprietary HepDirect technology may delay or prevent the commercialization of our product candidates.***

We applied our HepDirect technology to pradefovir, MB07811 and MB07133, and have applied it in certain other programs as well. Our proprietary HepDirect technology is subject to many of the same risks as our product candidates, including risks related to:

obtaining and maintaining patent and trade secret protection,

avoiding infringement of the proprietary rights of third parties,

the development of competing technologies by others, and

## **Table of Contents**

the safety and effectiveness of this technology in humans.

Because certain of our product candidates and research programs are dependent on our proprietary HepDirect technology, adverse events affecting our proprietary HepDirect technology may in turn delay or prevent the development or commercialization of our product candidates, which could impede our ability to generate revenues and achieve or maintain profitability.

***Our product candidates are subject to extensive regulation, which can be costly and time consuming, cause unanticipated delays or prevent the receipt of the required approvals to commercialize our product candidates.***

The clinical development, manufacturing, labeling, storage, record-keeping, advertising, promotion, export, marketing and distribution of our product candidates are subject to extensive regulation by the FDA and other regulatory agencies in the U.S. and by comparable governmental authorities in foreign markets. In the U.S., neither we, nor our collaborators, are permitted to market our product candidates until we or our collaborators receive approval of an NDA, from the FDA or receive similar approvals abroad. The process of obtaining these approvals is expensive, often takes many years, and can vary substantially based upon the type, complexity and novelty of the product candidates involved. Approval policies or regulations may change and may be influenced by the results of other similar or competitive products. For example, in February 2008 the FDA released draft guidance regarding clinical trials for product candidates treating diabetes that may result in more stringent requirements for the clinical testing and regulatory approval of such product candidates. This and any future guidance that may result from recent FDA advisory panel discussions may make it more expensive to develop and commercialize such product candidates. Such increased expense could make it more difficult to obtain favorable terms in the collaborative arrangements we require to maximize the value of our programs seeking to develop new product candidates for diabetes. In addition, as a company, we have not previously filed NDAs with the FDA or filed similar applications with other foreign regulatory agencies. This lack of experience may impede our ability to obtain FDA or other foreign regulatory agency approval in a timely manner, if at all, for our product candidates for which development and commercialization is our responsibility.

Despite the time and expense invested, regulatory approval is never guaranteed. The FDA or other foreign regulatory agencies can delay, limit or deny approval of a product candidate for many reasons, including:

a product candidate may not be safe and effective,

FDA or other foreign regulatory agency officials may not find the data from preclinical testing and clinical trials generated during development sufficient,

the FDA or other foreign regulatory agency may not approve of our third-party manufacturers' processes or facilities, or

the FDA or other foreign regulatory agency may change its approval policies or adopt new regulations.

Any delay in obtaining, or inability to obtain, these approvals would prevent us from commercializing our product candidates.

***Even if any of our product candidates receive regulatory approval, our product candidates may still face future development and regulatory difficulties.***

If any of our product candidates receive regulatory approval, the FDA or other foreign regulatory agencies may still impose significant restrictions on the indicated uses or marketing of the product candidates or impose on-going requirements for potentially costly post-approval studies. In addition, regulatory agencies subject a product, its manufacturer and the manufacturer's facilities to continual review and periodic inspections. If a regulatory agency discovers previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product, our collaborators or us, including requiring withdrawal of the product from the market. Our product candidates will also be subject to on-going FDA and other foreign regulatory agency requirements for the labeling, packaging, storage, advertising, promotion, record-keeping and submission of safety and other post-market information on the drug. If our product candidates fail to comply with applicable regulatory requirements, a regulatory agency may:

## Edgar Filing: METABASIS THERAPEUTICS INC - Form 10-Q

issue warning letters or other notices of possible violations,

impose civil or criminal penalties or seek disgorgement of revenue or profits,

suspend regulatory approval,

suspend any on-going clinical trials,

refuse to approve pending applications or supplements to approved applications filed by us or our collaborators,

impose restrictions on operations, including costly new manufacturing requirements, or

seize or detain products or require a product recall.

In order to market any products outside of the U.S., we and our collaborators must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks regarding FDA approval in the U.S. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others. Failure to obtain



## **Table of Contents**

regulatory approval in other countries or any delay or setback in obtaining such approval could have the same adverse impact regarding FDA approval in the U.S., including the risk that our product candidates may not be approved for all indications requested, which could limit the uses of our product candidates and adversely impact potential royalties and product sales, and that such approval may be subject to limitations on the indicated uses for which the product may be marketed or require costly, post-marketing follow-up studies.

If we and our collaborators fail to comply with applicable foreign regulatory requirements, we and our collaborators may be subject to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

***If we are unable to enter into agreements with third parties to sell, develop, obtain regulatory approval and market our product candidates, we may be unable to generate significant revenues.***

We do not have a research and development, sales and marketing organizations, and we have no experience as a company in the sales, marketing and distribution of pharmaceutical products. Should our hepatitis C collaboration with Roche yield a product candidate, Roche will be responsible for worldwide marketing and commercialization of a resulting product candidate. In order to commercialize MB07811, MB07803, our glucagon antagonist program, prafefovir, MB07133 or any future product candidates for which we retain commercialization rights, we may be required to establish a sales, marketing and distribution capabilities, or make arrangements with a third party to perform these services. We may be unable to establish and manage an effective sales force in a timely or cost-effective manner, if at all, and any sales force we do establish may not be capable of generating sufficient demand for our product candidates. To the extent that we enter into arrangements with collaborators or other third parties to perform sales and marketing services, our product revenues are likely to be lower than if we directly marketed and sold our product candidates. If we are unable to establish adequate sales and marketing capabilities, independently or with others, we may not be able to generate significant revenues and may not become profitable.

***If our competitors have products that are approved faster, marketed more effectively or demonstrated to be more effective than ours, our commercial opportunity will be reduced or eliminated.***

The biotechnology and biopharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. We face competition from many different sources, including commercial pharmaceutical and biotechnology enterprises, academic institutions, government agencies and private and public research institutions. Due to the high demand for treatments for liver and metabolic diseases, research is intense and new treatments are being sought out and developed by our competitors.

We are aware of many competitive products currently marketed or under development that are used to treat some of the diseases we have targeted. If MB07811 is ultimately determined safe and effective and approved for marketing, it would compete with products marketed by several large pharmaceutical companies that currently comprise a large share of the hyperlipidemia market. Major classes of hyperlipidemia drugs include, but are not limited to:

statins, which reduce serum cholesterol levels by inhibiting a key enzyme involved in the biosynthesis of cholesterol,

fibrates, which reduce the amount of cholesterol and triglycerides (fatty substances) in blood,

nicotinic acid derivatives, which lower cholesterol, triglycerides and low density lipoproteins and increase high density lipoproteins,

CAIs, which inhibit the absorption of dietary and biliary cholesterol,

bile acid sequestrants, which bind with cholesterol-containing bile acids in the intestines and remove them in bowel movements, and

statin combination therapies, which combine statins with members of the above-mentioned classes, particularly CAIs.

## Edgar Filing: METABASIS THERAPEUTICS INC - Form 10-Q

Several large pharmaceutical companies are also developing novel therapies that target hyperlipidemia. These companies may develop and introduce products competitive with or superior to MB07811. Atorvastatin is currently one of the best selling prescription medicines. In addition, generic statins (cholesterol-reducers) have recently been approved in the major pharmaceutical markets and would also compete with MB07811.

If MB07803 is ultimately determined safe and effective and approved for marketing, it may compete for market share with established therapies from a number of competitors, including large pharmaceutical companies. Such marketed products include, but are not limited to the following classes:

sulfonylureas, which lower glucose levels by inducing insulin secretion from the pancreas. This drug class has been associated with a significant risk of hypoglycemia,

thiazolidinediones, which lower glucose levels by enhancing insulin sensitivity. This drug class has been associated with fluid retention, weight gain and a risk of heart attacks and angina,

hepatic glucose output inhibitors, which lower glucose levels by inhibiting liver glucose production. The only drug in this class is metformin, which, based on a study reported in the medical journal *Diabetes*, inhibits glucose production by the

## **Table of Contents**

liver by only approximately 20-25%, even when administered at the maximum allowed dose. Metformin therapy is associated with an increased risk of lactic acidosis in certain patient populations, including patients with kidney dysfunction. In addition, metformin therapy commonly leads to transient gastrointestinal disturbances such as nausea, diarrhea and vomiting, which may compromise patient compliance,

incretin mimetics, which lower glucose by exhibiting many of the same glucose regulating actions of naturally occurring GLP-1. GLP-1 is a peptide that facilitates the response of the pancreas and liver to fluctuations in glucose levels by its action on pancreatic beta and alpha cells. Exenatide injection is currently the only marketed drug in this class, and

DPP-4 inhibitors, which inhibit an enzyme in the bloodstream that cleaves and inactivates GLP-1. Inhibition of DPP-4 thus increases the half-life of endogenous GLP-1 by preventing cleavage and inactivation of GLP-1. The overall effect of drugs in this class is to enhance glucose-dependent insulin secretion and suppress inappropriate glucagon secretion.

If pradefovir is ultimately determined safe and effective and approved for marketing, it may compete for market share with established therapies from a number of competitors, including large pharmaceutical companies. Such marketed products include, but are not limited to the following classes:

interferons, which mimic interferon, the naturally occurring infection-fighting immune substance produced by the body,

nucleoside analogues, which are chemically engineered nucleoside compounds that are converted inside cells into other compounds that are structurally similar to the building blocks of DNA and RNA that interfere with the replication of hepatitis B, and

nucleotide analogues, which are chemically engineered nucleotide compounds that are converted inside cells into other compounds that are structurally similar to the building blocks of DNA and RNA that interfere with the replication of hepatitis B.

A competitor to pradefovir would be adefovir dipivoxil, which is a nucleotide analogue currently marketed in the U.S. and Europe. Pradefovir and adefovir dipivoxil are prodrugs of the same active drug, PMEA, and therefore may directly compete. In order to effectively compete with adefovir dipivoxil, pradefovir may have to be significantly more beneficial or less expensive than adefovir dipivoxil. Other competitors to pradefovir include the nucleotide analogue, tenofovir, which has been shown to be very effective in treating hepatitis B infection and has recently been approved for marketing in the U.S. and Europe.

A competitor to MB07133 would be sorafenib, which is a chemotherapy agent approved in the U.S., Europe and most of Asia for the treatment of primary liver cancer. In addition, companies are developing therapies for other solid tumors which may be efficacious in treating primary liver cancer. These companies may develop and introduce products competitive with or superior to MB07133.

Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, clinical trials, regulatory approvals and marketing approved products than we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Our competitors may succeed in developing technologies and therapies that are more effective, better tolerated or less costly that would render our product candidates obsolete and noncompetitive. Our competitors may succeed in obtaining approvals from the FDA and foreign regulatory authorities for their products sooner than we do for ours.

***The commercial success of our product candidates depends upon their market acceptance among physicians, patients, healthcare payors and the medical community.***

Even if our product candidates obtain regulatory approval, our products, if any, may not gain market acceptance among physicians, patients, healthcare payors and the medical community. The degree of market acceptance of any of our approved product candidates will depend on a number of factors, including:

## Edgar Filing: METABASIS THERAPEUTICS INC - Form 10-Q

our licensees' ability to provide acceptable evidence of safety and efficacy,

relative convenience and ease of administration,

the prevalence and severity of any adverse side effects,

restrictions on use in combination with other products,

availability of alternative treatments,

pricing and cost effectiveness assuming either competitive or potential premium pricing requirements, based on the profile of our product candidates and target markets,

effectiveness of our or our partners' sales and marketing strategy, and

our ability to obtain sufficient third-party coverage or reimbursement.

---

## **Table of Contents**

*We are subject to uncertainty relating to health care reform measures and reimbursement policies which, if not favorable to our product candidates, could hinder or prevent our product candidates' commercial success.*

The continuing efforts of the government, insurance companies, managed care organizations and other payors of health care costs to contain or reduce costs of health care may adversely affect:

our ability to set a price we believe is fair for our products,

our ability to generate revenues and achieve or maintain profitability,

our ability to distribute our products due to constraints imposed by a risk management plan,

the future revenues and profitability of our potential customers, suppliers and collaborators, and

the availability of capital.

In certain foreign markets, the pricing of prescription drugs is subject to government control. In the U.S., given recent federal and state government initiatives directed at lowering the total cost of health care, Congress and state legislatures will likely continue to focus on health care reform, the cost of prescription drugs and the reform of the Medicare and Medicaid systems. For example, in January 2007, the House of Representatives passed the Medicare Prescription Drug Price Negotiation Act of 2007. The bill requires the federal government (specifically the Department of Health and Human Services) to negotiate with drug companies over the price of drugs for Medicare participants. In addition, the Medicare Prescription Drug, Improvement and Modernization Act of 2003 provides a Medicare prescription drug benefit that began in 2006 and mandates other reforms. While we cannot predict the full outcome of the implementation of these legislations, it is possible that the new Medicare prescription drug benefit, which is managed by private health insurers and other managed care organizations, will result in decreased reimbursement for prescription drugs, which may further exacerbate industry-wide pressure to reduce prescription drug prices. This could harm our ability to market our products and generate revenues. It is also possible that other similar proposals will be adopted.

Our ability to commercialize our product candidates successfully will depend in part on the extent to which governmental authorities, private health insurers and other organizations establish appropriate coverage and reimbursement levels for the cost of our products and related treatments. Third-party payors including state governments are increasingly challenging the prices charged for medical products and services. Also, the trend toward managed health care in the U.S., which could significantly influence the purchase of health care services and products, as well as legislative proposals to reform health care or reduce government insurance programs, may result in lower prices for our product candidates or exclusion of our product candidates from coverage and reimbursement programs. The cost containment measures that health care payors and providers are instituting and the effect of any health care reform could significantly reduce our revenues from the sale of any approved product. Restrictions imposed by a risk management plan could limit accessibility and distribution of our products.

### **Risks Related to our Intellectual Property**

*Our success depends upon our ability to protect our intellectual property, including the proprietary HepDirect technology and compounds used in our business.*

Our commercial success depends on obtaining and maintaining patent protection and/or trade secret protection of our product candidates, our proprietary HepDirect technology and their uses, as well as successfully defending any patents that issue against third-party challenges. We may only be able to protect our product candidates, proprietary HepDirect technology and their uses from unauthorized use by third parties to the extent that valid and enforceable patents or trade secrets cover them.

The filing, prosecution and defense of patents at pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in biotechnology patents has emerged to date in the U.S. The biotechnology patent situation outside the U.S. is even more uncertain. We may be particularly affected by this because we expect that pradefovir and MB07133, if approved, will be marketed in foreign countries with high

## Edgar Filing: METABASIS THERAPEUTICS INC - Form 10-Q

incidences of hepatitis B and primary liver cancer, respectively. Decisions or actions regarding patent filing and/or changes in either the patent laws or in interpretations of patent laws in the U.S. and other countries may diminish the value of our intellectual property.

Decisions or actions regarding patent filing are complex and we may not be successful in protecting our products from competition. Patent positions for products are highly uncertain and involve complex legal and factual questions which may ultimately be decided to the detriment of our products competitive positions in the U.S. and these other countries. We may not be able to develop patentable products or processes in the U.S. and these other countries, and may not be able to obtain patents from pending applications. Even if patent claims are allowed in the U.S. and these other countries, the claims may not issue, or in the event of issuance, may not be sufficient to protect the technology owned by or licensed to us. Any patents or patent rights that we obtain in the U.S. and other countries may be circumvented, challenged or invalidated by our competitors. In addition, we are dependent on outside patent firms for advice and action regarding our efforts to secure patents. Should these firms fail to take appropriate action to secure or enforce our patents in a timely manner, or should they provide us with incorrect or inappropriate advice it could be detrimental to our patent positions.

Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our patents or in third-party patents in the U.S. and other countries.

## **Table of Contents**

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

we might not have been the first to make the inventions covered by each of our pending patent applications and issued patents,

we might not have been the first to file patent applications for these inventions,

others may independently develop similar or alternative technologies or duplicate any of our technologies,

it is possible that none of our pending patent applications will result in issued patents,

our issued patents may not provide a basis for commercially viable products, may not provide us with any competitive advantages, or may be challenged by third parties,

our issued patents may not be valid or enforceable,

we may not develop additional proprietary HepDirect technology that is patentable, or

the patents of others may have an adverse effect on our business.

Proprietary trade secrets and unpatented know-how are also very important to our business. Although we have taken steps to protect our trade secrets and unpatented know-how, including entering into proprietary information and inventions agreements with our employees and consultants and entering into confidentiality agreements with other third parties to whom we disclose our proprietary information, third parties may still obtain this information without our knowledge and consent. Enforcing a claim that a third party illegally obtained and is using our trade secrets or unpatented know-how is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the U.S. may be less willing to protect this information. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

***If we are sued for infringing intellectual property rights of third parties, it will be costly and time consuming, and an unfavorable outcome in that litigation would have a material adverse effect on our business.***

Our commercial success depends upon our ability and the ability of our collaborators to develop, manufacture, market and sell our product candidates and use our proprietary HepDirect technology without infringing the proprietary rights of third parties. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we and our collaborators are developing products. Because patent applications can take many years to issue, there may be currently pending applications, unknown to us, which may later result in issued patents that our product candidates or proprietary HepDirect technology may infringe. We have not conducted a complete search of existing patents to identify existing patents that our product candidates or proprietary HepDirect technology may inadvertently infringe.

We may be exposed to future litigation by the companies holding these patents or other third parties based on claims that our product candidates and/or proprietary HepDirect technology infringe their intellectual property rights. If one of these patents was found to cover our product candidates, proprietary HepDirect technology or their uses, we or our collaborators could be required to pay damages and could be unable to commercialize our product candidates or use our proprietary HepDirect technology unless we or they obtained a license to the patent. In addition, while we are not currently subject to pending litigation nor are we aware of any threatened litigation, third parties may contact us or our collaborators in the ordinary course of business to bring certain patents to our attention. We and our collaborators evaluate all such communications on a case-by-case basis to assess whether such patents cover our product candidates or proprietary HepDirect technology and if so, whether to seek a license from such third parties. A license may not be available to us or our collaborators on acceptable terms, if at all.

## Edgar Filing: METABASIS THERAPEUTICS INC - Form 10-Q

There is a substantial amount of litigation involving patent and other intellectual property rights in the biotechnology and biopharmaceutical industries generally. If a third party claims that we or our collaborators infringe on its technology, we may face a number of issues, including:

infringement and other intellectual property claims which, with or without merit, may be expensive and time-consuming to litigate and may divert our management's attention from our core business,

substantial damages for infringement, including treble damages and attorneys' fees, as well as damages for products developed using allegedly infringing drug discovery tools or methods, which we may have to pay if a court decides that the product or proprietary technology at issue infringes on or violates the third party's rights,

a court prohibiting us from selling or licensing the product or using the proprietary technology unless the third party licenses its technology to us, which it is not required to do,

if a license is available from the third party, we may have to pay substantial royalties, fees and/or grant cross licenses to our technology, and

redesigning our products or processes so they do not infringe, which may not be possible or may require substantial funds and time. We have conducted searches of U.S. and foreign patents, but cannot guarantee that the searches were comprehensive and therefore whether any of our product candidates or the methods of using, making or identifying our product candidates infringe the patents searched, or that other patents do not exist that cover our product candidates or these methods. There may also be pending



## **Table of Contents**

patent applications that are unknown to us and may prevent us from marketing our product candidates. Other product candidates that we may develop, either internally or in collaboration with others, could be subject to similar delays and uncertainties.

***Existing patents and patent applications covering PMEA or prodrugs of PMEA in the U.S. and foreign countries may prevent the commercialization of pradefovir in the future.***

Our product candidate pradefovir is a prodrug of PMEA. A third party, Gilead, has rights to another product called adefovir dipivoxil that is a non-liver specific prodrug of PMEA. We are aware of third party patents and patent applications in the U.S. and in European and other foreign countries with claims to prodrugs of PMEA. These patents are scheduled to expire in September 2011 overseas and in 2014 in the U.S. Although we do not believe that any valid claim covers pradefovir, we cannot guarantee this. If it is determined that patent claims are valid and cover pradefovir, we may not be able to commercialize pradefovir in such countries, including those in Europe. Further, we are aware that a patent term extension of one of these prodrug patents has been granted in multiple European countries based on the regulatory approval of adefovir dipivoxil thereby extending protection of adefovir dipivoxil in those countries to September 2016. Additional third party patents covering adefovir dipivoxil or PMEA may exist, and may expire later than our expected date of regulatory approval in the country where the patent is in force.

### **Risks Related to Other Legal Matters**

***We may incur significant costs complying with environmental laws and regulations.***

We use hazardous materials, including chemicals, biological agents and radioactive isotopes and compounds that could be dangerous to human health and safety or the environment. As appropriate, we store these materials and wastes resulting from their use at our facility pending their ultimate use or disposal. We currently contract with a third party to dispose of these materials and wastes. We are subject to a variety of federal, state and local laws and regulations governing the use, generation, manufacture, storage, handling and disposal of these materials and wastes. We may also incur significant costs complying with environmental laws and regulations adopted in the future.

***We may incur substantial liabilities from any product liability claims if our insurance coverage for those claims is inadequate.***

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials, and will face an even greater risk if we sell our product candidates commercially. An individual may bring a liability claim against us if one of our product candidates causes, or merely appears to have caused, an injury. If we cannot successfully defend ourselves against the product liability claim, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

injury to our reputation,

withdrawal of clinical trial participants,

costs of related litigation,

substantial monetary awards to patients or other claimants,

loss of revenues, and

the inability to commercialize our product candidates.

We have product liability insurance that covers our clinical trials, up to an annual aggregate limit of \$10 million. We intend to expand our insurance coverage to include the sale of commercial products if marketing approval is obtained for any of our product candidates. However, insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost and we may not be able to

obtain insurance coverage that will be adequate to satisfy any liability that may arise.

*If we use biological and hazardous materials in a manner that causes injury, we may be liable for damages.*

Our research and development and manufacturing activities involve the use of biological and hazardous materials. Although we believe our safety procedures for handling and disposing of these materials comply with federal, state and local laws and regulations, we cannot entirely eliminate the risk of accidental injury or contamination from the use, storage, handling or disposal of these materials. If one of our employees was accidentally injured from the use, storage, handling or disposal of these materials, the medical costs related to his or her treatment would be covered by our workers' compensation insurance policy. While our property and casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination, we do carry separate pollution legal liability coverage that is intended to cover third party claims for bodily injury, property damage and remediation costs. However, in the event of contamination or injury, we could be held liable for damages or penalized with fines in an amount exceeding our insurance and/or resources.

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

None.

**Table of Contents****Item 3. Defaults Upon Senior Securities**

None.

**Item 4. Submission of Matters to a Vote of Security Holders**

We held our 2009 Annual Meeting of Stockholders on June 23, 2009. As of the close of business on April 27, 2008, the record date for the Annual Meeting, there were 35,152,359 shares of our common stock entitled to vote, of which there were 21,054,629 shares present at the Annual Meeting in person or by proxy. At the Annual Meeting, our stockholders approved the following matters:

Proposal 1. Election of four directors to serve as Class II directors until our 2012 Annual Meeting of Stockholders. The vote for the nominees for Class II directors were as follows:

<b>Nominee</b>	<b>Shares Voted in Favor of Nominee</b>	<b>Shares Withheld</b>
Mark D. Erion, Ph.D.	20,992,244	62,385
Arnold L. Oronsky, Ph.D.	18,959,374	2,095,255
William R. Rohn	20,655,861	398,768
Elizabeth Stoner, M.D.	21,026,503	28,126

Our Class III directors, David F. Hale, Paul K. Laikind, Ph.D., and George F. Schreiner, M.D., Ph.D., continue in office until our 2010 Annual Meeting of Stockholders. Our Class I directors, Daniel D. Burgess, M.B.A and Luke B. Evnin, Ph.D., continue in office until our 2011 Annual Meeting of Stockholders.

Proposal 2. Ratification of the selection by the Audit Committee of our Board of Directors of Ernst & Young LLP as our independent registered public accounting firm for the fiscal year ending December 31, 2009. 19,351,667 shares voted in favor of the proposal; 1,697,962 shares voted against the proposal; and 5,000 shares abstained from voting.

**Item 5. Other Information**

None.

## **Table of Contents**

### **Item 6. Exhibits**

#### **Exhibit**

<b>Number</b>	<b>Description</b>
3.1(1)	Amended and Restated Certificate of Incorporation.
3.2(2)	Amended and Restated Bylaws.
4.1(1)	Form of Common Stock Certificate.
10.1+	Severance Agreement dated April 22, 2009 between the Company and Barry Gumbiner.
10.2	Amended and Restated Loan Agreement dated May 28, 2009 between the Company and Oxford Finance Corporation.
10.3*	Letter Agreement to Collaboration and License Agreement dated June 1, 2009 between the Company and Hoffmann-La Roche Inc., F. Hoffmann-La Roche Ltd. and Roche Palo Alto LLC.
10.4	Amendment to Collaboration and License Agreement dated June 1, 2009 between the Company and Merck & Co.
10.5	Agreement for Termination of Lease dated July 21, 2009 between the Company and ARE-SD Region No. 24, LLC.
10.6	Sellers/Listing Services Addendum dated July 14, 2009 between the Company and EquipNet, Inc.
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

+ Indicates management contract or compensatory plan.

\* Confidential treatment has been requested with respect to certain portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.

(1) Incorporated by reference to the exhibit of the same number to the Company's Registration Statement on Form S-1 (No. 333-112437), originally filed on February 3, 2004.

(2) Incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on October 2, 2007.

**Table of Contents**

**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.

Date: August 7, 2009

By: /s/ Tran B. Nguyen  
Tran B. Nguyen, M.B.A.

*Vice President, Chief Financial Officer, Treasurer and*

*Corporate Secretary (Principal Financial Officer)*