

METABASIS THERAPEUTICS INC

Form 10-Q

November 10, 2008

[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 September 30, 2008.**

**OR**

**o 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)

Edgar Filing: METABASIS THERAPEUTICS INC - Form 10-Q

**Delaware**

(State or other jurisdiction of  
incorporation or organization)

**33-0753322**

(I.R.S. Employer  
Identification No.)

**11119 North Torrey Pines Road,  
La Jolla, CA**

(Address of principal executive offices)

**92037**

(Zip code)

**(858) 587-2770**

(Registrant's telephone number, including area code)

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 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   
(Do not check if a smaller reporting company)

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 November 6, 2008 was 35,043,026.

---

Table of Contents

**METABASIS THERAPEUTICS, INC.**

**FORM 10-Q**

**FOR THE QUARTERLY PERIOD ENDED September 30, 2008**

**TABLE OF CONTENTS**

<u>PART I. FINANCIAL INFORMATION</u>	2
<u>Item 1. Financial Statements</u>	2
<u>Balance Sheets at September 30, 2008 (Unaudited) and December 31, 2007</u>	2
<u>Statements of Operations for the three and nine months ended September 30, 2008 and 2007 (Unaudited)</u>	3
<u>Statements of Cash Flows for the nine months ended September 30, 2008 and 2007 (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>	9
<u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u>	18
<u>Item 4. Controls and Procedures</u>	18
<u>PART II. OTHER INFORMATION</u>	19
<u>Item 1. Legal Proceedings</u>	19
<u>Item 1A. Risk Factors</u>	19
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	39
<u>Item 3. Defaults Upon Senior Securities</u>	39
<u>Item 4. Submission of Matters to a Vote of Security Holders</u>	39
<u>Item 5. Other Information</u>	39
<u>Item 6. Exhibits</u>	40
<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)**

	September 30, 2008 (Unaudited)	December 31, 2007
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 17,109	\$ 14,141
Securities available-for-sale	15,673	28,297
Prepays and other current assets	1,369	1,157
Total current assets	34,151	43,595
Property and equipment, net	5,285	6,356
Other assets	297	172
Total assets	\$ 39,733	\$ 50,123
<b>Liabilities and stockholders equity</b>		
Current liabilities:		
Accounts payable	\$ 662	\$ 802
Accrued compensation	3,018	3,181
Accrued liabilities	2,142	4,132
Deferred revenue, current portion	5,721	1,321
Current portion of long-term debt	3,717	2,068
Current portion of capital lease obligations	26	23
Total current liabilities	15,286	11,527
Deferred revenue, net of current portion	3,458	
Deferred rent	2,964	2,595
Long-term debt	5,634	3,845
Capital lease obligations, net of current portion	33	55
Other long-term liabilities	200	
Total liabilities	27,575	18,022
Stockholders equity:		
Preferred stock, \$0.001 par value; 5,000 shares authorized at September 30, 2008 and December 31, 2007, no shares issued or outstanding		
Common stock, \$0.001 par value; 100,000 shares authorized at September 30, 2008 and December 31, 2007; 35,043 and 30,754 shares issued and outstanding at September 30, 2008 and December 31, 2007, respectively	35	31
Additional paid-in capital	194,576	182,003
Accumulated deficit	(182,488)	(150,012)

Edgar Filing: METABASIS THERAPEUTICS INC - Form 10-Q

Accumulated other comprehensive loss		35		79
Total stockholders' equity		12,158		32,101
Total liabilities and stockholders' equity	\$	39,733	\$	50,123

*See accompanying notes.*

Table of Contents

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
<b>Revenues:</b>				
Sponsored research	\$ 659	\$ 937	\$ 1,698	\$ 2,813
License fees	743	1,417	1,333	4,550
Other revenue		299		320
Total revenues	1,402	2,653	3,031	7,683
<b>Operating expenses:</b>				
Research and development	8,480	10,866	27,892	31,437
General and administrative	2,659	2,834	7,747	9,284
Total operating expenses	11,139	13,700	35,639	40,721
Loss from operations	(9,737)	(11,047)	(32,608)	(33,038)
<b>Other income (expense):</b>				
Interest income	169	708	812	2,522
Interest expense	(266)	(141)	(680)	(405)
Total other (expense) income	(97)	567	132	2,117
Net loss	\$ (9,834)	\$ (10,480)	\$ (32,476)	\$ (30,921)
Basic and diluted net loss per share	\$ (0.28)	\$ (0.34)	\$ (0.97)	\$ (1.01)
Shares used to compute basic and diluted net loss per share	35,042	30,650	33,354	30,552

*See accompanying notes.*

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

	<b>Nine Months Ended September 30,</b>	
	<b>2008</b>	<b>2007</b>
<b>Operating activities</b>		
Net loss	\$ (32,476)	\$ (30,921)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	2,904	3,938
Depreciation and amortization	1,558	1,496
Deferred rent	369	847
Amortization of discount and premium on securities available-for-sale	(407)	(1,883)
Loss on disposal of assets	29	
Realized gain on securities available-for-sale	(7)	
Change in operating assets and liabilities:		
Trade accounts receivable	61	(225)
Other current assets	(273)	(94)
Other assets	75	5
Deferred revenue	7,858	(2,751)
Accounts payable	(140)	(502)
Accrued compensation and other liabilities	(2,153)	2,571
Net cash flows used in operating activities	(22,602)	(27,519)
<b>Investing activities</b>		
Purchases of securities available-for-sale	(24,498)	(63,977)
Sales/maturities of securities available-for-sale	37,492	93,707
Purchases of property and equipment	(516)	(2,094)
Net cash flows provided by investing activities	12,478	27,636
<b>Financing activities</b>		
Issuance of common stock, net	9,673	425
Principal payments on debt and capital lease obligations	(1,581)	(1,447)
Proceeds received from debt	5,000	2,047
Net cash flows provided by financing activities	13,092	1,025
Increase in cash and cash equivalents	2,968	1,142
Cash and cash equivalents at beginning of year	14,141	12,052
Cash and cash equivalents at end of period	\$ 17,109	\$ 13,194
<b>Supplemental schedule of noncash investing and financing activities:</b>		
Accrued debt issuance costs	\$ 200	\$
Unrealized (loss) gain on securities available-for-sale	\$ (44)	\$ 55
Net share settlement of warrant	\$	\$ 56

*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, 2007 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 nine months ended September 30, 2008 are not necessarily indicative of the results that may be expected for the year ending December 31, 2008. For further information, see the financial statements and notes thereto for the year ended December 31, 2007 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. Comprehensive Loss**

Statement of Financial Accounting Standard ( SFAS ) No. 130, *Reporting Comprehensive Income*, requires that all components of comprehensive income (loss), including net 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 loss is as follows (in thousands):

**Three Months Ended  
September 30,**

**Nine Months Ended  
September 30,**

Edgar Filing: METABASIS THERAPEUTICS INC - Form 10-Q

	2008	2007	2008	2007
Net loss	\$ (9,834)	\$ (10,480)	\$ (32,476)	\$ (30,921)
Unrealized gain (loss) on available-for-sale investments	10	35	(44)	55
Comprehensive loss	\$ (9,824)	\$ (10,445)	\$ (32,520)	\$ (30,866)

**3. Net Loss Per Share**

The Company calculates net loss per share in accordance with SFAS No. 128, *Earnings Per Share*. Basic earnings per share ( EPS ) is calculated by dividing the net 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 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 7,906,668 and 7,575,946 for the three months ended September 30, 2008 and 2007, respectively, and 7,580,525 and 7,262,816 for the nine months ended September 30, 2008 and 2007, respectively.

Edgar Filing: METABASIS THERAPEUTICS INC - Form 10-Q

Table of Contents

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
<b>Actual:</b>				
<i>Numerator:</i>				
Net loss	\$ (9,834)	\$ (10,480)	\$ (32,476)	\$ (30,921)
<i>Denominator:</i>				
Weighted average common shares	35,042	30,652	33,354	30,573
Weighted average unvested common shares subject to repurchase		(2)		(21)
Denominator for basic and diluted net loss per share	35,042	30,650	33,354	30,552
Basic and diluted net loss per share	\$ (0.28)	\$ (0.34)	\$ (0.97)	\$ (1.01)

**4. Fair Value of Financial Instruments**

In September 2006, the Financial Accounting Standards Board (the FASB) issued SFAS No. 157, *Fair Value Measurements* (SFAS No. 157). This statement provides a definition of fair value, establishes a hierarchy for measuring fair value in GAAP, and requires certain disclosures about fair values used in financial statements. This statement does not extend the use of fair value beyond what is currently required by other pronouncements, and it does not pertain to stock-based compensation under SFAS No. 123(R), *Share-Based Payment*, or to leases under SFAS No. 13, *Accounting for Leases*.

This statement was effective for financial statements issued for fiscal years beginning after November 15, 2007 (beginning with the Company's 2008 fiscal year), although earlier application was encouraged.

On February 14, 2008, FASB Staff Position (FSP) FAS 157-2, *Effective Date of FASB Statement No. 157* (FSP FAS 157-2), was issued. FSP FAS 157-2 defers application of SFAS No. 157 for non-financial assets and liabilities to years beginning after November 15, 2008 (beginning with the Company's 2009 fiscal year). As a result, the Company is only partially adopting SFAS No. 157 as it relates to the Company's financial assets and liabilities until it is required to apply this pronouncement to its non-financial assets and liabilities beginning with fiscal year 2009.

The Company applies fair value accounting to its securities available-for-sale in accordance with SFAS No. 115, *Accounting for Certain Investments in Debt and Equity Securities* (SFAS No. 115). These securities consist of treasury backed money market funds, corporate bonds and commercial paper. Due to the current market conditions, the Company no longer invests in asset backed securities. The following table shows the fair value measurement for its financial assets at September 30, 2008 and the fair value hierarchy level, as defined in SFAS No. 157.

Asset	Fair Value Measurements (in thousands)		
	Quoted Prices in Active Markets for Identical Assets	Significant Other Observable Inputs	Significant Unobservable Inputs

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

Description	Total	(Level 1)	(Level 2)	(Level 3)
Securities available-for-sale	\$ 15,673	\$ 15,673	\$	\$

Asset classes that fall within the Level 1 fair value hierarchy are those assets whose fair value assumptions are based on market data obtained from sources independent of the Company (observable inputs). Level 1 observable inputs are quoted prices for identical items in active markets that the Company has access to at the measurement date.

Asset classes that fall within the Level 2 fair value hierarchy are those assets whose fair value assumptions are also based on independent market data. Level 2 observable inputs are quoted prices for similar items in active markets or quoted prices for identical or similar items in inactive markets. An inactive market is one where there are few transactions, the prices are not current, price quotations vary substantially over time or among market makers or where little information is released publicly.

Asset classes that fall within the Level 3 fair value hierarchy are those assets whose fair value assumptions are based on the Company's own information.

Table of Contents

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities, including an amendment of SFAS No. 115* ( SFAS No. 159 ). SFAS No. 159 expands the use of fair value accounting but does not affect existing standards that require assets or liabilities to be carried at fair value. Under SFAS No. 159, a company may elect to use fair value to measure accounts and loans receivable, available-for-sale and held-to-maturity securities, equity method investments, accounts payable, guarantees and issued debt. Other eligible items include firm commitments for financial instruments that otherwise would not be recognized at inception and non-cash warranty obligations where a warrantor is permitted to pay a third party to provide the warranty goods or services. If the use of fair value is elected, any upfront costs and fees related to the item must be recognized in earnings and cannot be deferred, such as debt issuance costs. The fair value election is irrevocable and generally made on an instrument-by-instrument basis, even if a company has similar instruments that it elects not to measure based on fair value. At the adoption date, unrealized gains and losses on existing items for which fair value has been elected are reported as a cumulative adjustment to beginning retained earnings. Subsequent to the adoption of SFAS No. 159, changes in fair value are recognized in earnings. SFAS No. 159 was effective for fiscal years beginning after November 15, 2007 (beginning with the Company's 2008 fiscal year).

The Company considers the carrying amount of cash and cash equivalents, prepaid expenses and other current assets, securities available-for-sale, accounts receivable, accounts payable, accrued liabilities and deferred revenue to be representative of their respective fair values because of the short-term nature of those instruments. Based on the borrowing rates currently available to the Company for loans with similar terms, management believes the fair value of the long-term obligations approximate their carrying value. Therefore, the Company has elected not to apply the fair value option to these financial assets and liabilities under SFAS No. 159. However, the Company does apply fair value accounting to its securities available-for-sale in accordance with SFAS No. 115.

Realized gains and losses and declines in value judged to be other-than-temporary, if any, on available-for-sale securities are included in other income. The cost of securities sold is based on the specific-identification method. Interest and dividends on securities classified as available-for-sale are included in interest income. Total realized gains from fair value changes included in earnings for the three and nine months ended September 30, 2008 were immaterial. There were no cumulative adjustments to beginning retained earnings as a result of adopting SFAS No. 159.

**5. Collaboration Agreements**

In September 2008, the Company, Valeant Pharmaceuticals North America ( Valeant ) and Schering Corporation ( Schering ) entered into an agreement (the Amendment Agreement ) to amend certain terms of the Assignment and Assumption Agreement, dated January 9, 2007 (the Assignment Agreement ) and the Termination Agreement, dated September 19, 2007 (the Termination Agreement ), each entered into by Valeant, Schering and the Company. Pursuant to the Amendment Agreement, among other things, the Assignment Agreement was amended to provide for a reduction in the total number and value of milestone payments payable by the Company to Valeant upon the achievement of certain specified events to a single milestone payment due upon the first regulatory approval of pradefovir, and to reduce certain royalty payments due from the Company to Valeant upon commercialization of pradefovir. In addition, the Termination Agreement was amended to transfer certain patient registry obligations, should they be required, to the Company from Valeant (excluding the cost thereof, up to a specified limit). The Company does not anticipate incurring any costs related to the Amendment Agreement.

In August 2008, the Company entered into a two-year Research Collaboration and License Agreement with Hoffmann-La Roche Inc., F. Hoffmann-La Roche LTD and Roche Palo Alto LLC (collectively, Roche ). Under the terms of the Roche agreement, the Company's HepDirect liver-targeted technology will be applied to proprietary Roche compounds to develop second-generation nucleoside analog drug candidates for treating hepatitis C virus. The Company received an upfront payment of \$10.0 million from Roche in August 2008. Roche may also pay up to \$2.1 million in sponsored research funding at the beginning of the second year of the research term, if applicable. In the event a development candidate is identified, Roche will assume development responsibility and the Company will be eligible to receive up to \$193 million in

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

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.

Pursuant to SEC Staff Accounting Bulletin No. 104, *Revenue Recognition*, and Emerging Issues Task Force ( EITF ) Issue No. 00-21, *Revenue Arrangements with Multiple Deliverables*, the Company has determined that the \$10.0 million upfront payment should be accounted for as a single unit of accounting with two deliverables: access to the licensed technology over the two-year research term and research and development services over the first year of the research term. The \$10.0 million payment shall be allocated to each deliverable based on its relative fair value and shall be deferred and recognized over each deliverable's period of performance. If Roche pays up to an additional \$2.1 million for sponsored research at the beginning of the second year of the research term, such amounts would also be deferred and recognized over the second year of the research term as earned. Amounts attributable to any milestone payments or royalties will be recognized as earned.

Table of Contents

**6. Recent Accounting Pronouncements**

In June 2007, the EITF issued EITF Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to be Used in Future Research and Development Activities* ( EITF Issue No. 07-3 ). The consensus requires companies to defer and capitalize prepaid, nonrefundable research and development payments to third parties over the period that the research and development activities are performed or the services are provided, subject to an assessment of recoverability. EITF Issue No. 07-3 is effective for new contracts entered into in fiscal years beginning after December 15, 2007, including interim periods within those fiscal years. The adoption of EITF Issue No. 07-3 did not have a material impact on the Company's financial statements.

In November 2007, the EITF issued EITF Issue No. 07-1, *Accounting for Collaborative Arrangements Related to the Development and Commercialization of Intellectual Property* ( EITF Issue No. 07-1 ). Companies may enter into arrangements with other companies to jointly develop, manufacture, distribute and market a product. Often the activities associated with these arrangements are conducted by the collaborators without the creation of a separate legal entity (that is, the arrangement is operated as a virtual joint venture ). The arrangements generally provide that the collaborators will share, based on contractually defined calculations, the profits or losses from the associated activities. Periodically, the collaborators share financial information related to product revenues generated (if any) and costs incurred that may trigger a sharing payment for the combined profits or losses. The consensus requires collaborators in such an arrangement to present the result of activities for which they act as the principal on a gross basis and report any payments received from (made to) other collaborators based on other applicable GAAP or, in the absence of other applicable GAAP, based on analogy to authoritative accounting literature or a reasonable, rational and consistently applied accounting policy election. EITF Issue No. 07-1 is effective for collaborative arrangements already in place at the beginning of the annual period beginning after December 15, 2008 (beginning with our 2009 fiscal year), and retrospective application of EITF Issue No. 07-1 to all prior periods presented should be reported as a change in accounting principle. The Company is in the process of determining the effect, if any, the adoption of EITF Issue No. 07-1 will have on its financial statements.

In December 2007, the FASB issued SFAS No. 141(R), *Business Combinations* ( SFAS No. 141(R) ). SFAS No. 141(R) replaces SFAS No. 141. SFAS No. 141(R) requires the acquirer of a business to recognize and measure the identifiable assets acquired, the liabilities assumed and any non-controlling interest in the acquiree at fair value. SFAS No. 141(R) also requires transaction costs related to the business combination to be expensed as incurred. SFAS No. 141(R) applies prospectively to business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008 (the Company's 2009 fiscal year). The adoption of SFAS No. 141(R) is not expected to have a material impact on the Company's financial statements.

In May 2008, the FASB issued SFAS No. 162, *The Hierarchy of Generally Accepted Accounting Principles* ( SFAS No. 162 ). SFAS No. 162 identifies the sources of accounting principles and provides entities with a framework for selecting the principles used in preparation of financial statements that are presented in conformity with GAAP. The current GAAP hierarchy has been criticized because it is directed to the auditor rather than the entity, it is complex and it ranks FASB Statements of Financial Accounting Concepts, which are subject to the same level of due process as FASB SFAS, below industry practices that are widely recognized as generally accepted but that are not subject to due process. The FASB believes the GAAP hierarchy should be directed to entities because it is the entity (not its auditors) that is responsible for selecting accounting principles for financial statements that are presented in conformity with GAAP. SFAS No. 162 is effective 60 days following the SEC's approval of the Public Company Accounting Oversight Board amendments to AU Section 411, *The Meaning of Present Fairly in Conformity With Generally Accepted Accounting Principles*. The adoption of SFAS No. 162 is not expected to have a material impact on the Company's financial statements.

In June 2008, the EITF issued EITF No. 08-3, *Accounting by Lessees for Maintenance Deposits under Lease Agreements* ( EITF No. 08-3 ). Under certain lease arrangements, the lessee is contractually responsible for repair and maintenance of the leased asset, and the lessee is required to make deposits with the lessor to fund that maintenance. The deposit is refunded to the lessee only to the extent that the lessee incurs qualified

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

maintenance costs. Questions have arisen as to the proper accounting for these deposits as some companies account for the maintenance deposits as deposits, while other companies account for them as contingent rental expense. EITF No. 08-3 concludes that maintenance deposits should be considered deposits when paid to the lessor if it is probable that the deposits will be refunded to the lessee. If it is not probable, then the deposits are recognized as rental expense. If it is determined at the inception of the lease that a portion of the deposits is not probable of being refunded to the lessee, then the lessee should recognize as expense a pro-rata portion of the deposits as they are paid. The cost of maintenance activities should be expensed or capitalized, as appropriate. The definition of "probable" will fall under the guidance of FASB Concept Statement No. 6, *Elements of Financial Statements*. EITF No. 08-3 is effective for fiscal years beginning after December 15, 2008 (beginning with the Company's fiscal year 2009). Early application is not permitted. The adoption of EITF No. 08-3 is not expected to have a material impact on the Company's financial statements.



Table of Contents

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



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

*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, 2007 included in our annual report on Form 10-K filed with the Securities and Exchange Commission on March 17, 2008. 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 focused on discovering, developing and commercializing novel drugs by applying our proprietary technologies, scientific expertise and unique capabilities for targeting the liver and liver pathways. We have established a broad pipeline of product candidates and advanced research programs targeting large markets with significant unmet needs. Our product pipeline includes product candidates and advanced research programs for the treatment of metabolic diseases such as diabetes and hyperlipidemia, which we refer to as our core assets, as well as product candidates and advanced research programs for the treatment of liver diseases such as hepatitis and primary liver cancer, which we refer to as our non-core assets. All of our product candidates were developed internally using our proprietary technologies.

We currently have four product candidates at the clinical stage of development. These product candidates include our core metabolic disease product candidates, MB07803 and MB07811, which are being developed as potential treatments for type 2 diabetes and hyperlipidemia, respectively, and our non-core liver disease product candidates, pradefovir and MB07133, which have been developed as potential treatments for hepatitis B and primary liver cancer, respectively. In addition, our core assets include our glucagon antagonist program, which is in the advanced research stage of development for the treatment of diabetes.

### Recent Events

In September 2008, we, Valeant Pharmaceuticals North America, or Valeant, and Schering Corporation, or Schering, entered into an agreement, or the Amendment Agreement, to amend certain terms of the Assignment and Assumption Agreement, dated January 9, 2007, or the Assignment Agreement, and the Termination Agreement, dated September 19, 2007, or the Termination Agreement, each entered into by Valeant, Schering and us. Pursuant to the Amendment Agreement, among other things, the Assignment Agreement was amended to provide for a reduction in the total number and value of milestone payments payable by us to Valeant upon the achievement of certain specified events to a single milestone payment due upon the first regulatory approval of pradefovir, and to reduce certain royalty payments due from us to Valeant upon commercialization of pradefovir. In addition, the Termination Agreement was amended to transfer certain patient registry obligations, should they be required, to us from Valeant (excluding the cost thereof, up to a specified limit). We do not anticipate incurring any costs related to the Amendment Agreement.

In August 2008, we entered into a two-year Research Collaboration Agreement with Hoffman-La Roche Inc., F. Hoffman-La Roche LTD and Roche Palo Alto LLC, collectively referred to as Roche. Under the terms of the Roche agreement, Metabasis HepDirect liver-targeting technology will be applied to proprietary Roche compounds to develop second-generation nucleoside analog drug candidates for the treatment of hepatitis C virus. We received an upfront payment of \$10.0 million from Roche in August 2008. In the event a development candidate is identified, Roche will assume development responsibility and we will be eligible to receive up to \$193 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 us a royalty on net sales of such products.

*Strategic Plan*

Under our strategic plan we are focusing our internal resources primarily on our clinical and advanced research core metabolic disease programs. This includes funding the further clinical evaluation of our core assets, MB07803 and MB07811, with a focus on achieving key milestones. Continued development of these core assets thereafter will require significant resources. Therefore, we plan to establish strategic collaborations for these core assets at appropriate times to secure additional resources, accelerate progress and share risk. In addition, we plan to advance additional metabolic disease product candidates discovered by our research group into clinical development either independently, or with current or future strategic collaborators.

Table of Contents

In order to reduce future expenses and to minimize the potential dilution associated with financing internal development, we intend to license our glucagon antagonist program, pradefovir and MB07133 for further development and commercialization for upfront fees, milestones and royalties on future sales, if any, or we may directly sell these assets. If we are unsuccessful in monetizing these assets, we may be required to raise additional capital by issuing securities or obtaining debt financing, or consider other strategic alternatives. The recent global financial crisis and other current negative macroeconomic indicators may negatively impact our ability to issue securities or obtain debt financing. Given the economic and corporate uncertainties, the Company is planning to institute various cost saving measures to be announced when final decisions are made.

*History of Losses, Prior Funding*

We have incurred annual net losses since inception. As of September 30, 2008, our accumulated deficit was approximately \$182.5 million. We expect to incur losses for the next several years as we:

- continue to develop our current and future core metabolic disease clinical development candidates,
- participate in the commercialization of our product candidates, if any, that receive regulatory approval and for which we retain commercialization rights, and
- continue our research and development programs.

We have a limited history of operations and, to date, we have not generated any product revenues. In addition to our initial public offering in June 2004, our private placement of common stock and warrants in October 2005, our registered direct offering of common stock in March 2006 and our warrant exchange and concurrent private placement in April 2008, we have financed our operations and internal growth through private placements of preferred stock as well as direct payments of sponsored research funding, license fees, milestone payments, equity investments from collaborative partners, debt financing and, to a lesser extent, the sale of common stock through our stockholder approved equity incentive plans.

*Commercial, Manufacturing Rights, Risks*

We currently do not have strategic collaborations in place related to MB07803 or MB07811 and we intend to license our glucagon antagonist program, pradefovir and MB07133. We retain worldwide commercialization rights to all of the compounds that we have generated from our past and current research programs, with the exception of any potential future product candidates that may result from our collaborations with Merck & Co. Inc., or Merck, Idenix Pharmaceuticals, Inc., or Idenix, and Roche. Our potential future agreements with strategic collaborators may include joint marketing or promotion arrangements which may allow us to eventually co-market one or more of our product candidates through our own sales force or with a co-promotion partner. Alternatively, we may grant exclusive rights to our collaborators in exchange for upfront fees, milestones and royalties on future sales, if any, or directly sell certain of our assets.

We will rely on our collaborators or third-party manufacturers to produce sufficient quantities of our product candidates for clinical studies and large-scale commercialization upon their approval. Since we do not currently possess the resources necessary to independently develop and commercialize all of the potential product candidates that may be based upon our technologies, we plan to enter into additional collaborative agreements to assist in the development and commercialization of some or all of our product candidates. However, our discussions with potential collaborators may not lead to the establishment of new collaborations on acceptable terms, if at all, or it may take longer than expected to establish new collaborations, leading to development and commercialization delays.

Our business is subject to significant risks, including the risks inherent in our ongoing clinical trials and the regulatory review and approval process, the results of our research and development efforts, reliance on third parties for the development and commercialization of our product candidates, competition from other products and uncertainties associated with obtaining and enforcing patent rights.

### **Research and Development**

Our research and development expenses consist primarily of cash and 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. Beginning January 1, 2008, we revised our estimate of the rate we use to allocate occupancy and information systems costs between research and development expenses and general and administrative expenses. We feel the current allocation is more reflective of the actual consumption of these expenses in these operational functions for fiscal 2008.

Table of Contents

Our development activities are focused on the clinical development of our core metabolic disease assets, MB07803 and MB07811. Our activities related to our non-core liver disease assets, pradeфовir and MB07133, are currently limited to planning, consultation, design and other efforts preparatory to their potential future clinical development by licensees. In addition, our research activities include work on a variety of compounds in our advanced research programs. We are responsible for all costs incurred for our product candidates and our advanced research programs with the exception of the AMPK program partnered with Merck and the hepatitis C programs partnered with Merck, Idenix and Roche (excluding costs associated with manufacturing compounds that Idenix is currently evaluating, for which we are responsible).

Our AMPK collaboration with Merck seeks to develop and commercialize new products to treat type 2 diabetes and potentially other metabolic diseases. Under the terms of our AMPK collaboration agreement with Merck, we have received approximately \$11.6 million in cumulative sponsored research and license fees funding through September 30, 2008, which includes funding for sponsored research efforts through June 2009.

Our collaborations with Merck and Idenix sought to develop and commercialize new products for treating hepatitis C infection. Our efforts and internal costs related to the hepatitis C collaboration with Merck ceased upon completion of its research term in December 2005. Under the terms of the Merck agreement, we have received approximately \$3.2 million in cumulative license fees and sponsored research funding through December 31, 2005. Our efforts and internal costs related to the hepatitis C collaboration with Idenix ceased upon completion of its research term in October 2007. Under the terms of the Idenix agreement, we have received approximately \$3.4 million in cumulative license fees and sponsored research funding through December 31, 2007.

Although the funded research phases of the hepatitis C collaborations with Merck and Idenix are completed, Merck and Idenix are currently evaluating certain candidate compounds discovered during the collaborations to determine if one or more will be recommended for clinical development. Merck and Idenix are solely responsible for conducting and funding all development work for any compounds resulting from these collaborations (excluding costs and work associated with manufacturing candidate compounds Idenix is currently evaluating, for which we are responsible) and for commercializing any resulting products. If a product is successfully developed, we will receive substantial milestone payments as well as receive a portion of the revenue from sales of a drug in the form of a royalty on net sales.

Our new two-year collaboration with Roche also seeks to develop and commercialize new products for treating hepatitis C infection. Under the terms of the Roche agreement, we received an upfront payment of \$10.0 million in August 2008. We are entitled to receive payments on the achievement of certain milestones and during the second year of the agreement, we are entitled to additional sponsored research funding.

At this time, due to the risks inherent in the clinical trial process and given the early stage of development of our product candidates and lead compounds from our research programs, we are unable to estimate with any certainty the costs we will incur in the continued development of our product candidates for commercialization. Other than costs for outsourced services associated with our clinical programs, we generally do not track our research and development expenses by project; rather, we track such expenses by the type of cost incurred. Due to these and other factors, we are unable to determine the anticipated completion dates for our current research and development projects. However, we expect our research and development costs to be substantial as we continue the development of our core assets, as well as continue to expand our research programs.

Generally, Phase 1 clinical trials can be expected to last from 6 to 18 months, Phase 2 clinical trials can be expected to last from 12 to 24 months and Phase 3 clinical trials can be expected to last from 18 to 36 months. However, clinical development timelines vary widely, as do the total costs of clinical trials and the likelihood of success. Although we are currently focused primarily on advancing MB07803 and MB07811 through clinical development, we anticipate that we will make determinations as to which research and development projects to pursue and how

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

much funding to direct to each project on an ongoing basis in response to the scientific and clinical success of each product candidate, our ongoing assessment of its market potential and consideration of our available financial resources.

The lengthy process of seeking regulatory approvals for our product candidates, and the compliance with applicable regulations, require the expenditure of substantial resources. Any failure by us to obtain, or any delay in obtaining, regulatory approvals could cause our research and development expenditures to increase and, in turn, have a material unfavorable effect on our results of operations. Additionally, under our strategic plan, we intend to establish strategic collaborations for our core assets and non-core assets at appropriate times to secure additional resources, accelerate progress and share risk. However, delays in finding appropriate partnerships could also have a material unfavorable effect on our results of operations. We cannot be certain when or if any net cash inflow due to sales of any of our current product candidates will commence.



Table of Contents

**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, investor relations, 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. Beginning January 1, 2008, we revised our estimate of the rate we use to allocate occupancy and information systems costs between research and development expenses and general and administrative expenses. We feel the current allocation is more reflective of the actual consumption of these expenses in these operational functions for fiscal 2008.

**Other Income (Expense)**

Other income (expense) includes interest earned on our cash, cash equivalents and securities available-for-sale, net of interest expense on capital lease obligations, debt, and the related issuance costs.

**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 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 technologies and research and development services. Payments under our collaborations are generally made in the form of upfront license fees, milestone payments and downstream royalties. All fees are nonrefundable. Revenue from milestones is recognized when earned, provided that:

- 1) the milestone event is substantive and its achievability was not reasonably assured at the inception of the agreement, and
- 2) collaborator funding, if any, of our performance obligations after the milestone achievement will continue at a level comparable to before the milestone achievement.

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

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. Upfront, 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.

*Clinical Trial Expenses.* Our clinical trials are often conducted under contracts with multiple research institutions and clinical research organizations that conduct and manage clinical trials on our behalf. The financial terms of these agreements are subject to negotiation and vary from contract to contract and may result in uneven payment flows. Generally, these agreements set forth the scope of work to be performed at a fixed fee or unit price. Payments under the contracts depend on factors such as the successful enrollment of patients or the completion of clinical trial milestones. Expenses related to clinical trials generally are accrued based on contracted amounts applied to the actual level of patient enrollment and activity according to the protocol. Other incidental costs related to patient enrollment are accrued when known. If contracted amounts are modified based upon changes in the clinical trial protocol or scope of work to be performed, we modify our accruals accordingly on a prospective basis.

*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 revised Statement of Financial Accounting Standards, or SFAS, No. 123R, *Share-Based Payment*, which we adopted effective January 1, 2006. We elected to use the modified prospective application in adopting SFAS No. 123R and therefore have not restated results for prior periods. The valuation provisions of SFAS No. 123R apply to new awards and to awards that are outstanding on the adoption date and subsequently modified or cancelled.

Table of Contents

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. Expected volatility is based on the weighted average volatility of our stock factoring in daily share price observations and the historical price volatility of certain peers within our industry sector. In computing expected volatility, the length of the historical period used is equal to the length of the expected term of the option and the share purchase right. The expected life of employee stock options represents the average of the contractual term of the options and the weighted average vesting period, as permitted under the simplified method, under SAB No. 107.

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. In our pro forma information required under SFAS No. 123, *Accounting for Stock-Based Compensation*, for the periods prior to fiscal 2006, we accounted for forfeitures as they occurred.

**Recently Issued Accounting Pronouncements**

In June 2007, the EITF issued EITF Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to be Used in Future Research and Development Activities*. The consensus requires companies to defer and capitalize prepaid, nonrefundable research and development payments to third parties over the period that the research and development activities are performed or the services are provided, subject to an assessment of recoverability. EITF Issue No. 07-3 is effective for new contracts entered into in fiscal years beginning after December 15, 2007, including interim periods within those fiscal years. The adoption of EITF Issue No. 07-3 did not have a material impact on our financial statements.

In November 2007, the EITF issued EITF Issue No. 07-1, *Accounting for Collaborative Arrangements Related to the Development and Commercialization of Intellectual Property*. Companies may enter into arrangements with other companies to jointly develop, manufacture, distribute, and market a product. Often the activities associated with these arrangements are conducted by the collaborators without the creation of a separate legal entity (that is, the arrangement is operated as a virtual joint venture). The arrangements generally provide that the collaborators will share, based on contractually defined calculations, the profits or losses from the associated activities. Periodically, the collaborators share financial information related to product revenues generated (if any) and costs incurred that may trigger a sharing payment for the combined profits or losses. The consensus requires collaborators in such an arrangement to present the result of activities for which they act as the principal on a gross basis and report any payments received from (made to) other collaborators based on other applicable GAAP or, in the absence of other applicable GAAP, based on analogy to authoritative accounting literature or a reasonable, rational, and consistently applied accounting policy election. EITF Issue No. 07-1 is effective for collaborative arrangements already in place at the beginning of the annual period beginning after December 15, 2008 (beginning with our 2009 fiscal year), and retrospective application of EITF Issue No. 07-1 to all prior periods presented should be reported as a change in accounting principle. We are in the process of determining the effect, if any, the adoption of EITF Issue No. 07-1 will have on our financial statements.

In December 2007, the Financial Accounting Standards Board, or FASB, issued SFAS No. 141(R), *Business Combinations*. SFAS No. 141(R) replaces SFAS No. 141. SFAS No. 141(R) requires the acquirer of a business to recognize and measure the identifiable assets acquired, the liabilities assumed, and any non-controlling interest in the acquiree at fair value. SFAS No. 141(R) also requires transaction costs related to the business combination to be expensed as incurred. SFAS No. 141(R) applies prospectively to business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008 (beginning with our 2009 fiscal year). We do not anticipate that the impact of adopting SFAS No. 141(R) will have a material effect on our financial statements.

In May 2008, the FASB issued SFAS No. 162, *The Hierarchy of Generally Accepted Accounting Principles*. SFAS No. 162 identifies the sources of accounting principles and provides entities with a framework for selecting the principles used in preparation of financial statements that are presented in conformity with GAAP. The current GAAP hierarchy has been criticized because it is directed to the auditor rather than the entity, it is complex, and it ranks FASB Statements of Financial Accounting Concepts, which are subject to the same level of due process as FASB SFAS, below industry practices that are widely recognized as generally accepted but that are not subject to due process. The FASB believes the GAAP hierarchy should be directed to entities because it is the entity (not its auditors) that is responsible for selecting accounting principles for financial statements that are presented in conformity with GAAP. SFAS No. 162 is effective 60 days following the SEC's approval of the Public Company Accounting Oversight Board amendments to AU Section 411, *The Meaning of Present Fairly in Conformity With Generally Accepted Accounting Principles*. The adoption of SFAS No. 162 is not expected to have a material impact on our financial statements.

Table of Contents

In June 2008, the EITF issued EITF 08-3, *Accounting by Lessees for Maintenance Deposits under Lease Agreements*. Under certain lease arrangements, the lessee is contractually responsible for repair and maintenance of the leased asset, and the lessee is required to make deposits with the lessor to fund that maintenance. The deposit is refunded to the lessee only to the extent that the lessee incurs qualified maintenance costs. Questions have arisen as to the proper accounting for these deposits as some companies account for the maintenance deposits as deposits, while other companies account for them as contingent rental expense. EITF 08-3 concludes that maintenance deposits should be considered deposits when paid to the lessor if it is probable that the deposits will be refunded to the lessee. If it is not probable, then the deposits are recognized as rental expense. If it is determined at the inception of the lease that a portion of the deposits is not probable of being refunded to the lessee, then the lessee should recognize as expense a pro-rata portion of the deposits as they are paid. The cost of maintenance activities should be expensed or capitalized, as appropriate. The definition of probable will fall under the guidance of FASB Concept Statement No. 6, *Elements of Financial Statements*. EITF 08-3 is effective for fiscal years beginning after December 15, 2008 (beginning with our fiscal year 2009). Early application is not permitted. The adoption of EITF 08-3 is not expected to have a material impact on our financial statements.

**Results of Operations**

*Comparison of the Three Months Ended September 30, 2008 and 2007*

*Revenues.* Revenues were \$1.4 million for the three months ended September 30, 2008, compared with \$2.7 million for the three months ended September 30, 2007. The \$1.3 million decrease was mainly due to lower license fee and sponsored research revenues of \$1.4 million from Idenix as a result of the end of the sponsored research term of our collaboration in October 2007, and a decrease in the Merck AMPK license fee revenue recognized as a result of an extension of the research term through June 2009. These reductions were partially offset by license fees and sponsored research revenues recognized in connection with the Roche agreement we entered into in August 2008.

*Research and Development Expenses.* Research and development expenses were \$8.5 million for the three months ended September 30, 2008, compared with \$10.9 million for the three months ended September 30, 2007. The \$2.4 million decrease was mainly due to net decreases of \$2.8 million in clinical and development expenses for the MB07803, MB07811 and MB07133 programs and \$0.1 million in non-cash stock-based compensation expense. These decreases were partially offset by an aggregate increase of approximately \$0.5 million of non-cash depreciation and occupancy costs as a result of a change in the allocation rate of these costs, as discussed under *Research and Development* above, and payroll and related benefits.

*General and Administrative Expenses.* General and administrative expenses were \$2.7 million for the three months ended September 30, 2008, compared with \$2.8 million for the three months ended September 30, 2007. The \$0.1 million decrease was mainly due to an aggregate decrease of \$0.5 million in occupancy and non-cash depreciation due to a change in the allocation rate of these costs, as discussed under *General and Administrative* above, and non-cash stock-based compensation, partially offset by increases in professional services and payroll and related benefits.

*Other Income (Expense).* Net interest expense was \$0.1 million for the three months ended September 30, 2008, compared to net interest income of \$0.6 million for the three months ended September 30, 2007. The \$0.7 million decrease was a result of lower cash balances in the third quarter of 2008 as compared to the third quarter of 2007 as well as increased interest expense related to long-term debt acquired in the first quarter of 2008.

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

*Comparison of the Nine Months Ended September 30, 2008 and 2007*

*Revenues.* Revenues were \$3.0 million for the nine months ended September 30, 2008, compared with \$7.7 million for the nine months ended September 30, 2007. The \$4.7 million decrease was mainly due to lower license fee and sponsored research revenues of \$3.5 million from Idenix as a result of the end of the sponsored research term of our collaboration in October 2007 and a decrease in the Merck AMPK license fee revenue recognized as a result of the extension of the research term through June 2009. The decrease was also due to the absence of \$1.8 million in license fees due to the termination of our Schering collaboration in September 2007. These reductions were partially offset by an increase of \$1.0 million in license fees and sponsored research revenues recognized in connection with the Roche agreement we entered into in August 2008.

*Research and Development Expenses.* Research and development expenses were \$27.9 million for the nine months ended September 30, 2008, compared with \$31.4 million for the nine months ended September 30, 2007. The \$3.5 million decrease was mainly due to net decreases of \$4.8 million in clinical and development expenses for the MB07803, MB07133 and MB07811 programs and \$0.6 million in non-cash stock-based compensation expense. These decreases were partially offset by an increase of approximately \$1.3 million of non-cash depreciation and occupancy costs as a result of a change in the allocation rate of these costs, as discussed above, and \$0.6 million in payroll and related benefits due to our Ann Arbor, Michigan office being fully staffed during the first nine months of 2008 as compared to a proportional two months of 2007.

Table of Contents

*General and Administrative Expenses.* General and administrative expenses were \$7.7 million for the nine months ended September 30, 2008, compared with \$9.3 million for the nine months ended September 30, 2007. The \$1.6 million decrease was mainly due to a decrease of \$0.9 million in occupancy and non-cash depreciation due to a change in the allocation rate of these costs, as discussed above, and an aggregate of \$0.6 million in non-cash stock-based compensation, payroll and related benefits and professional services.

*Other Income (Expense).* Net interest income was \$0.1 million for the nine months ended September 30, 2008, compared to net interest income of \$2.1 million for the nine months ended September 30, 2007. The \$2.0 million decrease was a result of lower cash balances in the first nine months of 2008 as compared to the first nine months of 2007 as well as interest expense incurred in 2008 as a result of the long-term debt acquired in March 2008.

**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.

In August 2008, we entered into a two-year collaboration with Roche to develop new products for treating hepatitis C infection. Under the terms of the Roche agreement, we received an upfront payment of \$10.0 million in August 2008. We are entitled to receive payments on the achievement of certain milestones and during the second year of the agreement, we are entitled to additional sponsored research funding.

In April 2008, we entered into a warrant exchange and concurrent private placement, referred to together as the Transaction, which raised \$9.9 million in cash. The investors in the Transaction were certain current investors who held existing warrants for the purchase of our common stock issued previously by us in our October 2001 and October 2005 private placements.

In connection with the Transaction, we entered into a Warrant Exercise Agreement pursuant to which we reduced the exercise prices of the investors' warrants to purchase our common stock acquired in our October 2001 and October 2005 private placements to an exercise price of \$2.34 per share, in exchange for an irrevocable commitment by the investors to exercise such warrants at the closing. As a result of the Warrant Exercise Agreement, warrants for the purchase of 127,557 shares of our common stock with a prior exercise price of \$8.70 per share and warrants for the purchase of 1,558,279 shares of our common stock with a prior exercise price of \$6.74 per share were exercised at \$2.34 per share.

Additionally, in connection with the Transaction, we entered into a Securities Purchase Agreement pursuant to which we issued and sold to the investors 2,485,103 shares of our common stock at an exercise price of \$2.34 per share, and warrants to purchase up to 1,057,196 shares of our common stock at an exercise price of \$2.69 per share. At the closing, the investors paid an additional purchase price for the warrants equal to \$0.125 per whole share issuable upon exercise of the warrants. In connection with the Securities Purchase Agreement, we also entered into a Registration Rights Agreement pursuant to which we granted to the investors certain registration rights relating to the securities issued and sold in the Securities Purchase Agreement. We filed a registration statement pursuant to the Registration Rights Agreement on May 9, 2008 and the Securities and Exchange Commission declared the registration statement effective on May 30, 2008.

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

Certain of our existing stockholders, including entities affiliated with MPM Capital, Hale BioPharma Ventures and InterWest Partners, invested in the Transaction. Certain of such investors and/or their affiliates are parties to our amended and restated investors' rights agreement dated October 28, 2003. Luke B. Evin, Ph.D., David F. Hale and Arnold L. Oronsky, Ph.D., members of our board of directors, are associated with MPM Capital, Hale BioPharma Ventures and InterWest Partners, respectively.

In March 2008, we entered into a venture debt facility with a lender, pursuant to which the lender provided us with a three-year, \$5.0 million term loan. Interest accrues at an annual rate of 9.83%, with six interest-only monthly payments, made in arrears, beginning in May 2008, followed by 30 equal monthly payments of principal and interest beginning in November 2008. We have the option to prepay the outstanding balance of the term loan in full, subject to a prepayment fee. The loan is collateralized by our general assets, excluding intellectual property and assets of certain subsidiaries. There are no financial covenants associated with the venture debt facility. In connection with the venture debt facility, we issued to the lender a warrant to purchase up to 154,639 shares of our common stock at an exercise price of \$1.94 per share. The warrant is currently exercisable and expires in March 2018.



Table of Contents

In April 2007, we filed an additional shelf registration statement to increase the amount of common stock and warrants available for issuance under our existing shelf registration statement by approximately \$40 million to a total of \$75 million, subject to substantial limitations relating to the aggregate market value of our common stock held by non-affiliates. The additional shelf registration statement was declared effective in May 2007.

We have entered into a Committed Equity Financing Facility, or CEFF, with an institutional investor, under the terms of which, the investor is committed to providing us up to \$50 million or 6,046,471 shares of common stock, based on certain market capitalization levels, in funding from time to time for a period up to 36 months that commenced in December 2006 through the purchase of newly-issued shares of our common stock. In February 2008, the CEFF was amended to reduce the minimum market capitalization required to permit a draw down and to eliminate certain termination rights maintained by the investor, among other things. Under the amended CEFF, we may access capital, subject to certain conditions, under this facility in tranches of up to the lesser of \$10 million or:

- 1.0% of our market capitalization if, at the time of the draw down of such tranche, our market capitalization equals or exceeds \$53 million but is less than \$100 million,
- 1.25% of our market capitalization if, at the time of the draw down of such tranche, our market capitalization equals or exceeds \$100 million but is less than \$175 million, and
- 1.5% of our market capitalization if, at the time of the draw down of such tranche, our market capitalization equals or exceeds \$175 million.

If our market capitalization is less than \$53 million, we will not have access to this capital. As of September 30, 2008, our market capitalization did not meet the minimum threshold of \$53 million, and therefore, we did not have access to this capital as of such date.

In the event of a draw down, the investor will purchase shares of our common stock pursuant to the CEFF at discounts ranging from 6% to 10%, depending on the average market price of our common stock during an eight-day pricing period, provided that the minimum acceptable purchase price for any shares to be issued to the investor during the eight-day pricing period is determined by the higher of \$1.75 or 90% of our share price the day before the commencement of each draw down. Pursuant to the agreement we filed a registration statement with the Securities and Exchange Commission for the resale of the shares of common stock issuable in connection with the CEFF and the shares of common stock underlying the warrant issued in connection with this transaction, which became effective on December 22, 2006. As of September 30, 2008, we have not utilized the CEFF.

As of September 30, 2008, we had \$32.8 million in cash and cash equivalents and securities available-for-sale as compared to \$42.4 million as of December 31, 2007, a decrease of \$9.6 million. The decrease is primarily a result of net cash used in operations of \$22.6 million offset by \$13.1 million of net cash flows provided by financing activities.

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

As of September 30, 2008, we have financed through leases and loans the purchase of equipment and leasehold improvements totaling approximately \$12.4 million, of which \$4.4 million was outstanding at that date. The loans are collateralized with the purchased equipment, bear interest at rates ranging from approximately 8.0% to 12.85%, and are due in monthly installments through October 2015. We currently anticipate capital spending on equipment and leasehold improvements to be in the range of \$0.5 million to \$1.0 million in 2008. We do not plan on financing our equipment and leasehold improvements through fiscal 2008, as we no longer have available funds through this financing facility.

We intend to use our existing cash reserves, proceeds from our ongoing collaboration with Merck, proceeds from our new collaboration with Roche and proceeds from other planned business development activities to execute our strategic plan through 2008. Under our strategic plan, we will focus our internal resources primarily on our core metabolic disease clinical and advanced research programs. This includes funding the further clinical evaluation of our core assets, MB07803 and MB07811, with a focus on achieving key milestones. Continued development of these core assets thereafter will require significant resources. Therefore, we plan to establish strategic collaborations for these product candidates at appropriate times to secure additional resources, accelerate progress and share risk. In addition, we plan to advance additional metabolic disease product candidates discovered by our research group into clinical development either independently or with current or future strategic collaborators. In order to reduce future expenses and to minimize the potential dilution associated with financing their internal development, we intend to license our glucagon antagonist program, pradefovir and MB07133 for further development and commercialization for upfront fees, milestones and royalties on future sales, if any, or we may directly sell these assets.

Table of Contents

Our strategic plan contemplates funding the ongoing development of our core assets by monetizing our glucagon antagonist program and certain non-core assets. We may not be successful in entering into additional collaboration agreements, or in receiving milestone or royalty payments under current or future agreements. Additionally, we may be required to relinquish greater or all rights to product candidates at an earlier stage of development or on less favorable terms than we would otherwise choose. Also, based on recent Food and Drug Administration, or FDA, draft guidelines and advisory panel discussions, the cost to develop and commercialize our diabetes programs may increase beyond current expectations and such increases may make it more difficult to obtain favorable terms in the collaborative arrangements we require to maximize the value of these programs. Having insufficient funds may require us to delay, scale back or eliminate some or all of our research or development programs. No assurances can be made that additional funding, through any resources, including our CEFF, will be available when needed or that, if available, financing will be obtained on terms favorable to us or our stockholders. To the extent that we raise additional capital by issuing equity securities, our existing stockholders' ownership will be diluted. 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 or sales of our assets as well as prohibitions on our ability to create liens, pay dividends, redeem our stock or make investments. The recent global financial crisis and other current negative macroeconomic indicators may negatively impact our ability to issue securities or obtain debt financing. Given the economic and corporate uncertainties, the Company is planning to institute various cost saving measures to be announced when final decisions are made. Failure to obtain adequate financing and to curtail or delay cash expenditures adequately will have a significant negative impact on our future operations and our ability to continue as a going concern. Based on our current rate of cash usage and absent any cash sources from business development, financings or other strategic initiatives, we anticipate that our cash balances as of September 30, 2008 will fund our operations through mid-2009.

The following summarizes our long-term contractual obligations as of September 30, 2008 (in thousands):

	Total	Less than 1 Year	Payments Due by Period		
			1 to 3 Years	4 to 5 Years	After 5 Years
Operating leases	\$ 22,823	\$ 2,658	\$ 6,259	\$ 6,606	\$ 7,300
Long-term debt	9,351	3,717	5,472	79	83
Interest on long-term debt	1,475	773	676	19	7
Purchase commitments	1,462	1,462			
Capital leases	59	26	33		
Interest on capital leases	8	5	3		
<b>Total</b>	<b>\$ 35,178</b>	<b>\$ 8,641</b>	<b>\$ 12,443</b>	<b>\$ 6,704</b>	<b>\$ 7,390</b>

We also enter into agreements with clinical sites and contract research organizations for the conduct of our clinical trials. We will make payments to these sites and organizations based upon the number of patients enrolled and the length of their participation in the clinical trials. In addition, under certain agreements, we may be subject to penalties in the event we prematurely discontinue performance under these agreements. At this time, due to the variability associated with these agreements, we are unable to estimate with certainty the future costs we will incur.

We have entered into 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 terminated under specified circumstances. These agreements generally expire upon termination for cause or when we have met our obligations under these agreements. As of September 30, 2008, no events have occurred resulting in the obligation of any such payments.

Our future capital uses and requirements depend on numerous forward-looking factors. These factors may include but are not limited to the following:

- the rate of progress and cost of our clinical trials and other research and development activities,
- the scope, prioritization and number of clinical development and research programs we pursue,
- the terms and timing of any collaborative, licensing and other arrangements that we may establish,
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights,
- the costs and timing of regulatory approvals,

Table of Contents

- the costs of establishing or contracting for manufacturing, sales and marketing capabilities, and
- the effect of competing technological and market developments.

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 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, 2007 and our quarterly reports on Form 10-Q for the quarters ended March 31, 2008 and June 30, 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**



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

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. A 100 basis point increase or decrease in interest rates would increase or decrease our current investment balance by approximately \$80,000 annually. 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.

Our long-term capital lease obligations and debt bear interest at fixed rates and therefore we do not have significant market risk exposure with respect to these obligations.

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





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

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Exchange Act 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.

Table of Contents

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 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 effective at the reasonable assurance level.

There has been no change in our internal control over financial reporting during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**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, 2007 and our subsequent filings with the Securities and Exchange Commission.*

**Risks Related to our Business**

*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 core metabolic disease assets, MB07803 and MB07811, and our non-core liver disease assets, pradefovir and MB07133. Early clinical trials conducted to date have provided initial evidence of safety and

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

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 animal 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 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 time or during any phase of development, we would experience potentially significant delays in, or be required to abandon, development of the product candidate.

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 reasons. These include, for example, the availability of alternative treatments, lack of cost effectiveness, 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.

Table of Contents

*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 core metabolic disease assets, MB07803 and MB07811, our non-core liver disease assets, pradeфовir 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.

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

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. For example, in July 2007, we were informed by Daiichi Sankyo, our collaborative partner on CS-917, that results from a completed Phase 2b clinical trial showed that this product candidate failed to achieve the primary endpoint of the clinical trial despite having successfully achieved the primary endpoints of other earlier clinical trials. In January 2008, we and Daiichi Sankyo agreed to terminate our strategic collaboration on CS-917 and return the rights to this product candidate to us. We do not intend to further develop this product candidate.

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. If formally adopted, these 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.

We currently do not have strategic collaborations in place for any of our current product candidates. Therefore, in the future, we and/or any potential future collaborative partner 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 collaborators. 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.

Table of Contents

***We may not be able to enter into collaborations with respect to our glucagon antagonist program and our non-core assets, pradefovir and MB07133, on acceptable terms, if at all, which would lead to development and commercialization delays.***

Since we do not currently possess the resources necessary to independently develop and commercialize all of the potential product candidates that may be based upon our technologies, including MB07803, MB07811, our glucagon antagonist program, pradefovir and MB07133, we plan to enter into additional collaborative agreements to assist in the development and commercialization of some or all of these assets as a component of our strategic plan. However, our discussions with potential collaborators may not lead to the establishment of new collaborations on acceptable terms, if at all, or it may take longer than expected to establish new collaborations, leading to development and commercialization delays, which would adversely affect our business.

***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 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.

For example, data from 24-month oral carcinogenicity studies of pradefovir in rats and mice showed that the incidence of rats or mice with tumors was increased in the animals dosed with the highest dose levels tested and was slightly increased at the intermediate dose levels. The low dose levels were considered no-effect dose levels in both studies. As a result of numerous factors which may include these findings, we entered into an agreement with Schering and Valeant Pharmaceuticals North America, or Valeant, to terminate our agreements for the development and commercialization of pradefovir, and all commercial rights to pradefovir have been returned to us subject to certain milestone and royalty payments we may be required to make to Valeant should pradefovir be subsequently developed.

Our product candidates could also exhibit adverse interactions with other drugs. For example, in earlier clinical trials conducted by Daiichi Sankyo, CS-917, our first generation product candidate for type 2 diabetes which we are no longer developing, was associated with incidents of lactic acidosis in two patients when it was combined with metformin in a Phase 1 clinical trial. After extensive analysis, Daiichi Sankyo concluded that these incidents were likely due to significantly increased blood levels of metformin. CS-917 was also associated in a limited number of patients with episodes of hypoglycemia, asymptomatic lactate elevation as well as lactate elevation with clinical symptoms that could be considered signs of lactic acidosis. We are currently conducting clinical trials of our second-generation product candidate for type 2 diabetes, MB07803, which works by the same mechanism as CS-917 and thus may be subject to some or all of the same risks as CS-917. To date, no incidents of lacticemia, lactic acidosis, hypoglycemia or other significant adverse side effects have been observed in clinical trials of MB07803.

The unique nature of our proprietary technologies including HepDirect and NuMimetic 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.

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

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,

Table of Contents

- 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:

- regulatory authorities may withdraw their approval of the product, or we 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.

***We are currently dependent on our collaborations with Merck, Idenix and Roche for the development and commercialization of product candidates related to those collaborations, and we may be dependent on future collaborators for the development of our current and future product candidates. Events involving our collaborations with Merck, Idenix and Roche, or any future collaborations could prevent us from developing and commercializing our product candidates and achieving or sustaining profitability.***

We have entered into two collaborations with Merck, a collaboration with Idenix and a collaboration with Roche. The first collaboration with Merck sought to develop and commercialize new products for treating hepatitis C infection and the second seeks to develop and commercialize new products to treat type 2 diabetes and potentially other metabolic diseases. Our collaboration with Idenix sought to develop and commercialize new products for treating hepatitis C infection, and our new collaboration with Roche seeks to develop new products for treating hepatitis C. Although the funded research phases of the hepatitis C collaborations with Merck and Idenix are completed, certain candidate compounds discovered during the collaborations are being evaluated to determine if one or more will be recommended for clinical



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

development. The sponsored research term of our second collaboration with Merck continues through June 2009, and the research term of our collaboration with Roche continues through August 2010. Although our collaborations with Merck, Idenix and Roche have not yet yielded any product candidates, should they ultimately be successful, we will be dependent on Merck, Idenix and/or Roche, as applicable, for further development and commercialization of any resulting product candidates.

We have limited control over the amount and timing of resources that Merck, Idenix, 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. However, in the event that we do not have sufficient resources to independently develop or commercialize the product candidate or drug compound, and 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 pradefovir or MB07133 and intend to license or sell these product candidates.

We and our present and future collaborators may fail to develop or effectively commercialize products or drug compounds covered by our present and future collaborations if:

- we do not achieve our objectives under our collaboration agreements,

Table of Contents

- 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 proprietary technologies we discover in our collaborations,
- 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 achieve or maintain profitability.

***Because our collaborations with Merck, Idenix and Roche may involve Merck's, Idenix's or Roche's proprietary compounds, if Merck, Idenix or 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.***

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

The objective of our hepatitis C collaboration with Merck was to discover product candidates for the treatment of this disease by applying our technology to certain compounds provided by Merck. The funded research phase of this collaboration has ended. Merck has evaluated and may continue to evaluate the drug compounds discovered under the research phase of the collaboration to determine if one or more will be recommended for clinical development. If Merck so designates a product candidate and then subsequently terminates this collaboration before a defined stage of development of that product candidate, which it may do without cause at any time upon 90 days advance written notice to us, we will not have any right to develop or commercialize that product candidate. In addition, if this collaboration with Merck terminates and Merck successfully develops products based on these proprietary compounds without applying our technology, we will not be entitled to milestone payments or royalties with respect to those products.

Our agreement with Merck to develop and commercialize new products to treat type 2 diabetes and potentially other metabolic diseases may include the development of compounds owned or controlled by Merck. Accordingly, if Merck terminates this collaboration, it may prove difficult for us to continue development of such compounds. Similarly, our former agreement with Idenix to develop and commercialize new products to treat hepatitis C infection may include the development of compounds owned or controlled by Idenix. Although the funded research phase of our collaboration with Idenix has ended, certain compounds are under evaluation for further development. It may prove difficult for us to continue development of such compounds if Idenix chooses not to develop them upon further evaluation. 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 Merck, Idenix, 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:

Table of Contents

- unwillingness on the part of a collaborator to pay us research funding, 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.

***Our efforts to discover product candidates beyond our current product candidates may not succeed, and any product candidates we recommend for clinical development may not actually begin clinical trials.***

We intend to use our proprietary technologies and our knowledge and expertise to develop and commercialize novel drugs to address some of the world's most widespread and costly chronic diseases. Our goal is to expand our core metabolic disease clinical development pipeline by continuing to develop and move additional new drug compounds into clinical development. However, the process of researching and discovering drug compounds is expensive, time-consuming and unpredictable. Data from our current research programs may not support the clinical development of our lead compounds or other compounds from these programs, and we may not identify any additional drug compounds suitable for recommendation for clinical development. Moreover, any drug compounds we recommend for clinical development may not demonstrate, through preclinical testing, indications of safety and potential efficacy, that such drug compounds warrant advancement into clinical trials. Such findings would potentially impede our ability to maintain or expand our clinical development pipeline. Our ability to identify new drug compounds and advance them into clinical development also depends upon our ability to fund our research and development operations, and we cannot be certain that additional funding will be available on acceptable terms, or at all.

***Delays in the commencement or completion of clinical trials could result in increased costs to us and delay our ability to generate significant revenues.***

Delays in the commencement or completion of clinical trials could significantly impact our product development costs. We do not know whether planned 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:

- obtaining regulatory approval to commence a clinical trial,

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

- 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
- 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

Table of Contents

- lack of adequate funding to continue the clinical trial.

If we experience significant delays in the commencement or completion of clinical testing, our product development costs may increase, we may lose any competitive advantage associated with early market entry and our ability to generate significant revenues may be delayed. 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 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.***

We rely on third parties, such as contract research organizations, medical institutions, clinical investigators and contract laboratories, to assist in the development of MB07803 and MB07811 and intend to rely on similar organizations to assist in the development of any other future product candidates that we may develop for which a collaborator is not responsible for development. At this time, we do not intend to independently develop pradeфовir or MB07133 and intend to license or sell these product candidates. We may rely on strategic collaborators for the development of our core metabolic disease assets, MB07803 and MB07811, in the future. If successful in entering into these future collaborations and license agreements, we will be dependent upon our collaborative partners and licensees for the further development and commercialization of these product candidates. Although our collaborations with Merck, Idenix and Roche have not yet yielded product candidates, should they do so, we will be dependent on Merck, Idenix and/or Roche, as applicable, to conduct the development of any resulting product candidates. If Merck, Idenix, Roche or these 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.

***Because our product candidates, research programs and collaborative efforts depend on our proprietary technologies, adverse events affecting our proprietary technologies may delay or prevent the commercialization of our product candidates.***

We used our NuMimetic technology to identify MB07803. We used our HepDirect technology to discover pradeфовir, MB07811 and MB07133, and have applied it in certain other programs as well. We intend to use these and future proprietary technologies to expand our product pipeline in the future. We may also leverage our HepDirect and other liver-targeting technology through strategic alliances and collaborations with other companies, such as our hepatitis C collaborations with Merck, Idenix and Roche in which we applied our technology to certain Merck, Idenix and Roche compounds. Our proprietary technologies are subject to many of the same risks as our product candidates, including risks related to:

- obtaining and maintaining patent and trade secret protection for these technologies,
- avoiding infringement of the proprietary rights of third parties,

- the development of competing technologies by others, and
- in HepDirect's case, the safety and effectiveness of this technology in humans.

Because certain of our product candidates and research programs are dependent on our proprietary technologies, adverse events affecting our proprietary technologies 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 a New Drug Application, or 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. If formally adopted, these and any future guidance that may result from

Table of Contents

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 ongoing 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 ongoing 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 ongoing 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 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.

Table of Contents

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 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 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:

- metformin, which is a member of the biguanide drug class, related to guanidine and currently is the most widely prescribed first line therapy for type 2 diabetes,
- sulfonylureas, which increase the secretion of insulin by the pancreas, thereby lowering the level of the sugar glucose in the blood,
- insulins, which mimic insulin, the naturally occurring hormone made by the pancreas to control blood glucose levels,
- PPAR agonists, which improve insulin sensitivity by activating certain genes involved in fat synthesis and carbohydrate metabolism,
- incretin-based therapies, including incretin mimetics and dipeptidyl peptidase IV, or DPP-IV inhibitors. Incretin mimetics lower glucose levels by increasing the levels of certain naturally occurring hormones from the pancreas, including glucagon-like peptide-1, or GLP-1, 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. Incretin mimetics include BYETTA® (exenatide), an injectable medication that exhibits many of the same glucose regulating actions of GLP-1. DPP-IV is an enzyme in the bloodstream that cleaves and inactivates GLP-1. DPP-IV inhibitors inhibit this enzyme, thus increasing the half-life of endogenous GLP-1 by preventing cleavage and inactivation of GLP-1. The overall effect of both of these classes of drugs is to enhance glucose-dependent insulin secretion and suppress inappropriate glucagon secretion,

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

- alpha-glucosidase inhibitors, which decrease the absorption of carbohydrates from the intestine, resulting in a slower and lower rise in blood glucose throughout the day,
- glinides, which stimulate the pancreas beta-cells to produce insulin, and
- combination therapies, which combine metformin with members of several or one of the above-mentioned classes, particularly sulfonylureas and PPAR agonists.

Metformin is a drug that inhibits liver glucose production like MB07803 but does so through an unknown mechanism. Because it does not cause weight gain, metformin is often prescribed as a first line therapy to obese patients with type 2 diabetes, who are reported to comprise more than 90% of patients newly diagnosed with type 2 diabetes. Generic forms of metformin have recently become available. Accordingly, unless MB07803 demonstrates significant benefits when compared to metformin or demonstrates that it can be used in the patient population who do not tolerate and/or adequately respond to metformin treatment, the price required to effectively compete with the generic form of metformin may be so low that it may limit the market's potential or make it uneconomical to market MB07803. In addition, many companies are developing novel therapies that target diabetes. These companies may develop and introduce products competitive with or superior to MB07803.

Table of Contents

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.

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. Lipitor (atorvastatin; a statin marketed by Pfizer) 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 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 HBV, 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 HBV.

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

Nexavar (sorafenib), a chemotherapy approved for treating kidney cancer, received FDA approval in November 2007 for the treatment of primary liver cancer. This follows the decision of the European Medicines Agency, or EMEA, in October 2007 to approve Nexavar in Europe. Nexavar is now the only drug approved for primary liver cancer in the United States or Europe.

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.

In addition, many other companies are developing products for the treatment of the diseases we are targeting and if successful, these products could compete with our products. If we receive approval to market and sell any of our product candidates, we may compete with these companies and their products as well as others in varying stages of development.

Table of Contents

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 than any which we are developing, or 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. We will also face competition from these third parties in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, and in acquiring and in-licensing technologies and products complementary to our programs or advantageous to our business.

***We do not have internal manufacturing capabilities, and if we fail to develop and maintain supply relationships with collaborators or other third-party manufacturers, we may be unable to develop or commercialize our products.***

Our ability to develop and commercialize our products depends in part on our ability to manufacture, or arrange for collaborators or other third parties to manufacture, our products at a competitive cost, in accordance with regulatory requirements and in sufficient quantities for development and eventual commercialization. We have relied on a number of suppliers to manufacture sufficient quantities of MB07803 and MB07811 for use in clinical trials during development. Although our suppliers have manufactured other companies' products on a commercial scale, we have not yet determined if they are capable of manufacturing our products on a commercial scale. We, our current and potential future collaborators and third-party manufacturers may encounter difficulties with the small- and large-scale formulation and manufacturing processes required to manufacture our product candidates, resulting in delays in our clinical trials development and regulatory submissions, in the commercialization of our product candidates or, if any of our product candidates is approved, in the recall or withdrawal of the product from the market. Further, development of large-scale manufacturing processes may require additional validation studies, which the FDA and other foreign regulatory agencies must review and approve. Our inability to enter into or maintain agreements with collaborators or capable third-party manufacturers on acceptable terms could delay or prevent the commercialization of our products, which would adversely affect our ability to generate revenues and could prevent us from achieving or maintaining profitability.

We currently expect that in any future development activities related to MB07803 and MB07811, we will rely on our current suppliers to manufacture these compounds. However, we do not have long-term supply agreements with these third parties, and we may not be able to enter into new supply agreements with them in a timely manner or on acceptable terms, if at all. These third parties may also be subject to capacity constraints that would cause them to limit the amount of these compounds that we can purchase. While we believe alternative sources to manufacture these compounds are readily available, in the event we have to seek such alternative sources we will incur costs associated with identifying and qualifying one or more alternate suppliers. In addition, any resulting interruption or delay we experience in the supply of MB07803 or MB07811 may impede the development of these compounds.

In addition, we, our collaborators or other third-party manufacturers of our products must comply with current good manufacturing practices, or CGMP, requirements enforced by the FDA and other foreign regulatory agencies through their facilities inspection programs. These requirements include quality control, quality assurance and the maintenance of records and documentation. In addition, product manufacturing facilities in California are subject to licensing requirements of the California Department of Health Services and may be inspected by the California Department of Health Services, and other applicable regulatory authorities, at any time. We, our collaborators or other third-party manufacturers of our products may be unable to comply with these CGMP requirements and with other FDA, state and foreign regulatory requirements. We have little control over third-party manufacturers' compliance with these regulations and standards. A failure to comply with these requirements may result in fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure or recall, or withdrawal of product approval.

*If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market our product candidates, we may be unable to generate significant revenues.*

We do not have a sales and marketing organization, and we have no experience as a company in the sales, marketing and distribution of pharmaceutical products. Although our hepatitis C and metabolic disease collaborations with Merck have not yet yielded product candidates, should they be successful, Merck will be responsible for worldwide marketing and commercialization of any resulting product candidates (subject to, in the case of our metabolic disease collaboration, our option to co-promote the product in the U.S. with certain financial assistance from Merck). Similarly, should our hepatitis C collaborations with Idenix and Roche yield any product candidates, Idenix and Roche will be responsible for worldwide marketing and commercialization of any resulting product candidates. In order to co-promote any of these products, or to commercialize MB07803, MB07811, pradefovir, MB07133 or any future product candidates for which we retain commercialization rights, we may be required to develop our sales, marketing and distribution capabilities, or make arrangements with a third party to perform these services. Even though we may receive financial assistance from Merck if we exercise our U.S. co-promotion option under the metabolic disease collaboration, developing a sales force for any resulting product or any product resulting from any of our other product candidates is expensive and time consuming and could delay any product launch. 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.

Table of Contents

*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:

- our 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.

*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.*



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

The continuing efforts of the government, insurance companies, managed care organizations and other payers 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,
- 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 will be 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.

Table of Contents

*We may need to decrease the size of our organization, and we may experience difficulties in managing those organizational changes.*

Since we became an independent company in 1999, we have increased the number of our full-time employees from 50 to 122 as of September 30, 2008. We may need to decrease the number of our full-time employees in the future in response to the recent global financial crisis or other adverse business events. Reducing our workforce may lead to additional unanticipated attrition. If our future staffing is inadequate because of additional unanticipated attrition or because we failed to retain the staffing level required to accomplish our business objectives we may be delayed or unable to continue the development or commercialization of our product candidates, which could impede our ability to generate revenues and achieve profitability.

*If we fail to attract and keep key management and scientific personnel, we may be unable to successfully develop or commercialize our product candidates.*

Our success depends on our continued ability to attract, retain and motivate highly qualified management and scientific personnel. The loss of the services of certain principal members of our management or scientific staff could delay or prevent the commercialization of our product candidates. 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 stock restriction agreements and severance agreements.

Competition for qualified personnel in the biotechnology field is intense. We will need to hire additional personnel as we establish and/or expand our sales, manufacturing, research and development activities in the future. We may not be able to attract and retain quality personnel on acceptable terms given the competition for such personnel among biotechnology, pharmaceutical and other companies.

We have established a scientific advisory board, the members of which assist us in formulating our research, development and clinical strategies. These scientific advisors are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us. In addition, our scientific advisors may have arrangements with other companies to assist those companies in developing products or technologies that may compete with ours

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

*We will need substantial additional funding and may be unable to raise capital when needed, which would force us to delay, reduce or eliminate our research and development programs or commercialization efforts and affect our ability to continue as a going concern.*

We intend to use our existing cash reserves, proceeds from our ongoing collaboration with Merck, proceeds from our new collaboration with Roche and proceeds from other planned business development activities to execute our strategic plan through 2008. Under our strategic plan we will need to secure additional cash proceeds through future strategic collaborations or other financing sources to fund certain MB07803 and MB07811 studies in 2009. In the event we are not able to generate sufficient financing through strategic collaborations or other financing activities, we have the ability and intent to, and will be required to, delay, scale back or eliminate some or all of our research or development programs and other outlays of cash in order to meet our cash requirements through 2009. Additionally, we may be required to relinquish greater

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

or all rights to product candidates at an earlier stage of development or on less favorable terms than we would otherwise choose. Alternatively, we may determine that seeking additional resources through traditional financing transactions may be appropriate to achieve certain key value-driving development milestones. No assurances can be made that additional funding through any resources will be available when needed. Given the recent financial crisis in the United States and other current negative macroeconomic indicators, such as the recession in the United States or other economic downturns in the global markets, our ability to issue securities or obtain debt financing may not be available or attainable on favorable terms, if at all. Failure to obtain adequate financing and to curtail or delay cash expenditures adequately will have a significant negative impact on our future operations and our ability to continue as a going concern. Because we do not anticipate that we will generate significant continuing revenues for several years, if at all, we will need to raise substantial additional capital to finance our operations in the future. Our additional funding requirements will depend on, and could increase significantly as a result of, many factors, including:

- the rate of progress and cost of our clinical trials and other research and development activities,

Table of Contents

- the scope, prioritization and number of clinical development and research programs we pursue,
- the terms and timing of any collaborative, licensing and other arrangements that we may establish,
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights,
- the costs and timing of regulatory approvals,
- the costs of establishing or contracting for sales and marketing capabilities, and
- the effect of competing technological and market developments.

Until we can generate significant continuing revenues, if ever, we expect to satisfy our future cash needs through public or private equity offerings, debt financings, grants or corporate collaboration and licensing arrangements, as well as through interest income earned on cash balances.

As noted above, we cannot be certain that additional funding will be available on acceptable terms, or at all. If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate one or more of our research and development programs or our commercialization efforts and we may be unable to continue as a going concern. Based on our current rate of cash usage and absent any cash sources from business development, financings or other strategic initiatives, we anticipate that our cash balances as of September 30, 2008 will fund our operations through mid-2009.

***Recent 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 collaborative partnerships. Recently, the credit markets and the financial services industry have been 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 United States 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 carry out our strategic plan, which would negatively impact our business, results of operations and financial condition.

*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 September 30, 2008, we had an accumulated deficit of approximately \$182.5 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.*

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 option fees. Our ability to generate significant continuing revenues depends on a number of factors, including:

- successful completion of ongoing development activities for our product candidates,
  
- achievement of regulatory approval for our product candidates,
  
- successful completion of our current and future strategic collaborations, and
  
- successful sales, manufacturing, distribution and marketing of our products.

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.

Table of Contents

***Raising additional funds by issuing securities, through collaboration and licensing arrangements or otherwise, will cause dilution to existing stockholders and may restrict our operations or require us to relinquish proprietary rights.***

We may raise additional funds through public or private equity offerings, corporate collaboration and licensing arrangements, debt financings, grants or our CEFF, if available. For example, 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. As of September 30, 2008, our market capitalization did not meet the CEFF minimum threshold of \$53 million, and therefore, we did not have access to this capital as of such date. 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.

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 technologies, or grant licenses on terms that are not favorable to us.

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

***Certain provisions of our financing facilities may require us to pay any outstanding balance of indebtedness and could limit our ability to fund ongoing operations or obtain additional financing.***

If we are required to pay any outstanding balance of indebtedness immediately, we may be faced with the following negative consequences:

- we will need a substantial portion of our cash flow to pay the principal and interest on our indebtedness,
  
- payments of our indebtedness will reduce the funds that would otherwise be available for our operations and future strategic initiatives, and
  
- there would be a material adverse effect on our business and financial condition if we were unable to service our indebtedness or obtain additional financing.

*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 development status of our product candidates, including results of our clinical trials and other studies,
- our recommendation of additional drug compounds for clinical development,
- our addition or termination of research programs or funding support,
- variations in the level of expenses related to our product candidates or research programs,
- our execution of collaborative, licensing or other arrangements, and the timing of payments we may make or receive under these arrangements, and
- changes in the use assumptions in the application of SFAS No. 123R in future periods.

Table of Contents

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.

***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. 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 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. As of September 30, 2008, our market capitalization did not meet the CEFF minimum threshold of \$53 million, and therefore, we did not have access to this capital as of such date.

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 our Intellectual Property**

***Our success depends upon our ability to protect our intellectual property, including the proprietary technologies 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, proprietary technologies 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 technologies 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 incidences of HBV 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.

Table of Contents

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.

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 technologies that are 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 technologies 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 technologies may infringe. We have not conducted a complete search of existing patents to identify existing patents that our product candidates or proprietary technologies 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 technologies infringe their intellectual property rights. If one of these patents was found to cover our product candidates, proprietary technologies 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 technologies 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 technologies 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.

Table of Contents

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 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 adefovir or prodrugs of adefovir in the U.S. and foreign countries may prevent the commercialization of pradefovir in the future.***

Our product candidate pradefovir is a prodrug of adefovir. A third party, Gilead, has rights to another product called Hepsera that is a non-liver specific prodrug of adefovir. 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 adefovir. 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 Hepsera thereby extending protection of Hepsera in those countries to September 2016. Additional third party patents covering Hepsera or adefovir 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:

- decreased demand for our product candidates,

Table of Contents

- 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.

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

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

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

The market price for 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 our development activities,
- establishment of new collaborative arrangements,
- events affecting Merck, Idenix, 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,
- sales of large blocks of our common stock, including sales by our executive officers, directors and significant stockholders,





Table of Contents

- 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.

***If we fail to meet one of Nasdaq's Global Market continued listing requirements, our common stock could be delisted from the Nasdaq Global Market, which could negatively impact the price of our common stock and our ability to access the capital markets.***

In order to maintain our listing on the Nasdaq Global Market, we will need to continue meeting certain minimum listing standards that include, or may include, our shareholders' 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 shareholders, the number of market makers and compliance with certain of our corporate governance policies. If we fail to maintain the standards required now or in the future, our common stock could be delisted from the Nasdaq Global 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 Global Market could also have other negative results, including the potential loss of confidence by suppliers and employees and the loss of institutional investor interest.

***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 auditors to attest to, our internal controls. These laws and regulations could make it more difficult or more costly

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

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 events 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. We are presently evaluating and monitoring developments with respect to these laws and regulations and cannot predict or estimate the amount or timing of additional costs we may incur to respond to their requirements. 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.

Table of Contents

*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 76% of our common stock as of September 30, 2008. 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.

*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 2,833,338 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. As of September 30, 2008, our market capitalization did not meet the CEFF minimum threshold of \$53 million, and therefore, we did not have access to this capital as of such date. 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.

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



None.

**Item 3. Defaults Upon Senior Securities**

None.

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

None.

**Item 5. Other Information**

None.

Table of Contents

**Item 6. Exhibits**

<b>Exhibit 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	Collaboration and License Agreement between the Company and Hoffman-La Roche Inc., F. Hoffman-La Roche LTD and Roche Palo Alto LLC dated August 7, 2008
10.2	Amendment Agreement between the Company, Schering Corporation and Valeant Pharmaceuticals North American dated September 24, 2008.
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	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

Edgar Filing: METABASIS THERAPEUTICS INC - Form 10-Q

---

- (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: November 10, 2008

By: /s/ Paul K. Laikind, Ph.D.  
*Paul K. Laikind, Ph.D., Chief Executive Officer and  
Interim Chief Financial Officer*

---