

METABASIS THERAPEUTICS INC  
Form 10-Q  
August 11, 2008  
[Table of Contents](#)

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

Washington, D.C. 20549

**FORM 10-Q**

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

For the quarterly period ended June 30, 2008.

OR

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

For the transition period from            to            .

Commission file number 000-50785

**METABASIS THERAPEUTICS, INC.**

(Exact name of registrant as specified in its charter)

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

Smaller reporting  
company

(Do not check if a smaller reporting company)

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

The number of outstanding shares of the registrant's common stock, par value \$0.001 per share, as of August 5, 2008 was 35,043,026.

---

Table of Contents

**METABASIS THERAPEUTICS, INC.**

**FORM 10-Q**

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

**TABLE OF CONTENTS**

<u>PART I FINANCIAL INFORMATION</u>	2
<u>Item 1. Financial Statements</u>	2
<u>Balance Sheets at June 30, 2008 (Unaudited) and December 31, 2007</u>	2
<u>Statements of Operations for the three and six months ended June 30, 2008 and 2007 (Unaudited)</u>	3
<u>Statements of Cash Flows for the six months ended June 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>	20
<u>Item 4. Controls and Procedures</u>	20
<u>PART II OTHER INFORMATION</u>	21
<u>Item 1. Legal Proceedings</u>	21
<u>Item 1A. Risk Factors</u>	21
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	42
<u>Item 3. Defaults Upon Senior Securities</u>	42
<u>Item 4. Submission of Matters to a Vote of Security Holders</u>	42
<u>Item 5. Other Information</u>	42
<u>Item 6. Exhibits</u>	43
<u>SIGNATURES</u>	44

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

	<b>June 30, 2008 (Unaudited)</b>	<b>December 31, 2007</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 13,798	\$ 14,141
Securities available-for-sale	18,703	28,297
Prepays and other current assets	1,215	1,157
Total current assets	33,716	43,595
Property and equipment, net	5,726	6,356
Other assets	322	172
Total assets	\$ 39,764	\$ 50,123
<b>Liabilities and stockholders equity</b>		
Current liabilities:		
Accounts payable	\$ 526	\$ 802
Accrued compensation	2,702	3,181
Accrued liabilities	1,929	4,132
Deferred revenue, current portion	581	1,321
Current portion of long-term debt	3,252	2,068
Current portion of capital lease obligations	26	23
Total current liabilities	9,016	11,527
Deferred rent	2,849	2,595
Long-term debt	6,617	3,845
Capital lease obligations, net of current portion	40	55
Other long-term liabilities	200	
Total liabilities	18,722	18,022
Stockholders equity:		
Preferred stock, \$0.001 par value; 5,000 shares authorized at June 30, 2008 and December 31, 2007, no shares issued or outstanding		
Common stock, \$0.001 par value; 100,000 shares authorized at June 30, 2008 and December 31, 2007; 35,036 and 30,754 shares issued and outstanding at June 30, 2008 and December 31, 2007, respectively	35	31
Additional paid-in capital	193,636	182,003
Accumulated deficit	(172,654)	(150,012)
Accumulated other comprehensive loss	25	79

Edgar Filing: METABASIS THERAPEUTICS INC - Form 10-Q

Total stockholders' equity		21,042		32,101
Total liabilities and stockholders' equity	\$	39,764	\$	50,123

*See accompanying notes.*

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

	<b>Three Months Ended June 30,</b>		<b>Six Months Ended June 30,</b>	
	<b>2008</b>	<b>2007</b>	<b>2008</b>	<b>2007</b>
<b>Revenues:</b>				
Sponsored research	\$ 514	\$ 938	\$ 1,039	\$ 1,876
License fees	173	666	590	3,133
Other revenue				21
<b>Total revenues</b>	<b>687</b>	<b>1,604</b>	<b>1,629</b>	<b>5,030</b>
<b>Operating expenses:</b>				
Research and development	9,667	11,065	19,412	20,571
General and administrative	2,569	3,186	5,088	6,450
<b>Total operating expenses</b>	<b>12,236</b>	<b>14,251</b>	<b>24,500</b>	<b>27,021</b>
Loss from operations	(11,549)	(12,647)	(22,871)	(21,991)
<b>Other income (expense):</b>				
Interest income	245	842	643	1,814
Interest expense	(238)	(130)	(414)	(264)
<b>Total other income</b>	<b>7</b>	<b>712</b>	<b>229</b>	<b>1,550</b>
<b>Net loss</b>	<b>\$ (11,542)</b>	<b>\$ (11,935)</b>	<b>\$ (22,642)</b>	<b>\$ (20,441)</b>
Basic and diluted net loss per share	\$ (0.34)	\$ (0.40)	\$ (0.70)	\$ (0.67)
Shares used to compute basic and diluted net loss per share	34,244	30,213	32,501	30,502

*See accompanying notes.*

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

	<b>Six Months Ended June 30,</b>	
	<b>2008</b>	<b>2007</b>
<b>Operating activities</b>		
Net loss	\$ (22,642)	\$ (20,441)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	1,967	2,694
Depreciation and amortization	1,037	978
Deferred rent	254	565
Amortization of discount and premium on securities available-for-sale	(334)	(1,351)
Loss on disposal of assets	20	
Realized gain on securities available-for-sale	(7)	
Change in operating assets and liabilities:		
Trade accounts receivable	61	(263)
Other current assets	(119)	72
Other assets	52	4
Deferred revenue	(740)	(1,334)
Accounts payable	(276)	653
Accrued compensation and other liabilities	(2,684)	1,916
Net cash flows used in operating activities	(23,411)	(16,507)
<b>Investing activities</b>		
Purchases of securities available-for-sale	(14,111)	(50,441)
Sales/maturities of securities available-for-sale	23,992	70,458
Purchases of property and equipment	(427)	(1,635)
Net cash flows provided by investing activities	9,454	18,382
<b>Financing activities</b>		
Issuance of common stock, net	9,670	404
Principal payments on debt and capital lease obligations	(1,056)	(936)
Proceeds received from debt	5,000	1,134
Net cash flows provided by financing activities	13,614	602
(Decrease) increase in cash and cash equivalents	(343)	2,477
Cash and cash equivalents at beginning of year	14,141	12,052
Cash and cash equivalents at end of period	\$ 13,798	\$ 14,529
<b>Supplemental schedule of noncash investing and financing activities:</b>		
Accrued debt issuance costs	\$ 202	\$
Unrealized (loss) gain on securities available-for-sale	\$ (54)	\$ 21
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 six months ended June 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 Accounting Financial 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 income (loss) is as follows (in thousands):

**Three Months Ended  
June 30,**

**Six Months Ended  
June 30,**

Edgar Filing: METABASIS THERAPEUTICS INC - Form 10-Q

	2008	2007	2008	2007
Net loss	\$ (11,542)	\$ (11,935)	\$ (22,642)	\$ (20,441)
Unrealized (loss) gain on available-for-sale investments	(57)	26	(54)	21
Comprehensive loss	\$ (11,599)	\$ (11,909)	\$ (22,696)	\$ (20,420)

**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 7,381,142 and 7,523,754 for the three months ended June 30, 2008 and 2007, respectively, and 7,168,734 and 7,145,040 for the six months ended June 30, 2008 and 2007, respectively.

Table of Contents

	Three Months Ended June 30,		Six Months Ended June 30,	
	2008	2007	2008	2007
<b>Actual:</b>				
<i>Numerator:</i>				
Net loss	\$ (11,542)	\$ (11,935)	\$ (22,642)	\$ (20,441)
<i>Denominator:</i>				
Weighted average common shares	34,244	30,228	32,501	30,533
Weighted average unvested common shares subject to repurchase		(15)		(31)
Denominator for basic and diluted net loss per share	34,244	30,213	32,501	30,502
Basic and diluted net loss per share	\$ (0.34)	\$ (0.40)	\$ (0.70)	\$ (0.67)

**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*, 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*. These securities consist of treasury backed money market funds, corporate bonds, commercial paper, and credit card asset backed securities. The following table shows the fair value measurement for this financial asset at June 30, 2008 and the fair value hierarchy level, as defined in SFAS No. 157.

Description	Asset Total	Fair Value Measurements (in thousands)		
		Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Securities available-for-sale	\$ 18,703	\$ 16,451	\$ 2,252	\$

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

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.

Table of Contents

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.

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 six months ended June 30, 2008 were approximately \$0 and \$7,000, respectively. There were no cumulative adjustments to beginning retained earnings as a result of adopting SFAS No. 159.

## **5. Warrant Exchange and Concurrent Private Placement**

In April 2008, the Company entered into a warrant exchange and concurrent private placement (together, 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 the Company's common stock issued previously in its October 2001 and October 2005 private placements. Investment banking fees and other offering expenses were approximately \$0.4 million.

In connection with the Transaction, the Company entered into a warrant exercise agreement (the Warrant Exercise Agreement ) pursuant to which the Company reduced the exercise prices of the investors' warrants to purchase the Company's common stock acquired in its 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 the Company's common stock with a prior exercise price of \$8.70 per share and warrants for the purchase of 1,558,279 shares of the Company's 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, the Company entered into a securities purchase agreement (the Securities Purchase Agreement ) pursuant to which the Company issued and sold to the investors 2,485,103 shares of its common stock at an exercise price of \$2.34 per share, and warrants to purchase up to 1,057,196 shares of its common stock at an exercise price of \$2.69 per share (the Warrants ). The Warrants are exercisable commencing six months after the Transaction date until April 16, 2013. 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, the Company also entered into a registration rights agreement (the Registration Rights Agreement ) pursuant to which the Company granted to the investors certain registration rights relating to the securities issued and sold in the Securities Purchase Agreement. The Company filed a registration statement pursuant to the Registration Rights Agreement on May 9, 2008 and the SEC declared the registration statement effective on May 30, 2008.

Table of Contents

Certain of the Company's 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 the Company's amended and restated investors' rights agreement dated October 28, 2003. Luke B. Evnin, Ph.D., David F. Hale and Arnold L. Oronsky, Ph.D., members of the Company's board of directors, are associated with MPM Capital, Hale BioPharma Ventures and InterWest Partners, respectively.

The Company accounted for the Warrants issued under the Securities Purchase Agreement in accordance with Emerging Issues Task Force (EITF) Issue No. 00-19, *Accounting for Derivative Financial Instruments Indexed to and Potentially Settled in a Company's Own Stock* (EITF No. 00-19). According to EITF No. 00-19, the Warrants met all criteria within the guidance providing for the classification of these financial instruments as equity. The fair values of the Warrants were approximately \$1.5 million in aggregate and was determined using the Black-Scholes model using the following assumptions: risk-free interest rates of 3.02%; dividend yield of 0%; expected volatility of 81.9%; and a term of 5 years.

## 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 Company does not anticipate that the impact of adopting SFAS No. 141(R) will have a material effect on its financial statements.

In December 2007, FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements – an amendment of ARB No. 51*, ( SFAS No. 160 ). This statement improves the relevance, comparability, and transparency of the financial information that a reporting entity provides in its consolidated financial statements by establishing accounting and reporting standards that require the ownership interests in subsidiaries held by parties other than the parent and the amount of consolidated net income attributable to the parent and to the non-controlling interest be clearly identified and presented on the face of the consolidated statement of income; changes in a parent’s ownership interest while the parent retains its controlling financial interest in its subsidiary be accounted for consistently; when a subsidiary is deconsolidated, any retained non-controlling equity investment in the former subsidiary be initially measured at fair value, and entities to provide sufficient disclosures that clearly identify and distinguish between the interests of the parent and the interests of the



Table of Contents

non-controlling owners. SFAS No. 160 affects those entities that have an outstanding non-controlling interest in one or more subsidiaries or that deconsolidate a subsidiary. SFAS No. 160 is effective for fiscal years, and interim periods within those fiscal years, beginning on or after December 15, 2008 (beginning with the Company's fiscal year 2009). Early adoption is prohibited. The adoption of SFAS No. 160 is not expected to have a material effect on the Company's financial statements.

In March 2008, the FASB issued SFAS No. 161, *Disclosures about Derivative Instruments and Hedging Activities, an amendment of FASB Statement No. 133*, ( SFAS No. 161 ). This statement is intended to improve transparency in financial reporting by requiring enhanced disclosures of an entity's derivative instruments and hedging activities and their effects on the entity's financial position, financial performance, and cash flows. SFAS No. 161 applies to all derivative instruments within the scope of SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities*, as well as related hedged items, bifurcated derivatives, and nonderivative instruments that are designated and qualify as hedging instruments. Entities with instruments subject to SFAS No. 161 must provide more robust qualitative disclosures and expanded quantitative disclosures. SFAS No. 161 is effective prospectively for financial statements issued for fiscal years and interim periods beginning after November 15, 2008 (beginning with the Company's 2009 fiscal year), with early application permitted. The Company does not anticipate that the impact of adopting SFAS No. 161 will have a material effect on its 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.

**7. Subsequent Event**

In August 2008, the Company announced the establishment of a two-year research collaboration with Roche, in which the Company's HepDirect liver-targeting technology will be applied to Roche's proprietary lead nucleosides for the treatment of hepatitis C virus (HCV). Under the terms of the agreement, the Company is entitled to an upfront payment of \$10.0 million. 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 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.

**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.*

Table of Contents

**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, prafefovir and MB07133, which have been developed as potential treatments for hepatitis B and primary liver cancer, respectively.

*Recent Events*

In August 2008, we entered into a two year Research Collaboration Agreement with Roche. Under the terms of the 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 will receive an upfront payment of \$10.0 million from Roche. 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.

In June 2008, we announced the results of our 14-day, Phase 1b multiple-dose clinical trial of MB07811 in subjects with mild hypercholesterolemia, which showed that MB07811 was safe and well tolerated across the seven doses tested. The clinical trial results also showed dose-related reductions in fasting low-density lipoprotein cholesterol (LDL-C) and fasting triglyceride (TG) levels at day 14. We are continuing to review these results and currently expect to initiate a 12-week Phase 2a clinical trial later in 2008 or early in 2009.

In April 2008, we announced that MB07803 met its primary efficacy endpoint with results demonstrating a statistically and clinically significant reduction in fasting plasma glucose at day 28 in its Phase 2a clinical trial. The study also showed that MB07803 was safe and well tolerated. We intend to initiate a clinical trial later in 2008 on MB07803 to test higher doses in patients, with the aim of using the results of this trial to select doses for a Phase 2b clinical trial, which we currently expect to begin in 2009.

In April 2008, we entered into a warrant exchange and concurrent private placement, which raised \$9.9 million in cash. The participants in the transaction were certain current investors who held existing warrants for the purchase of common stock issued previously by us in our October 2001 and October 2005 private placements. Pursuant to the transaction, we reduced the exercise prices of the existing warrants held by the participants in exchange for the immediate exercise of the warrants. We also sold additional shares of common stock and warrants for the

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

purchase of common stock in a concurrent private placement. We intend to use the proceeds from the transaction for general corporate purposes, including the further clinical development of MB07803 and MB07811 for the treatment of type 2 diabetes and hyperlipidemia, respectively.

Also in April 2008, we extended the research term of our AMPK collaboration with Merck & Co. Inc., or Merck, for an additional year, through June 2009. Under the extension, which was permitted under the terms of our existing collaboration agreement, we will continue working with Merck to identify novel small molecule therapeutics with the potential to treat several diseases, including type 2 diabetes and other metabolic diseases, by activation of an AMPK enzyme. Merck will continue to fund research efforts for this project and has primary responsibility, including financial responsibility, for clinical development of any resulting product candidates as well as the right to market such products worldwide, if approved. We are eligible to receive payments upon achievement of certain milestones during development of a product candidate. Should a product be commercialized, we will receive a royalty on net sales and have the option to co-promote the product in the United States. We will receive \$1.5 million over the course of the one year extension to support our research efforts.

Table of Contents

*Strategic Plan*

Under our strategic plan we will focus 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 potentially with current or future strategic collaborators.

In order to reduce future expenses and to minimize the potential dilution associated with financing internal development, we intend to license pradefovir and MB07133 for further development and commercialization.

Our strategic plan has the potential to reduce future expenses and to provide additional financial resources by:

- selectively funding only our core assets,
  
- licensing or selling our non-core assets,
  
- seeking to offset current and future research and development costs via additional strategic collaborations on our core advanced research and clinical programs, and
  
- utilizing our existing financing facilities, such as the Committed Equity Financing Facility, or CEFF.

We believe that these measures, if successful, along with our existing resources, will be sufficient to execute our strategic plan.

*History of Losses, Prior Funding*

We have incurred annual net losses since inception. As of June 30, 2008, our accumulated deficit was approximately \$172.7 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 our core assets, MB07803 or MB07811, and we intend to license our non-core assets, 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, 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 marketing rights to our collaborators in exchange for up-front fees, milestones and royalties on future sales, if any.

Table of Contents

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.

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, pradefovir 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 other 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 June 30, 2008, which includes funding for sponsored research efforts through September 2008. In April 2008, we agreed with Merck to extend the research term for an additional year through June 2009, in connection with which we are entitled to receive approximately \$1.5 million in additional sponsored research funding.

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.



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

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 are entitled to receive an upfront license fee of \$10.0 million in August 2008.

Table of Contents

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 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.

**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,

Table of Contents

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

- 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.

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.

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

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.

Table of Contents

**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*, or 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 (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 December 2007, FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements – an amendment of ARB No. 51*, or SFAS No. 160. This statement improves the relevance, comparability, and transparency of the financial information that a reporting entity provides in its consolidated financial statements by establishing accounting and reporting standards that require the ownership interests in subsidiaries held by parties other than the parent and the amount of consolidated net income attributable to the parent and to the non-controlling interest be clearly identified and presented on the face of the consolidated statement of income; changes in a parent's ownership interest while the parent retains its controlling financial interest in its subsidiary be accounted for consistently; when a subsidiary is deconsolidated, any retained non-controlling equity investment in the former subsidiary be initially measured at fair value, and entities to provide sufficient disclosures that clearly identify and distinguish between the interests of the parent and the interests of the non-controlling owners. SFAS No. 160 affects those entities that have an outstanding non-controlling interest in one or more subsidiaries or that deconsolidate a subsidiary. SFAS No. 160 is effective for fiscal years, and interim periods within those fiscal years, beginning on or after December 15, 2008 (beginning with our fiscal year 2009). Early adoption is prohibited. The adoption of SFAS No. 160 is not expected to have a material effect on our financial statements.

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

In March 2008, the FASB issued SFAS No. 161, *Disclosures about Derivative Instruments and Hedging Activities*, an amendment of FASB Statement No. 133, or SFAS No. 161. This statement is intended to improve transparency in financial reporting by requiring enhanced disclosures of an entity's derivative instruments and hedging activities and their effects on the entity's financial position, financial performance, and cash flows. SFAS No. 161 applies to all derivative instruments within the scope of SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities*, as well as related hedged items, bifurcated derivatives, and nonderivative instruments that are designated and qualify as hedging instruments. Entities with instruments subject to SFAS No. 161 must provide more robust qualitative disclosures and expanded quantitative disclosures. SFAS No. 161 is effective prospectively for financial statements issued for fiscal years and interim periods beginning after November 15, 2008 (beginning with our 2009 fiscal year), with early application permitted. We do not anticipate that the impact of adopting SFAS No. 161 will have a material effect on our financial statements.

Table of Contents

In May 2008, the FASB issued SFAS No. 162, *The Hierarchy of Generally Accepted Accounting Principles*, or 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 our financial statements.

**Results of Operations**

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

*Revenues.* Revenues were \$0.7 million for the three months ended June 30, 2008, compared with \$1.6 million for the three months ended June 30, 2007. The \$0.9 million decrease was mainly due to decreased license fee revenue of \$0.5 million and decreased sponsored research revenue of \$0.4 million. The decrease in license fee revenue was related to the absence of the Idenix license fee as a result of the end of the sponsored research term of our collaboration in October 2007. The decrease was also related to a decrease in the recognized amount of the Merck AMPK license fee as a result of a change in the period by which we recognize the remaining balance of the upfront \$5.0 million license fee we received in June 2005 over an additional year due to extension of the research term through June 2009. The decrease in sponsored research revenue primarily relates to the completion of the sponsored research portion of our agreement with Idenix in October 2007.

*Research and Development Expenses.* Research and development expenses were \$9.7 million for the three months ended June 30, 2008, compared with \$11.1 million for the three months ended June 30, 2007. The \$1.4 million decrease was mainly due to a net decrease of \$1.8 million in clinical and development expenses for the MB07803, MB07133 and MB07811 programs and \$0.3 million in non-cash stock-based compensation expense. These decreases were offset by an 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 \$0.2 million in payroll and related benefits due to a higher average headcount in the second quarter of 2008 as compared to the second quarter of 2007.

*General and Administrative Expenses.* General and administrative expenses were \$2.6 million for the three months ended June 30, 2008, compared with \$3.2 million for the three months ended June 30, 2007. The \$0.6 million decrease was mainly due to a decrease of \$0.4 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, \$0.2 million in non-cash stock-based compensation and \$0.1 million in payroll and related benefits due to a decrease in the average headcount for the



second quarter of 2008 as compared to the second quarter of 2007. These decreases were offset by an increase of approximately \$0.1 million in professional services.

*Other Income (Expense).* Net interest income was \$7,000 for the three months ended June 30, 2008, compared to net interest income of \$0.7 million for the three months ended June 30, 2007. The \$0.7 million decrease was a result of lower cash balances in the second quarter of 2008 as compared to the second quarter of 2007 as well as increased interest expense related to long-term debt acquired in the first quarter of 2008.

*Comparison of the Six Months Ended June 30, 2008 and 2007*

*Revenues.* Revenues were \$1.6 million for the six months ended June 30, 2008, compared with \$5.0 million for the six months ended June 30, 2007. The \$3.4 million decrease was mainly due to decreased license fee revenue of \$2.5 million and decreased sponsored research revenue of \$0.8 million. The decrease in license fee revenue primarily relates to the absence of license fees of \$1.8 million recognized in the first half of 2007 in conjunction with our former collaboration arrangement with Schering Corporation, which was terminated in September 2007, the absence of license fees of \$0.5 million recognized in the first half of 2007 related to Idenix as a result of the sponsored research portion of our agreement ending in October 2007, and \$0.2 million less recognized revenue related to extending the recognition period for the remaining unrecognized balance of the upfront \$5.0 million Merck AMPK license fee received in June 2005 over the additional one

Table of Contents

year extension of the research term through June 2009. The decrease in sponsored research revenue primarily relates to the completion of the sponsored research portion of our agreement with Idenix in October 2007.

*Research and Development Expenses.* Research and development expenses were \$19.4 million for the six months ended June 30, 2008, compared with \$20.6 million for the six months ended June 30, 2007. The \$1.2 million decrease was mainly due to a decrease of \$1.9 million in clinical and development expenses for the MB07803, MB07133, and MB07811 programs and \$0.5 million in non-cash stock-based compensation expense. These decreases were offset by an increase of approximately \$0.8 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 \$0.4 million in payroll and related benefits due to a higher average headcount in the first half of 2008 as compared to the first half of 2007.

*General and Administrative Expenses.* General and administrative expenses were \$5.1 million for the six months ended June 30, 2008, compared with \$6.5 million for the six months ended June 30, 2007. The \$1.4 million decrease was mainly due to a decrease of \$0.6 million in occupancy and non-cash depreciation due to a change in the allocation rate of these costs, as discussed above, \$0.3 million in professional services, \$0.2 million in non-cash stock-based compensation, \$0.2 million in payroll and related benefits due to a decrease in the average headcount for the first half of 2008 as compared to the first half of 2007 and \$0.1 million in other operating expenses.

*Other Income (Expense).* Net interest income was \$0.2 million for the six months ended June 30, 2008, compared to net interest income of \$1.6 million for the six months ended June 30, 2007. The \$1.4 million decrease was a result of lower cash balances in the first half of 2008 as compared to the first half of 2007 as well as interest expense incurred in the first half of 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 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.

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

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.

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. Evnin, 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.

Table of Contents

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.

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 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.

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 June 30, 2008, we have not utilized the CEFF.

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

As of June 30, 2008, we had \$32.5 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 \$9.9 million. The decrease is primarily a result of net cash used in operations of \$23.4 million offset by \$13.6 million of net cash flows provided by financing activities.

As of June 30, 2008, we have financed through leases and loans the purchase of equipment and leasehold improvements totaling approximately \$12.4 million, of which \$4.9 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, our CEFF, if available, 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

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

### Table of Contents

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 potentially 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 prafefovir and MB07133 for further development and commercialization.

We may not be successful in entering into additional collaboration agreements, or in receiving milestone or royalty payments under current or future agreements. 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. 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. 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. 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.

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

	Total	Payments Due by Period			
		Less than 1 Year	1 to 3 Years	4 to 5 Years	After 5 Years
Operating leases	\$ 23,399	\$ 2,501	\$ 6,207	\$ 6,552	\$ 8,139
Long-term debt	9,870	3,252	6,369	156	93
Interest on long-term debt	1,883	1,024	828	22	9
Purchase commitments	2,238	2,238			
Capital leases	60	23	37		
Interest on capital leases	10	6	4		
<b>Total</b>	<b>\$ 37,460</b>	<b>\$ 9,044</b>	<b>\$ 13,445</b>	<b>\$ 6,730</b>	<b>\$ 8,241</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 June 30, 2008, no events have occurred resulting in the obligation of any such payments.

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

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,

Table of Contents

- 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 manufacturing, sales and marketing capabilities, and
- the effect of competing technological and market developments.

**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 report on Form 10-Q for the quarter ended March 31, 2008. Given these uncertainties, you should not place undue reliance on these forward-looking statements.

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



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



## 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. 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

Table of Contents

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.

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, pradeфовir and MB07133. Clinical trials conducted to date have provided initial evidence of safety with all of our product candidates and initial evidence of efficacy in certain 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.

Table of Contents

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.

*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.

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

Table of Contents

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.

***We may not be able to enter into collaborations with respect to our non-core assets, pradefovir and MB07133, and certain metabolic disease advanced research programs 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, pradefovir and MB07133, and as a component of our strategic plan, we plan to enter into additional collaborative agreements to assist in the development and commercialization of some or all of these 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, 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.

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

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

Table of Contents

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.

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

- we may be unable to obtain additional financing on acceptable terms, if at all,
- our stock price could decline,
- our collaborators may ultimately terminate development of our partnered products, may further decide not to develop backup product candidates and may terminate our agreements,
- if these agreements were terminated we may determine not to further develop the affected product candidates due to resource constraints and may not be able to establish additional collaborations for their further development on acceptable terms, if at all,
- if we were to later continue the development of these product candidates and receive regulatory approval, earlier findings may significantly limit their marketability and thus significantly lower our potential future revenues from their sale,
- we may be subject to product liability or stockholder litigation, and
- we may be unable to attract and retain key employees.

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

- 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 and commercialize 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 development. The sponsored research term of our second collaboration with Merck continues through June 2009, and the

Table of Contents

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 these product candidates for further development and commercialization.

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,
  
- 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.***

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

Table of Contents

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 and commercialize 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 or commercialize 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:

- 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

Table of Contents

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 delays related to:

- obtaining regulatory approval to commence a clinical trial,
  
- reaching agreement on acceptable terms with prospective contract research organizations and clinical trial sites,
  
- manufacturing sufficient quantities of a product candidate or other materials necessary to conduct the clinical trial,
  
- obtaining institutional review board approval to conduct a clinical trial at a prospective site,
  
- recruiting and enrolling patients to participate in a clinical trial, and
  
- the failure of our collaborators to adequately resource our product candidates due to their focus on other programs or as a result of general market conditions.

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

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

- inspection of the clinical trial operations or clinical trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold,
- unforeseen safety issues, or
- lack of adequate funding to continue the clinical trial.

If we experience significant delays in the commencement or completion of clinical testing, 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 pradefovir or MB07133 and intend to license these product candidates for further development and commercialization. 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

Table of Contents

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 pradefovir, 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.

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

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. 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,

Table of Contents

- 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:

- 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.

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

Table of Contents

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 mimetics, which 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. This drug class includes dipeptidyl peptidase IV, or DPP-IV inhibitors, and BYETTA® (exenatide) injection. DPP-IV is an enzyme in the bloodstream that cleaves and inactivates GLP-1. Inhibition of DPP-IV thus increases the half-life of endogenous GLP-1 by preventing cleavage and inactivation of GLP-1. BYETTA is an injectable medication that exhibits many of the same glucose regulating actions of GLP-1. The overall effect of drugs in this class is to enhance glucose-dependent insulin secretion and suppress inappropriate glucagon secretion,
- 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.

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,

Table of Contents

- 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.

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

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.

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

Table of Contents

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

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

(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,

Table of Contents

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.

*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.*

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.

Table of Contents

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.

*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 126 as of June 30, 2008. We may need to decrease the number of our full-time employees in the future in response to 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 or maintain 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, our CEFF, if available, 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 and the CEFF or other financing sources to fund certain studies on the MB07803 and MB07811 programs in 2008. In the event we are not able to generate sufficient financing through the use of our CEFF or other planned financing and business development 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 2008. 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. Alternatively, we may determine that seeking additional resources through traditional financing transactions may be appropriate to achieve certain key value-driving

Table of Contents

development milestones. No assurances can be made that additional funding through any resources including, our CEFF, will be available when needed. 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,
- 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.

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.

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

We have incurred net losses from our inception. As of June 30, 2008, we had an accumulated deficit of approximately \$172.7 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 or through collaboration and licensing arrangements will cause dilution to existing stockholders, 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 allow us to issue shares of our common stock and warrants to purchase our common stock in the future for an aggregate initial offering price of up to \$75 million, subject to substantial limitations relating to the aggregate market value of our common stock held by non-affiliates. We have also filed a registration statement with the Securities and Exchange Commission covering the resale of shares issuable under the CEFF though to date, no shares have been issued under this resale registration statement. We may sell additional securities from time to time in one or more offerings in amounts, at prices and on terms that we will determine at the time of the offering. To the extent that we raise additional capital by issuing equity securities, pursuant to our effective shelf registration statements or otherwise, our existing stockholders ownership will be diluted.

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.

***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.***

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

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 or the use of different valuation methods in the application of SFAS No. 123R in future periods.

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

*Our CEFF may not be available to us if we elect to make a draw down, may require us to make additional blackout or*

Table of Contents

*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.

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

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

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

Table of Contents

provide us with incorrect or inappropriate advice it could be detrimental to our patent positions.

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

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.



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

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.

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

Table of Contents

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:

Table of Contents

- decreased demand for our product candidates,
- 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**

*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,

Table of Contents

- 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,
- additions or departures of key personnel, and
- discussion of us or our stock price by the financial and scientific press and in online investor communities.

*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 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

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

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.

***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 advances their best interests and not necessarily those 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 June 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 advances their best interests and not necessarily those of other stockholders.

Table of Contents

*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. 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**

We held our 2008 Annual Meeting of Stockholders on June 10, 2008. As of the close of business on April 16, 2008, the record date for the Annual Meeting, there were 34,930,843 shares of our common stock entitled to vote, of which there were 28,935,112 shares present at the Annual Meeting in person or by proxy. At the Annual Meeting, our stockholders approved the following matters:

*Proposal 1.* Election of two directors to serve as Class I directors until our 2011 Annual Meeting of Stockholders. The vote for the nominees for Class I director was as follows:

Daniel D. Burgess, M.B.A. 28,357,613 shares were voted in favor of the nominee; 577,499 shares withheld their vote.

Luke B. Evin, Ph.D. 28,359,613 shares were voted in favor of the nominee; 575,499 shares withheld their vote.

Our Class II directors, Mark D. Erion, Ph.D., Arnold L. Oronsky, Ph.D. William R. Rohn and Elizabeth Stoner, M.D., continue in office until our 2009 Annual Meeting of Stockholders. Our Class III directors, David F. Hale, Paul K. Laikind, Ph.D., and George F. Schreiner, M.D., Ph.D., continue in office until our 2010 Annual Meeting of Stockholders.

*Proposal 2.* Ratification of the selection by the Audit Committee of our Board of Directors of Ernst & Young LLP as our independent registered public accounting firm for the fiscal year ending December 31, 2008. 28,926,011 shares voted in favor of the proposal; 9,101 shares voted against the proposal; and no shares abstained from voting.

**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.
4.2(3)	Form of Warrant Exercise Agreement, dated April 14, 2008, by and among the Company and the individuals and entities identified on the signature page thereto.
4.3(3)	Form of Securities Purchase Agreement, dated April 14, 2008, by and among the Company and the individuals and entities identified on the signature page thereto.
4.4(3)	Form of Registration Rights Agreement, dated April 14, 2008, by and among the Company and the individuals and entities identified on the signature page thereto.
4.5(3)	Form of Warrant issued pursuant to the Securities Purchase Agreement.
10.1(3)	2008 Employee Incentive Compensation Plan.
10.2(4)	Collaboration Agreement Extension Letter dated April 16, 2008 between the Company and Merck & Co., Inc.
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32	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.
- (3) Incorporated by reference to the Company's Current Report on Form 8-K filed on April 22, 2008.
- (4) Incorporated by reference to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2008.

Table of Contents

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Date: August 8, 2008

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