

METABASIS THERAPEUTICS INC

Form 10-Q

May 15, 2009

Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended March 31, 2009.

OR

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

For the transition period from to .

Commission file number 000-50785

METABASIS THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of

incorporation or organization)

11119 North Torrey Pines Road,

La Jolla, CA

(Address of principal executive offices)

33-0753322

(I.R.S. Employer

Identification No.)

92037

(Zip code)

(858) 587-2770

(Registrant's telephone number, including area code)

Edgar Filing: METABASIS THERAPEUTICS INC - Form 10-Q

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

(Do not check if a smaller reporting company)

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

The number of outstanding shares of the registrant's common stock, par value \$0.001 per share, as of May 10, 2009 was 35,152,359.

Table of Contents

METABASIS THERAPEUTICS, INC.

FORM 10-Q

FOR THE QUARTERLY PERIOD ENDED March 31, 2009

TABLE OF CONTENTS

<u>PART I FINANCIAL INFORMATION</u>	2
<u>Item 1. Financial Statements</u>	2
<u>Balance Sheets at March 31, 2009 (Unaudited) and December 31, 2008</u>	2
<u>Statements of Operations for the three months ended March 31, 2009 and 2008 (Unaudited)</u>	3
<u>Statements of Cash Flows for the three months ended March 31, 2009 and 2008 (Unaudited)</u>	4
<u>Notes to Financial Statements (Unaudited)</u>	5
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	12
<u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u>	19
<u>Item 4. Controls and Procedures</u>	19
<u>PART II OTHER INFORMATION</u>	21
<u>Item 1. Legal Proceedings</u>	21
<u>Item 1A. Risk Factors</u>	21
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	41
<u>Item 3. Defaults Upon Senior Securities</u>	41
<u>Item 4. Submission of Matters to a Vote of Security Holders</u>	41
<u>Item 5. Other Information</u>	41
<u>Item 6. Exhibits</u>	42
<u>SIGNATURES</u>	

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

	March 31, 2009	December 31, 2008
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	\$ 11,768	\$ 12,599
Securities available-for-sale		9,000
Prepays and other current assets	1,018	1,091
Total current assets	12,786	22,690
Property and equipment, net	4,052	4,779
Other assets	249	273
Total assets	\$ 17,087	\$ 27,742
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 235	\$ 93
Accrued compensation	2,310	2,439
Accrued liabilities	1,248	1,798
Deferred revenue, current portion	4,800	5,652
Current portion of long-term debt	7,791	3,890
Current portion of capital lease obligations	47	26
Total current liabilities	16,431	13,898
Deferred revenue, net of current portion	1,461	2,499
Deferred rent	3,194	3,079
Long-term debt		4,658
Capital lease obligations, net of current portion		27
Other long-term liabilities		200
Total liabilities	21,086	24,361
Stockholders' equity:		
Preferred stock, \$0.001 par value; 5,000 shares authorized at March 31, 2009 and December 31, 2008, no shares issued or outstanding		
Common stock, \$0.001 par value; 100,000 shares authorized at March 31, 2009 and December 31, 2008; 35,152 shares issued and outstanding at March 31, 2009 and December 31, 2008	35	35
Additional paid-in capital	196,533	195,640
Accumulated deficit	(200,567)	(192,326)
Accumulated other comprehensive income		32
Total stockholders' (deficit) equity	(3,999)	3,381

Edgar Filing: METABASIS THERAPEUTICS INC - Form 10-Q

Total liabilities and stockholders' equity	\$ 17,087	\$ 27,742
--	-----------	-----------

See accompanying notes.

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

	Three Months Ended March 31,	
	2009	2008
Revenues:		
License fees	\$ 1,089	\$ 417
Sponsored research	800	525
Total revenues	1,889	942
Operating expenses:		
Research and development	7,416	9,745
General and administrative	2,523	2,519
Total operating expenses	9,939	12,264
Loss from operations	(8,050)	(11,322)
Other income (expense):		
Interest income	38	398
Interest expense	(229)	(176)
Total other (expense) income	(191)	222
Net loss	\$ (8,241)	\$ (11,100)
Basic and diluted net loss per share	\$ (0.23)	\$ (0.36)
Shares used to compute basic and diluted net loss per share	35,152	30,758

See accompanying notes.

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

	Three Months Ended March 31,	
	2009	2008
Operating activities		
Net loss	\$ (8,241)	\$ (11,100)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	893	983
Depreciation and amortization	487	528
Deferred rent	115	133
Amortization of discount and premium on securities available-for-sale	(32)	(199)
Loss on disposal or abandonment of assets	261	
Realized gain on securities available-for-sale		(7)
Change in operating assets and liabilities:		
Other current assets	52	(17)
Other assets	24	(7)
Deferred revenue	(1,890)	(468)
Accounts payable	142	(477)
Accrued compensation and other liabilities	(679)	133
Net cash flows used in operating activities	(8,868)	(10,498)
Investing activities		
Purchases of securities available-for-sale		(2,213)
Sales/maturities of securities available-for-sale	9,000	14,493
Purchases of property and equipment		(260)
Net cash flows provided by investing activities	9,000	12,020
Financing activities		
Issuance of common stock, net		7
Principal payments on debt and capital lease obligations	(963)	(529)
Proceeds received from debt		5,000
Net cash flows (used in) provided by financing activities	(963)	4,478
(Decrease) Increase in cash and cash equivalents	(831)	6,000
Cash and cash equivalents at beginning of year	12,599	14,141
Cash and cash equivalents at end of period	\$ 11,768	\$ 20,141
Supplemental schedule of noncash investing and financing activities:		
Unrealized (loss) gain on securities available-for-sale	\$ (32)	\$ 3
Fair value of warrants related to loan and security agreement	\$	\$ 220
Accrued debt issuance costs	\$	\$ 210

See accompanying notes.

Table of Contents

Metabasis Therapeutics, Inc.

Notes to Financial Statements

(Unaudited)

1. Basis of Presentation

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

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

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities as well as disclosures of contingent assets and liabilities at the date of the financial statements. Estimates also affect the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

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

2. Going Concern

The Company has incurred significant net losses since inception and has relied on its ability to fund its operations through private equity financings, an initial public offering, private placements of common stock, a registered direct offering of common stock, proceeds from business collaborations and other traditional debt financings. Management expects operating losses and negative cash flows to continue for the foreseeable future as the Company incurs additional costs and expenses related to the continued development of its products. The Company's working capital will not be sufficient to fund its operations through December 31, 2009 without additional sources of cash. The Company's current financial resources will support its on-going planned operating expenses into July 2009. The Company intends to raise additional resources through undertaking a financing to fund its operations beyond July 2009 and through the Phase 2 clinical trial on MB07811, its product candidate for treating hyperlipidemia. In the event the Company is unsuccessful in the near-term in its efforts to raise capital through undertaking a financing transaction, it will be required to pursue other strategic alternatives which may include a further reduction of its operating expenses, or the sale of some or all of its assets to another company, and/or cease operations entirely. These conditions raise substantial doubt about the Company's ability to continue as a going concern. The accompanying financial statements have been prepared on a going concern basis that contemplates the realization of assets and the satisfaction of liabilities in the normal course of business, except for the reclassification of the Company's long-term debt arrangements with Oxford Corporation (Oxford) (refer to Note 3). The financial statements do not include adjustments to reflect the possible future effects on the recoverability and classification of recorded assets or the amounts of liabilities that might be necessary should the Company be unable to continue as a going concern.

3. Debt

In March 2008, the Company entered into a Loan and Security Agreement (Agreement) with Oxford, pursuant to which Oxford provided the Company with a three-year, \$5.0 million term loan. The Company is using the proceeds from the loan for general working capital purposes. Interest accrues at an annual rate of 9.83%, with six interest-only monthly payments, made in arrears, which began in May 2008, followed by 30 equal monthly payments of principal and interest, which began in November 2008. The Company paid a facility fee of \$50,000 upon signing of the term sheet and is required to pay an additional fee of 4% of the term loan amount, or \$200,000, at the end of the three year term. The

Edgar Filing: METABASIS THERAPEUTICS INC - Form 10-Q

Company has the option to prepay the outstanding balance of the term loan in full, subject to a prepayment fee. The loan is collateralized by the general assets of the Company, excluding intellectual property. There are no financial covenants under the terms of this Agreement. The Company is required to comply with certain reporting covenants that notify the lender of any events of default, material changes to the original representations and warranties made in connection with the Agreement, notification of any liens or legal claims made against the Company and compliance with regulatory financial reporting requirements on a quarterly basis.

Table of Contents

In addition, the Company's outstanding debt and equipment loan agreements with Oxford contain events of default that may be triggered by a material adverse change, which is defined in the agreements as any material adverse change in the general affairs, senior management, results of operations, or financial condition of the Company, whether or not arising from transactions in the ordinary course of business, that is likely to impair the ability of the Company to repay any portion of the obligations or a material impairment in the value or priority of the lender's security interest in the collateral. The Company currently has sufficient working capital to fund its operations into July 2009 without additional sources of cash. In the event the Company is not successful in securing additional sources of cash in the near-term, Oxford may claim that a material adverse change has occurred under the debt or equipment loan agreements, and Oxford could demand immediate repayment of the balances outstanding under the agreements. In the event the Company becomes in default of the loan agreement, Oxford has the right under a control agreement to assume control over the Company's bank accounts, which include its operating and short-term investment accounts.

In accordance with Emerging Issues Task Force (EITF) Issue No. 86-30, *Classification of Obligations When a Violation is Waived by the Creditor*, where a borrower is in violation of a covenant under the terms of a debt agreement at the balance sheet date or received a waiver for non-compliance and it is probable that the borrower will not be able to cure the event of non-compliance within the near-term, the borrower is required to classify such debt as a current liability. The Company may not be able to obtain sufficient capital to remedy any future event of default that may be triggered by a material adverse change under the Agreement or under other terms of the Agreement. Given the current financial position of the Company and the subjective nature of various terms within the debt and equipment loan agreements with Oxford, the Company has determined that it is probable that an event of default may be triggered in the near term. As such, the Company has reclassified the long-term portion of its obligations as current liabilities within its balance sheet at March 31, 2009.

As of March 31, 2009, the Company's cash and cash equivalents totaled \$11.8 million. The outstanding principal balance of the Agreement with Oxford totaled \$4.3 million at March 31, 2009. In the event of default, the Company would be required to pay its outstanding principal balance, accrued and unpaid interest charges, a prepayment penalty of 6% of the then outstanding principal balance and an additional \$200,000, totaling approximately \$4.7 million at March 31, 2009. The outstanding principal balance of the other equipment loans entered into with Oxford totaled \$3.1 million at March 31, 2009. In the event of default, the Company would be required, at Oxford's option, to pay the Company's outstanding principal balance and accrued and unpaid interest charges, totaling approximately \$3.1 million at March 31, 2009.

4. Comprehensive Loss

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

	Three Months Ended	
	March 31,	
	2009	2008
Net loss	\$ (8,241)	\$ (11,100)
Unrealized (loss) gain on available-for-sale investments	(32)	3
Comprehensive loss	\$ (8,273)	\$ (11,097)

5. 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 6,630,530 and 7,143,311 for the three months ended March 31, 2009 and 2008, respectively.

Table of Contents

	Three Months Ended March 31,	
	2009	2008
	(in thousands, except per share data)	
Actual:		
<i>Numerator:</i>		
Net loss	\$ (8,241)	\$ (11,100)
<i>Denominator:</i>		
Weighted average common shares	35,152	30,758
Denominator for basic and diluted net loss per share	35,152	30,758
Basic and diluted net loss per share	\$ (0.23)	\$ (0.36)

6. Collaboration Agreements

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

Effective the quarter ended March 31, 2009, the Company implemented EITF No. 07-01, *Accounting for Collaborative Arrangements*, which prescribes that certain transactions between collaborators be recorded in the income statement on either a gross or net basis, depending on the characteristics of the collaboration relationship, and provides for enhanced disclosure of collaborative relationships. In accordance with EITF No. 07-01, the Company evaluated its collaborative agreements for proper income statement classification based on the nature of the underlying activity. If payments from collaborative partners are not within the scope of other authoritative accounting literature, the income statement classification for the payments is based on a reasonable, rational analogy to authoritative accounting literature that is applied in a consistent manner. Amounts due from collaborative partners related to research and development activities are generally reflected as sponsored research revenues if the proceeds are provided for research services performed or license fee revenues if the proceeds are provided for rights and access to certain know-how, technology and patent rights maintained by the Company. The adoption of EITF No. 07-01 did not affect the Company's financial position or results of operations, however it resulted in enhanced disclosures for its collaboration activities.

Roche

The Company maintains a two-year Research Collaboration and License Agreement with Hoffmann-La Roche Inc., F. Hoffmann-La Roche Ltd. and Roche Palo Alto LLC (collectively, *Roche*). The collaboration operates as an agreement rather than a joint venture or other legal entity. The Company's HepDirect liver-targeted technology is applied to proprietary Roche compounds to develop second-generation nucleoside analog drug candidates for treating hepatitis C virus. The Company provides a non-exclusive worldwide license to its proprietary know-how and technology to Roche through contracted research and development services during the research phase of this collaboration. In the event a development candidate is identified, Roche will assume development responsibility and the Company will be eligible to receive up to \$193.0 million in payments upon achievement of predetermined preclinical and clinical development events as well as regulatory and commercialization events. Roche will retain full commercial rights for any marketed products resulting from the collaboration and will pay the Company a royalty on net sales of such products.

The Company received a non-refundable upfront payment of \$10.0 million from Roche in August 2008, of which \$8.3 million will be recognized as license fee revenue and \$1.7 million will be recognized as sponsored research revenue. Roche may also pay up to an additional \$2.1 million in sponsored research funding at the beginning of the second year of the research term, if applicable. The Company recognizes the upfront, nonrefundable fee over the period the related services are provided. Amounts received for sponsored research funding for a specific number of full-time researchers are recognized as revenue as the services are provided. The Company recognized the following revenues and costs related to this collaboration (in thousands):

Table of Contents

	Three Months Ended March 31,	
	2009	2008
License fee revenue	\$ 1,038	\$
Sponsored research revenue		425
	\$ 1,463	\$

Research and development costs \$ 282 \$

Deferred revenue of approximately \$6.2 million is reflected on the balance sheet as of March 31, 2009 relating to this collaboration.

Merck

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

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

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

	Three Months Ended March 31,	
	2009	2008
License fee revenue	\$ 52	\$ 417
Sponsored research revenue	375	525
	\$ 427	\$ 942

Research and development costs \$ 522 \$ 675

Deferred revenue of approximately \$52,000 is reflected on the balance sheet as of March 31, 2009 relating to this agreement.

7. Offer to Exchange Stock Options

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

Table of Contents

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

In accordance with SFAS No. 123R, the Company accounted for the Offer as a short-term inducement and recognized \$83,000 of additional compensation expense during the three months ended March 31, 2009, representing the incremental fair value for those options that were exchanged for new options.

8. Corporate Restructurings

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

In accordance with SFAS No. 146, *Accounting for Costs Associated with Exit or Disposal Activities*, the Company recorded charges of approximately \$0.2 million for the three months ended March 31, 2009 related to the November 2008 restructuring, all of which were recorded in research and development expense. Since November 2008, the Company incurred restructuring charges of approximately \$1.6 million related to the November 2008 restructuring, of which \$1.3 million were recorded in research and development expense and \$0.3 million were recorded in general and administrative expense. All charges were primarily associated with personnel-related termination costs. The Company did not incur any expense related to contractual or lease obligation or other exit costs. The Company does not anticipate incurring any additional charges related to this restructuring.

On January 15, 2009, the Company committed to another restructuring plan that resulted in the further reduction of approximately 43% of the Company's workforce. In connection with this restructuring plan, the Company is focused on its clinical-stage product candidate, MB07811 for the treatment of hyperlipidemia, as well as on advancing its glucagon antagonist program and its second-generation TR β agonist program. Employees directly affected by this restructuring plan received notification and will be provided with severance payments, retention bonuses, where applicable, continued benefits for a specified period of time and outplacement assistance. The Company expects to complete the restructuring plan by the end of the second quarter of 2009.

In accordance with SFAS No. 146, the Company recorded charges of approximately \$1.5 million for the three months ended March 31, 2009 related to the January 2009 restructuring, of which approximately \$1.3 million were recorded in research and development expense and approximately \$0.2 million were recorded in general and administrative expense. It is anticipated that the Company will incur an additional \$24,000 in restructuring charges related to this restructuring during the second quarter of 2009. All charges were primarily associated with personnel-related termination costs. The Company did not incur any expense related to contractual or lease obligation or other exit costs.

The severance-related charge that the Company expects to incur in connection with the January 2009 restructuring is subject to a number of assumptions, and actual results may materially differ. The increase in the actual amount of restructuring charges incurred of \$1.5 million compared to the originally anticipated amount of \$1.4 million was due to employees remaining with the Company longer than originally planned. The Company may also incur other material charges not currently contemplated due to events that may occur as a result of, or associated with, the restructuring plan.

Table of Contents

	Termination Costs for Involuntary Employee Terminations (in thousands)
Accrual balance as of December 31, 2007	\$
Accruals	1,483
Payments	(901)
Accrual balance as of December 31, 2008	\$ 582
Accruals	1,622
Payments	(1,943)
Accrual balance as of March 31, 2009	\$ 261

9. Impairment and Disposal of Long-Lived Assets

In accordance with SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*, if indicators of impairment exist, the Company assesses the recoverability of the affected long-lived assets by determining whether the carrying value of such assets can be recovered through undiscounted future operating cash flows. In the instance where a long-lived asset is to be abandoned it is disposed of when it ceases to be used. The Company revises its estimates for depreciation based on the plan of disposal or when the Company ceases to use such assets.

In connection with the Company's corporate restructuring during the first quarter of 2009, the Company began the process of disposing and/or discontinuing the use of various lab equipment, office equipment and furniture resulting in \$0.3 million of impairment charges for the three months ended March 31, 2009.

10. Accounting Pronouncements*Adopted Accounting Pronouncements*

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

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

In June 2008, the EITF issued EITF Issue No. 07-5, *Determining Whether an Instrument (or Embedded Feature) Is Indexed to an Entity's Own Stock*. EITF No. 07-5 mandates a two-step process for evaluating whether an equity-linked financial instrument or embedded feature is indexed

Edgar Filing: METABASIS THERAPEUTICS INC - Form 10-Q

to the entity's own stock. EITF No. 07-5 is effective for fiscal years beginning after December 15, 2008

Table of Contents

(beginning with the Company's fiscal year 2009). The adoption of EITF No. 07-05 did not have a material impact on the Company's financial statements.

Recently Issued Accounting Pronouncements

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

In April 2009, the FASB issued FSP FAS No. 115-2, FAS No. 124-2 and EITF No. 99-20-2, *Recognition and Presentation of Other-Than-Temporary Impairments*. FSP FAS No. 115-2, FAS No. 124-2, and EITF No. 99-20-2 provides additional guidance to provide greater clarity about the credit and noncredit component of an other-than-temporary impairment event and to more effectively communicate when an other-than-temporary impairment event has occurred. This FSP applies to debt securities. This standard is effective for periods ending after June 15, 2009. The Company is evaluating the impact that these standards will have on its financial statements.

In April 2009, the FASB issued FSP FAS No. 107-1 and Accounting Principals Board (APB) No. 28-1, *Interim Disclosures about Fair Value of Financial Instruments*. FSP FAS No. 107-1 and APB No. 28-1 amends FASB Statement No. 107, *Disclosures about Fair Value of Financial Instruments*, to require disclosures about fair value of financial instruments in interim as well as in annual financial statements. This FSP also amends APB Opinion No. 28, *Interim Financial Reporting*, to require those disclosures in all interim financial statements. This standard is effective for periods ending after June 15, 2009. The Company is evaluating the impact that these standards will have on its financial statements.

Table of Contents

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

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

Overview

We are a biopharmaceutical company committed to the discovery, development and commercialization of novel drugs for metabolic diseases using our proprietary technology and our knowledge of processes and pathways within the liver that are useful for liver-selective drug targeting and treatment of metabolic diseases. We have established a broad pipeline of product candidates and advanced discovery programs targeting large markets with significant unmet needs. Our product pipeline includes product candidates and advanced discovery 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 discovery programs for the treatment of liver diseases such as hepatitis and primary liver cancer, which we refer to as our non-core assets.

We currently have four product candidates at the clinical stage of development. These product candidates include our core metabolic disease proprietary product candidates, MB07811 and MB07803, which are being developed as potential treatments for hyperlipidemia and type 2 diabetes, respectively, and our non-core liver disease proprietary product candidates, pradeфовir and MB07133, which have been developed as potential treatments for hepatitis B and primary liver cancer, respectively.

Recent Events

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

Our current financial resources will support our on-going planned operating expenses into July 2009. We intend to raise additional resources through undertaking a financing to fund our operations beyond July 2009 and through the Phase 2 clinical trial on MB07811. In the event we are unsuccessful in the near-term in our efforts to raise capital through undertaking a financing transaction, we will be required to pursue other strategic alternatives which may include a further reduction of our operating expenses, or the sale of some or all of our assets to another company, and/or cease our operations entirely. If we raise additional funds by issuing equity securities, our stockholders will experience dilution of their ownership interests. If we raise additional funds by issuing debt or other senior securities, then the rights, preferences and privileges of our existing common stock may be junior to any rights, preferences or privileges that may be established in connection with any such issuances.

Our outstanding debt and equipment loan agreements with Oxford Corporation, or Oxford, contain events of default that may be triggered by a material adverse change, which is defined in the agreements as any material adverse change in the general affairs, senior management, results of operations, or financial condition of the Company, whether or not arising from transactions in the ordinary course of business, that is likely to impair the ability of the Company to repay any portion of the obligations or a material impairment in the value or priority of the lender's security interest in the collateral. We currently have sufficient working capital to fund our operations into July 2009 without additional sources of cash. In the event we are not successful in securing additional sources of cash in the near-term, Oxford may claim that a material adverse change has occurred under the debt or equipment loan agreements, and Oxford could demand immediate repayment of the balances outstanding under the agreements. In the event we default on the loan agreement, Oxford has the right under a control agreement, to assume control over our bank accounts, which include our operating and short-term investment accounts.

As of March 31, 2009, our cash and cash equivalents totaled \$11.8 million. The outstanding principal balance of the loan agreement with Oxford totaled \$4.3 million at March 31, 2009. In the event of default, we would be required to pay the outstanding principal balance, accrued and unpaid interest charges, a prepayment penalty of 6% of the then outstanding principal balance and an additional \$200,000, totaling approximately \$4.7 million at March 31, 2009. The outstanding principal balance of the other equipment loans entered into with Oxford totaled \$3.1 million at March 31, 2009. In the event of default, we would be required, at Oxford's

Table of Contents

option, to pay the outstanding principal balance and accrued and unpaid interest charges, totaling approximately \$3.1 million at March 31, 2009.

In January 2009, we announced a plan to restructure our organization which followed the initiation of a separate restructuring plan that we announced in November 2008. The two restructuring plans resulted in an approximate 60% reduction of our workforce. As part of the January 2009 plan, we narrowed our research and development efforts and have utilized a significant portion of our resources since January 2009 on the planned Phase 2 clinical trial for MB07811, which we believe will provide significant value for stockholders. Initiation of the MB07811 Phase 2 clinical trial is dependent upon our ability to raise significant additional capital through the undertaking of a financing in the near-term to continue operations beyond July 2009. We expect to announce top-line results from the MB07811 Phase 2 clinical trial within six to nine months from the initiation of this clinical trial.

In addition, we continue to support our on-going sponsored research programs in collaboration with Merck & Co., or Merck, and Hoffman-La Roche Inc., F. Hoffman-La Roche Ltd. and Roche Palo Alto LLC, collectively referred to as Roche. To a lesser extent, we have committed resources towards the advancement of our second generation TR β agonist and our glucagon antagonist discovery programs to the preparatory stage of preclinical development. We believe the second generation TR β agonist discovery program could result in one or more compounds that could enhance the overall value of our hyperlipidemia program to potential strategic partners. Additionally, we believe the advancement of the glucagon antagonist program will improve our ability to secure additional financial resources under a collaborative arrangement.

Our pipeline of clinical-stage product candidates also consists of our core asset, MB07803, and our non-core assets, pradefovir and MB07133. As part of our near-term strategic focus, we have not committed resources for the further development of these product candidates as we intend to establish a strategic partnership with respect to MB07803 and, in the case of our non-core assets, license or monetize these product candidates to secure additional financial resources. In addition, we have suspended all activities related to various other metabolic disease advanced discovery programs.

History of Losses, Prior Funding

We have incurred annual net losses since inception. As of March 31, 2009, our accumulated deficit was approximately \$200.6 million. We expect to incur losses for the next several years as we:

continue to develop our current and future core metabolic disease clinical product candidates, and

continue and potentially expand 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 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 MB07811 or MB07803 and we intend to seek strategic collaborations for one or more of our core assets and license or sell our non-core assets. We retain worldwide commercialization rights to all of the compounds that we have generated from our past and current discovery programs, with the exception of any potential future product candidates that may result from our collaborations with Merck and Roche. Our potential future agreements with strategic collaborators may include joint marketing or promotion arrangements which may allow us to eventually co-market one or more of our product candidates through our own sales force or with a co-promotion partner. Alternatively, we may grant exclusive rights to our collaborators in exchange for upfront fees, milestones and royalties on future sales, if any, or directly sell certain of our assets.

We will rely on our collaborators or third-party manufacturers to produce sufficient quantities of our product candidates for clinical studies and large-scale commercialization upon their approval. Since we do not currently possess the resources necessary to independently develop and commercialize all of the potential product candidates that may be based upon our HepDirect technology, 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.

Table of Contents

Our business is subject to significant risks, including the risks inherent in our on-going 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 salaries, stock-based compensation and other expenses for research and development personnel, costs associated with the development and clinical trials of our product candidates, facility costs, supplies and materials, costs for consultants and related contract research and depreciation. We charge all research and development expenses to operations as they are incurred.

Our development activities are focused on the development of our core metabolic disease assets, MB07811, our glucagon antagonist program and our second-generation TR β agonist discovery program. Our activities related to MB07803 and 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. We are responsible for all costs incurred for our product candidates and our advanced discovery programs with the exception of the AMPK and hepatitis C programs partnered with Merck and the hepatitis C program partnered with Roche.

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 \$12.4 million in cumulative sponsored research and license fees funding through March 31, 2009, which includes funding for sponsored research efforts through March 2009.

Our other collaboration with Merck 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. Merck is solely responsible for conducting and funding all development work for any compounds resulting from these collaborations and for commercializing any resulting products.

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

At this time, due to the risks inherent in the clinical trial process and given the early stage of development of our product candidates and lead compounds from our discovery 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 discovery 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 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 on-going basis in response to the scientific and clinical success of each product candidate, our on-going 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 one or more of our core assets and our non-core assets to secure additional resources, accelerate progress and ensure their continued development. However, delays in finding appropriate partnerships could also have a material unfavorable effect on our ability to continue operations. We cannot be certain when or if any net cash inflow due to sales of any of our current product candidates will commence.

Table of Contents

General and Administrative

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

Other Income (Expense)

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

Critical Accounting Policies

Our discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles, or GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and related disclosure of contingent assets and liabilities. We review our estimates on an on-going basis. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results may differ from these estimates under different assumptions or conditions. We believe the following accounting policies to be critical to the judgments and estimates used in the preparation of our financial statements.

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

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

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

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

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 Statement of Financial Accounting Standard, or SFAS, No. 123R which we adopted effective January 1, 2006. As of March 31, 2009, we had approximately \$3.6 million of unrecognized compensation expense which we expect to recognize over a weighted average period of 2.4 years.

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. As stock-based compensation expense is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures. SFAS No. 123R

Table of Contents

requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Forfeitures were estimated based on historical experience. We may elect to use different assumptions under the Black-Scholes option valuation model in the future, which could materially affect our net loss and net loss per share.

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

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

Recently Issued Accounting Pronouncements

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

In April 2009, the FASB issued FSP FAS No. 115-2, FAS No. 124-2, and EITF No. 99-20-2, *Recognition and Presentation of Other-Than-Temporary Impairments*. FSP FAS No. 115-2, FAS No. 124-2 and EITF No. 99-20-2 provides additional guidance to provide greater clarity about the credit and noncredit component of an other-than-temporary impairment event and to more effectively communicate when an other-than-temporary impairment event has occurred. This FSP applies to debt securities. This standard is effective for periods ending after June 15, 2009. We are evaluating the impact that these standards will have on our financial statements.

In April 2009, the FASB issued FSP FAS No. 107-1 and Accounting Principals Board, or APB, 28-1, *Interim Disclosures about Fair Value of Financial Instruments*. FSP FAS No. 107-1 and APB 28-1 amends FASB Statement No. 107, *Disclosures about Fair Value of Financial Instruments*, to require disclosures about fair value of financial instruments in interim as well as in annual financial statements. This FSP also amends APB Opinion No. 28, *Interim Financial Reporting*, to require those disclosures in all interim financial statements. This standard is effective for periods ending after June 15, 2009. We are evaluating the impact that these standards will have on our financial statements.

Results of Operations*Comparison of the Three Months Ended March 31, 2009 and 2008*

Revenues. Revenues were \$1.9 million for the three months ended March 31, 2009, compared with \$0.9 million for the three months ended March 31, 2008. The \$1.0 million increase was mainly due to increased license fees and sponsored research revenues of \$1.5 million recognized in connection with the Roche agreement we entered into in August 2008, offset by a decrease in license fees and sponsored research revenues of \$0.5 million recognized in connection with the Merck AMPK collaboration. The decrease in the AMPK license fee revenue relates to a reduction in the rate of revenue recognized as a result of the extension of the research term (amortization period) through June 2009.

Research and Development Expenses. Research and development expenses were \$7.4 million for the three months ended March 31, 2009, compared with \$9.7 million for the three months ended March 31, 2008. The \$2.3 million decrease was mainly due to a decrease of \$2.3 million in payroll and related benefits as a result of lower headcount, a decrease in clinical and development expenses for the MB07811, MB07803 and MB07133 programs of \$1.3 million, a decrease in non-cash stock-based compensation and

Table of Contents

depreciation and occupancy costs of \$0.4 million offset by a \$1.4 million increase in severance and related benefits associated with our corporate restructuring efforts and \$0.2 million in costs associated with the disposal and/or discontinued use of various long-lived assets.

General and Administrative Expenses. General and administrative expenses were \$2.5 million for the three months ended March 31, 2009 and 2008. The lack of a change from the prior period was mainly due to decreased payroll and related benefit costs of \$0.2 million, offset by increased severance and related benefits of \$0.2 million in connection with our corporate restructuring efforts.

Other Income (Expense). Net interest expense was \$0.2 million for the three months ended March 31, 2009, compared to net interest income of \$0.2 million for the three months ended March 31, 2008. The \$0.4 million decrease was a result of lower cash balances in the first quarter of 2009 as compared to the first quarter of 2008, as well as increased interest expense related to long-term debt acquired in the first quarter of 2008 and decreased yields on investment assets.

Liquidity and Capital Resources

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

As of March 31, 2009, we had \$11.8 million in cash and cash equivalents as compared to cash, cash equivalents and securities available-for-sale of \$21.6 million as of December 31, 2008, a decrease of \$9.8 million. The decrease is primarily a result of net cash used in operations of \$8.9 million and \$0.9 million of payments made on our outstanding debt facilities.

As of March 31, 2009, we have financed through leases and loans the purchase of equipment and leasehold improvements totaling approximately \$12.4 million, of which \$3.3 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. Until additional funding sources are available, we plan to limit the use of our cash reserves for leasehold improvements and capital equipment necessary to support our clinical development efforts and research programs for 2009. We no longer have available funds through this financing facility.

Our outstanding debt and equipment loan agreements with Oxford contain events of default that may be triggered by a material adverse change, which is defined in the agreements as any material adverse change in the general affairs, senior management, results of operations, or financial condition of the Company, whether or not arising from transactions in the ordinary course of business, that is likely to impair the ability of the Company to repay any portion of the obligations or a material impairment in the value or priority of the lender's security interest in the collateral. We currently have sufficient working capital to fund our operations into July 2009 without additional sources of cash. In the event we are not successful in securing additional sources of cash in the near-term, Oxford may claim that a material adverse change has occurred under the debt or equipment loan agreements, and Oxford could demand immediate repayment of the balances outstanding under the agreements. In the event we default on the loan agreement, Oxford has the right under a control agreement, to assume control over our bank accounts, which include our operating and short-term investment accounts.

The outstanding principal balance of the loan agreement with Oxford totaled \$4.3 million at March 31, 2009. In the event of default, we would be required to pay the outstanding principal balance, accrued and unpaid interest charges, a prepayment penalty of 6% of the then outstanding principal balance and an additional \$200,000, totaling approximately \$4.7 million at March 31, 2009. The outstanding principal balance of the other equipment loans entered into with Oxford totaled \$3.1 million at March 31, 2009. In the event of default, we would be required, at Oxford's option, to pay the outstanding principal balance and accrued and unpaid interest charges, totaling approximately \$3.1 million at March 31, 2009.

We believe we have adequate financial resources to fund our current operations into July 2009. We intend to raise additional resources through undertaking a financing to fund our operations beyond July 2009 and through the Phase 2 clinical trial on MB07811. In the event we are unsuccessful in the near-term in our efforts to raise capital through undertaking a financing transaction, we will be required to pursue other strategic alternatives which may include a further reduction of our operating expenses, or the sale of some or all of our assets to another company, and/or cease our operations entirely. If we raise additional funds by issuing equity securities, our stockholders will experience dilution of their ownership interests. If we raise additional funds by issuing debt or other senior securities, then the rights, preferences and privileges of our existing common stock may be junior to any rights, preferences or privileges that may be established in connection with any such issuances.

In January 2009, we announced a plan to restructure our organization which followed the initiation of a separate restructuring plan that we announced in November 2008. The two restructuring plans resulted in an approximate 60% reduction of our workforce.

Table of Contents

As part of the January 2009 plan, we scaled back efforts on certain research and development programs. Having insufficient funds may require us to delay, scale back or eliminate some or all of our research or development programs even further. No assurances can be made that additional funding, through any resources, including our Committed Equity Financing Facility, or 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. If we raise additional capital by issuing debt or other senior securities, then the rights, preferences and privileges of our existing common stock may be junior to any rights, preferences or privileges that may be established in connection with any such issuances. Any debt financing we enter into may involve covenants that restrict our operations. These restrictive covenants may include limitations on additional borrowing, specific restrictions on the use or sales of our assets as well as prohibitions on our ability to create liens, pay dividends, redeem our stock or make investments. The global financial crisis and the deterioration of the U.S. capital markets may negatively impact our ability to issue securities or obtain debt financing. In the event we are not able to generate sufficient capital through debt or equity financings, business development activities or we are not successful in attaining contractual milestones, we will be required to seek additional resources by pursuing other strategic alternatives, including the merger with, or sale of some or all of our assets to, another company, or cease operations entirely.

The following summarizes our long-term contractual obligations as of March 31, 2009 (in thousands):

	Payments Due by Period				
	Total	Less than 1 Year	1 to 3 Years	4 to 5 Years	After 5 Years
Operating leases	\$ 21,623	\$ 3,007	\$ 6,337	\$ 6,699	\$ 5,580
Long-term debt	7,791	3,873	3,782	71	65
Interest on long-term debt	977	562	415		
Purchase commitments	106	106			
Capital leases	47	26	21		
Interest on capital leases	5	4	1		
Total	\$ 30,549	\$ 7,578	\$ 10,556	\$ 6,770	\$ 5,645

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 these individuals are terminated under specified circumstances. These agreements generally expire upon termination for cause or when we have met our obligations under these agreements. In March 2009, \$0.4 million in severance and other separation benefit costs were accrued in connection with the separation of our former chief executive officer.

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

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

the scope, prioritization and number of clinical development and research programs we pursue,

the terms and timing of any collaborative, licensing and other arrangements that we may establish,

the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights,

the costs and timing of regulatory approvals,

the costs of establishing or contracting for manufacturing, sales and marketing capabilities, and

the effect of competing technological and market developments.

Table of Contents

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

FORWARD-LOOKING STATEMENTS

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

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

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Our exposure to market risk for changes in interest rates relates primarily to the increase or decrease in the amount of interest income we can earn on our investment portfolio. Our risk associated with fluctuating interest income is limited to our investments in interest rate sensitive financial instruments. Under our current policies, we do not use interest rate derivative instruments to manage this exposure to interest rate changes. We seek to ensure the safety and preservation of our invested principal by limiting default risk, market risk, and reinvestment risk. We mitigate default risk by investing in short-term investment grade securities such as treasury-backed money market funds, corporate bonds and commercial paper. Due to the current market conditions, we no longer invest in asset-backed securities. In accordance with our investment policy, we do not invest in auction rate securities. A 100 basis point increase or decrease in interest rates would increase or decrease our current investment balance by approximately \$13,000 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

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

Table of Contents

As required by the Securities and Exchange Commission Rule 13a-15(b), we carried out an evaluation, under the supervision and with the participation of our management, including our chief executive officer and chief financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this report. Based on the foregoing, our chief executive officer and chief financial officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level.

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

Table of Contents

PART II OTHER INFORMATION

Item 1. Legal Proceedings

None.

Item 1A. Risk Factors

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

Risks Related to our Finances and Capital Requirements

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

We believe we have adequate financial resources to fund our current operations into July 2009. We intend to raise additional resources through undertaking a financing to fund our operations beyond July 2009 and through the Phase 2 clinical trial on MB07811. In the event we are unsuccessful in the near-term in our efforts to raise capital through undertaking a financing transaction, we will be required to pursue other strategic alternatives which may include a further reduction of our operating expenses, or the sale of some or all of our assets to another company, and/or cease our operations entirely. If we raise additional funds by issuing equity securities, our stockholders will experience dilution of their ownership interests. If we raise additional funds by issuing debt or other senior securities, then the rights, preferences and privileges of our existing common stock may be junior to any rights, preferences or privileges that may be established in connection with any such issuances.

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, 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 corporate collaboration and licensing arrangements, public or private equity offerings and debt financings, as well as through interest income earned on cash balances.

Edgar Filing: METABASIS THERAPEUTICS INC - Form 10-Q

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 and we may be unable to continue our operations.

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

Our outstanding debt and equipment loan agreements with Oxford contain events of default that may be triggered by a material adverse change, which is defined in the agreements as any material adverse change in the general affairs, senior management, results of operations, or financial condition of the Company, whether or not arising from transactions in the ordinary course of business, that is likely to impair the ability of the Company to repay any portion of the obligations or a material impairment in the

Table of Contents

value or priority of the lender's security interest in the collateral. We currently have sufficient working capital to fund our operations into July 2009 without additional sources of cash. In the event we are not successful in securing additional sources of cash in the near-term, Oxford may claim that a material adverse change has occurred under the debt or equipment loan agreements, and Oxford could demand immediate repayment of the balances outstanding under the agreements. In the event we default on the loan agreement, Oxford has the right under a control agreement, to assume control over our bank accounts, which include our operating and short-term investment accounts.

As of March 31, 2009, our cash and cash equivalents totaled \$11.8 million. The outstanding principal balance of the loan agreement with Oxford totaled \$4.3 million at March 31, 2009. In the event of default, we would be required to pay the outstanding principal balance, accrued and unpaid interest charges, a prepayment penalty of 6% of the then outstanding principal balance and an additional \$200,000, totaling approximately \$4.7 million at March 31, 2009. The outstanding principal balance of the other equipment loans entered into with Oxford totaled \$3.1 million at March 31, 2009. In the event of default, we would be required, at Oxford's option, to pay the outstanding principal balance and accrued and unpaid interest charges, totaling approximately \$3.1 million at March 31, 2009.

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 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.

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

In addition to our efforts to undertake a financing transaction, we are seeking to fund our on-going cash requirements by establishing strategic collaborations with respect to one or more of our core assets and licensing or selling our non-core assets, among other means. Payments under our collaborations are generally made in the form of up-front license fees, milestone payments and downstream royalties. The amount of these payments are generally determined as a factor of the future estimated economic realizable return on the eventual commercialization of these products.

Our core assets consist of product candidates and advanced discovery programs being developed for the treatment of metabolic diseases. The clinical development, manufacturing and commercialization of our product candidates are subject to extensive regulation by the FDA and other regulatory agencies in the U.S. In the U.S., neither we, nor our collaborators, are permitted to market our product candidates until we or our collaborators receive approval of a New Drug Application, or NDA, from the FDA. The process of obtaining these approvals is expensive, often takes many years, and can vary substantially based upon the type, complexity and novelty of the product candidates involved. Approval policies or regulations may change and may be influenced by the results of other similar or competitive products. For example, in February 2008 the FDA released draft guidance regarding clinical trials for product candidates treating diabetes that may result in more stringent requirements for the clinical testing and regulatory approval of such product candidates. 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. Certain large pharmaceutical and/or biotechnology companies may elect to terminate development activities for diabetes products as a result of this draft guidance and possible increases in development costs and therefore become unavailable as potential licensing partners. Similarly, product candidates for treating hyperlipidemia may be subject to guidance in the future that limits the number of potential licensing partners.

The anticipated increases in the cost of development, complexity and time associated with expected additional regulatory requirements inherently increases the risk of delaying and/or not obtaining the FDA approvals necessary to develop, manufacture or commercialize products in metabolic diseases. Moreover, if any of our product candidates receive regulatory approval, the FDA or other foreign regulatory agencies may still impose significant restrictions on the indicated uses or marketing of the product candidates or impose on-going requirements for potentially costly post-approval studies. The increased costs associated with more stringent regulatory requirements may negatively impact the amount of up-front license fees, milestone payments or downstream royalties we may receive under any collaboration arrangements. If we are unsuccessful

Edgar Filing: METABASIS THERAPEUTICS INC - Form 10-Q

in establishing strategic collaborations for one or more of our core assets or generating sufficient up-front license fees from the collaborations we do establish, we may be required to delay, reduce the scope of or eliminate one or more of our research and development programs and we may be unable to continue our operations.

Table of Contents

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

Since our inception, we have funded our operations primarily with net proceeds from equity financings, our venture debt facility and strategic alliances and collaborative partnerships. Under our strategic plan we intend to fund our near-term and on-going cash requirements through equity financings or other means, including the achievement of milestones from existing collaboration agreements, the entry into new strategic collaborations with respect to one or more of our core assets or the license or monetization of our non-core assets. In the event we are not able to generate sufficient capital through equity financings or business development activities or we are not successful in attaining contractual milestones, we will be required to seek additional resources by pursuing other strategic alternatives. The credit markets and the financial services industry are currently experiencing a period of unprecedented turmoil and upheaval characterized by the bankruptcy, failure, collapse or sale of various financial institutions and an unprecedented level of intervention from the U.S. federal government. While the ultimate outcome of these events cannot be predicted, they may have a material adverse effect on our ability to obtain the capital necessary to carry out our strategic plan, which would negatively impact our business, results of operations and financial condition.

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

We have incurred net losses from our inception. As of March 31, 2009, we had an accumulated deficit of approximately \$200.6 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.

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

In its audit opinion issued in connection with our balance sheets as of December 31, 2008 and 2007 and our statements of operations, stockholder's equity and cash flows for the years ended December 31, 2008, 2007 and 2006, our independent registered public accounting firm has expressed substantial doubt about our ability to continue as a going concern given our recurring net losses, negative cash flows from operations and our working capital not being sufficient to fund our operations through December 31, 2009. The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. The financial statements do not include any adjustments relating to reflect the possible future effects on the recoverability and classification of recorded assets or the amounts and classification of liabilities that might be necessary should we be unable to continue in existence.

Our independent registered public accounting firm's substantial doubt about our ability to continue as a going concern may negatively impact our ability to enter into new strategic alliances and collaborations. Traditional out-licensing arrangements may include participation from the licensor on the research and development of the program and in some cases co-promotion rights. If we are not able to demonstrate an ability to continue operations to participate in the development or commercialization of our proprietary products and discovery programs, we may be unsuccessful in entering into strategic alliances or collaborations under favorable terms, if at all. Although we do not maintain financial covenants on our existing debt facilities, our independent registered public accounting firm's opinion may be perceived by our existing creditors and investors as a risk of insolvency and potentially impair our ability to enter into new debt facilities or equity financings.

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

successful completion of on-going development activities for our product candidates,

achievement of regulatory approval for our product candidates, and

Edgar Filing: METABASIS THERAPEUTICS INC - Form 10-Q

successful completion of our current and future strategic collaborations.

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

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

We had 54,012,415 authorized shares of common stock available for future issuance as of April 30, 2009. If we are unable to obtain shareholder approval to increase our authorized shares, then our ability to raise additional funds through public or private equity

Table of Contents

offerings may be limited due to our having insufficient authorized and available shares of common stock. If we are unable to raise additional funds through the issuance of securities and no alternative source of funds is available, we may be required to delay, reduce the scope of or eliminate one or more of our research and development programs and we may be unable to continue our operations.

Our quarterly operating results and stock price may fluctuate significantly.

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

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

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,

impact of restructuring costs, and

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

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

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

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

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

Edgar Filing: METABASIS THERAPEUTICS INC - Form 10-Q

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

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

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

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

Table of Contents

permitted to terminate the CEFF by providing written notice to us within 10 business days after it obtains actual knowledge that an event has occurred resulting in a material and adverse effect on our business, operations, properties or financial condition (subject to specified exceptions, including conditions or events that are reasonably expected to occur in the ordinary course of our business). If we are unable to access funds through the CEFF, or if the investor terminates the CEFF, we may be unable to access capital on favorable terms, or at all.

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

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

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

As of March 31, 2009 we failed to meet one of the Nasdaq Capital Market's continued listing requirements and our common stock could be delisted from the Nasdaq Capital Market, which could negatively impact the price of our common stock and our ability to access the capital markets.

As of March 31, 2009, we maintained a stockholders' deficit of \$4.0 million which does not meet the minimum stockholders' equity requirement for continued listing on the Nasdaq Capital Market. In order to maintain our listing on the Nasdaq Capital Market, we will need to regain compliance with certain minimum listing standards that include, or may include, requirements related to our stockholders' equity, the market value of our listed or publicly-held securities, the number of publicly-held shares, our net income, a minimum bid price for our common stock, the number of stockholders, the number of market makers and compliance with certain corporate governance policies. Failing to regain compliance and maintain compliance with the standards in the future may result in the delisting of our common stock from the Nasdaq Capital Market. The delisting of our common stock would significantly affect the ability of investors to trade our securities and would negatively affect the value and liquidity of our common stock. In addition, the delisting of our common stock could materially adversely affect our ability to raise capital on terms acceptable to us, or at all. Delisting from the Nasdaq Capital Market could also have other negative results, including the potential loss of confidence by suppliers and employees and the loss of institutional investor interest.

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

Our executive officers, directors and holders of 5% or more of our outstanding common stock, beneficially owned approximately 74% of our common stock as of March 31, 2009. As a result, these stockholders, acting together, are able to control all matters requiring approval by our stockholders, including the election of directors and the approval of mergers or other business combination transactions. The interests of this group of stockholders may not always coincide with our interests or the interests of other stockholders, and they may act in a manner that is not necessarily consistent with the interests of other stockholders.

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

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

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

establishment of new collaborative arrangements,

Edgar Filing: METABASIS THERAPEUTICS INC - Form 10-Q

events affecting Merck, 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,

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

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

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

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

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

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

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

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

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

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

Table of Contents

million, and therefore, we do not currently have access to this capital. Sales by these current and potential future stockholders or warrant holders of a substantial number of shares could significantly reduce the market price of our common stock.

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

We do not anticipate that any of our current product candidates will be eligible to receive regulatory approval and begin commercialization for a number of years, if at all. Even if we were ultimately to receive regulatory approval for these product candidates, we and/or our potential future partners, as applicable, may be unable to commercialize them successfully for a variety of reasons. These include, for example, the availability of alternative treatments, lack of cost effectiveness, the cost of manufacturing the product on a commercial scale and the effect of competition with other drugs. The success of our product candidates may also be limited by the prevalence and severity of any adverse side effects. If we fail to commercialize one or more of our current product candidates, we may be unable to generate sufficient revenues to attain or maintain profitability, and our reputation in our industry and the investment community may be damaged.

Delays in the commencement or completion of clinical trials could result in increased costs to us and delay our ability to establish strategic collaborations.

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

obtaining regulatory approval to commence a clinical trial,

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.

Edgar Filing: METABASIS THERAPEUTICS INC - Form 10-Q

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 establish strategic collaborations 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. In addition, given our limited

Table of Contents

financial resources, a delay in our 12-week Phase 2 clinical trial for MB07811 would negatively impact our business, including our ability to complete the study.

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

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

clinical trials may produce negative or inconclusive results,

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

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

costs of development may be greater than we anticipate,

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

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

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

Success in early development does not mean that later development will be successful because, for example, product candidates in later-stage clinical trials may fail to demonstrate sufficient safety and efficacy despite having progressed through initial clinical testing. For example, in July 2007, we were informed by Daiichi Sankyo, our former collaborative partner on CS-917, that results from a completed Phase 2 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

Edgar Filing: METABASIS THERAPEUTICS INC - Form 10-Q

in more stringent requirements for the clinical testing and regulatory approval of such product candidates. This and any future guidance that may result from recent FDA advisory panel discussions may make it more expensive to develop and commercialize such product candidates. Such increased expense could make it more difficult to obtain favorable terms in the collaborative arrangements we require to maximize the value of our programs seeking to develop new product candidates for diabetes.

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

Table of Contents

We may not be able to enter into collaborations with respect to our core assets, MB07811, MB07803 and our glucagon antagonist program and our non-core assets, pradefovir and MB07133, on acceptable terms, if at all, which would lead to development and commercialization delays.

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

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

Prior to receiving regulatory approval, undesirable side effects observed in human clinical trials or in supportive animal studies with our product candidates could interrupt, delay or halt their development and could result in the denial of regulatory approval by the FDA or other regulatory authorities for any or all targeted indications or adversely affect the marketability of any such product candidates that receive regulatory approval. In turn, this could eliminate or limit our ability to commercialize our product candidates and generate revenues from their sale.

Our product candidate may exhibit adverse effects in animal toxicology studies. 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. As a result of numerous factors which may have included these findings, we entered into an agreement with Schering and Valeant to terminate our agreements for the development and commercialization of pradefovir, and all commercial rights to pradefovir have been returned to us, subject to certain milestone and royalty payments we may be required to make to Valeant should pradefovir be subsequently developed.

Our product candidates could also exhibit adverse interactions with other drugs. For example, in earlier clinical trials conducted by Daiichi Sankyo, CS-917, our first generation product candidate for type 2 diabetes which we are no longer developing, was associated with incidents of lactic acidosis in two patients when it was combined with metformin in a Phase 1 clinical trial. After extensive analysis, Daiichi Sankyo concluded that these incidents were likely due to significant interactions with 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.

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

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

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

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

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

our stock price could decline,

Table of Contents

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 or our partners may decide to cease marketing and sale of the product voluntarily,

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

our reputation may suffer.

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

We are currently dependent on our collaborations with Merck 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 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 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 Roche seeks to develop new products for treating hepatitis C. The sponsored research term of our hepatitis C collaboration with Merck has ended. The sponsored research term of our AMPK collaboration with Merck continues through June 2009, and the research term of our collaboration with Roche continues through July 2010. Although our collaborations with Merck and Roche have not yet yielded any product candidates, should they ultimately be successful, we will be dependent on Merck 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 or 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

Edgar Filing: METABASIS THERAPEUTICS INC - Form 10-Q

product candidate or drug compound independently or together with a new collaborator. However, in the event that we do not have sufficient resources to independently develop or commercialize the product candidate or drug compound, and we cannot establish a new collaboration on acceptable terms, we would be forced to discontinue its development or commercialization. For example, at this time, we do not intend to independently develop pradefovir or MB07133 and intend to license or sell these product candidates.

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

we do not achieve our objectives under our collaboration agreements,

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

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

Table of Contents

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 and Roche may involve Merck's or Roche's proprietary compounds, if Merck 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 proprietary compounds provided by Merck. The funded research phase of this collaboration has ended. If Merck so designates a product candidate and then subsequently terminates this collaboration before a defined stage of development of that product candidate, which it may do without cause at any time upon 90 days' advance written notice to us, we will not have any right to develop or commercialize that product candidate. In addition, if this collaboration with Merck terminates and Merck successfully develops products based on these proprietary compounds without applying our technology, we will not be entitled to milestone payments or royalties with respect to those products.

Our agreement with Merck to develop and commercialize new products to treat type 2 diabetes and potentially other metabolic diseases may include the development of compounds owned or controlled by Merck. Accordingly, if Merck terminates this collaboration, it may prove difficult for us to continue development of such compounds. Our agreement with Roche to develop new products to treat hepatitis C infection may include the development of compounds owned or controlled by Roche. If our collaboration with Roche is terminated, we may not have any right to develop product candidates developed in connection with the collaboration.

Table of Contents

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 or 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 HepDirect technology and our knowledge and expertise to develop novel drugs to address some of the world's most widespread and costly chronic diseases. We intend to expand our existing pipeline of core assets by advancing drug compounds from current on-going discovery programs into clinical development. However, the process of researching and discovering drug compounds is expensive, time-consuming and unpredictable. Data from our current discovery programs may not support the clinical development of our lead compounds or other compounds from these programs, and we may not identify any additional drug compounds suitable for recommendation for clinical development. Moreover, any drug compounds we recommend for clinical development may not demonstrate, through preclinical testing, indications of safety and potential efficacy, that such drug compounds warrant advancement into clinical trials. Such findings would potentially impede our ability to maintain or expand our clinical development pipeline. Our ability to identify new drug compounds and advance them into clinical development also depends upon our ability to fund our research and development operations, and we cannot be certain that additional funding will be available on acceptable terms, or at all. For example, we recently implemented a restructuring plan that resulted in the suspension of certain discovery programs in order to preserve our cash and focus our resources on the clinical development of our core assets, MB07811 and our TRß agonist discovery program.

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 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 MB07803, our glucagon antagonist program, pradefovir or MB07133 and intend to establish strategic collaborations, license or, as in the case of our non-core assets, sell these product candidates. We may rely on strategic collaborators for the development of our other core metabolic disease assets, MB07811 and our TRß agonist program, 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 and Roche have not yet yielded product candidates, should they do so, we will be dependent on Merck and/or Roche, as applicable, to conduct the development of any resulting product candidates. If Merck or Roche or these other third parties do not successfully meet their obligations under our agreements, or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to applicable protocols or for other reasons, clinical trials or other studies may be extended, delayed or terminated, and these product candidates may not receive regulatory approval or be successfully commercialized.

Table of Contents

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

We applied our HepDirect technology to pradefovir, MB07811 and MB07133, and have applied it in certain other programs as well. We intend to use this 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 collaboration with Roche in which we applied our technology to certain Roche compounds. Our proprietary HepDirect technology is subject to many of the same risks as our product candidates, including risks related to:

obtaining and maintaining patent and trade secret protection,

avoiding infringement of the proprietary rights of third parties,

the development of competing technologies by others, and

the safety and effectiveness of this technology in humans.

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

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

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

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

a product candidate may not be safe and effective,

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

Edgar Filing: METABASIS THERAPEUTICS INC - Form 10-Q

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.

Table of Contents

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

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

issue warning letters or other notices of possible violations,

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

suspend regulatory approval,

suspend any on-going clinical trials,

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

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

seize or detain products or require a product recall.

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

Edgar Filing: METABASIS THERAPEUTICS INC - Form 10-Q

liver and metabolic diseases, research is intense and new treatments are being sought out and developed by our competitors.

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

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

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

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

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

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

Table of Contents

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. Atorvastatin is currently one of the best selling prescription medicines. In addition, generic statins (cholesterol-reducers) have recently been approved in the major pharmaceutical markets and would also compete with MB07811.

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

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

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

hepatic glucose output inhibitors, which lower glucose levels by inhibiting liver glucose production. The only drug in this class is metformin, which, based on a study reported in the medical journal *Diabetes*, inhibits glucose production by the liver by only approximately 20-25%, even when administered at the maximum allowed dose. Metformin therapy is associated with an increased risk of lactic acidosis in certain patient populations, including patients with kidney dysfunction. In addition, metformin therapy commonly leads to transient gastrointestinal disturbances such as nausea, diarrhea and vomiting, which may compromise patient compliance,

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

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

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

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

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

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

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

Edgar Filing: METABASIS THERAPEUTICS INC - Form 10-Q

recently been approved for marketing in the U.S. and Europe.

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

Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, clinical trials, regulatory approvals and marketing approved products than we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Our competitors may succeed in developing technologies and therapies that are more effective, better tolerated or less costly 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

Table of Contents

personnel, establishing clinical trial sites and patient registration for clinical trials, and in acquiring and in-licensing technologies and products complementary to our programs or advantageous to our business.

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

Our ability to develop 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 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 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 MB07811 may impede the development of this compound.

In addition, we, our collaborators or other third-party manufacturers of our products must comply with current good manufacturing processes, 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 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 a product candidate, should they be successful, Merck will be responsible for worldwide marketing and commercialization of any resulting product candidate subject to, our option to co-promote the product in the U.S. with certain financial assistance from Merck. Similarly, should our hepatitis C collaboration with Roche yield a product candidate, Roche will be responsible for worldwide marketing and commercialization of a resulting product candidate. In order to commercialize MB07811, MB07803, pradevovir, 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 our metabolic disease collaboration, developing a sales force for any resulting product or any product resulting from any of our other product candidates is expensive and time consuming and could delay any product launch. We may be unable to establish and manage an effective sales force in a timely or cost-effective manner, if at all, and any sales force we do establish may not be capable of generating sufficient demand for our product candidates. To the extent that we enter into arrangements with collaborators or other third parties to perform sales and marketing services, our product revenues are likely to be lower than if we directly marketed and sold our product candidates. If we are unable to establish adequate sales and marketing capabilities, independently or with others, we may not be able to generate significant revenues and may not become profitable.

Table of Contents

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

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

our ability to provide acceptable evidence of safety and efficacy,

relative convenience and ease of administration,

the prevalence and severity of any adverse side effects,

restrictions on use in combination with other products,

availability of alternative treatments,

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

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

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

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

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

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

our ability to generate revenues and achieve or maintain profitability,

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

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

the availability of capital.

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

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

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

In November 2008 and January 2009 we committed to two separate restructuring plans that resulted in the aggregate reduction of approximately 60% of our workforce. We are highly dependent on principal members of our management team and scientific staff to operate our business and have become even more dependent on existing personnel since the significant workforce reductions. We are more susceptible to remaining team members voluntarily leaving employment with us given the uncertainty of our ability to continue to fund our on-going operations. We are located in southern California, which is headquarters to many other biotechnology

Table of Contents

and biopharmaceutical companies and many academic and research institutions. As a result, there remains competition for certain skilled personnel in our market. Former employees may seek employment with competitors. Also, when recruiting new personnel, the occurrence of our recent restructurings may make it more difficult to attract new personnel and we may not have the ability to respond rapidly to new growth, if necessary.

We may need to further decrease the number of our full-time employees in the event we are unsuccessful in generating sufficient resources to fund our on-going operations or in the event of other adverse business events. Further reducing our workforce may lead to additional unanticipated attrition. None of our employees have employment commitments for any fixed period of time and may leave our employment at will. If our future staffing is inadequate because of additional unanticipated attrition or because we failed to retain or replace the staffing level required to accomplish our business objectives we may be delayed or unable to continue the development of our product candidates, which could impede our ability to generate revenues and achieve profitability.

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

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

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 Intellectual Property

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

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

The filing, prosecution and defense of patents at pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in biotechnology patents has emerged to date in the U.S. The biotechnology patent situation outside the U.S. is even more uncertain. We may be particularly affected by this because we expect that pradeфовir and MB07133, if approved, will be marketed in foreign countries with high incidences of hepatitis B and primary liver cancer, respectively. Decisions or actions regarding patent filing and/or changes in either the patent laws or in interpretations of patent laws in the U.S. and other countries may diminish the value of our intellectual property.

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

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

Table of Contents

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

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

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

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

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

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

our issued patents may not be valid or enforceable,

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

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

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

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

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

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

Edgar Filing: METABASIS THERAPEUTICS INC - Form 10-Q

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

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

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

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

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

redesigning our products or processes so they do not infringe, which may not be possible or may require substantial funds and time.

Table of Contents

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 PMEA or prodrugs of PMEA in the U.S. and foreign countries may prevent the commercialization of pradefovair in the future.

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

Risks Related to Other Legal Matters

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

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

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

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

injury to our reputation,

withdrawal of clinical trial participants,

costs of related litigation,

substantial monetary awards to patients or other claimants,

loss of revenues, and

the inability to commercialize our product candidates.

Edgar Filing: METABASIS THERAPEUTICS INC - Form 10-Q

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.

Table of Contents

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

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

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

None.

Item 3. Defaults Upon Senior Securities

None.

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

None.

Item 5. Other Information

None.

Table of Contents

Item 6. Exhibits

Exhibit

Number	Description
3.1(1)	Amended and Restated Certificate of Incorporation.
3.2(2)	Amended and Restated Bylaws.
4.1(1)	Form of Common Stock Certificate.
10.1	Severance Agreement dated April 22, 2009 between the Company and Barry Gumbiner.
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

- (1) Incorporated by reference to the exhibit of the same number to the Company's Registration Statement on Form S-1 (No. 333-112437), originally filed on February 3, 2004.
- (2) Incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on October 2, 2007.

Table of Contents

SIGNATURES

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

Date: May 15, 2009

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

Vice President, Chief Financial Officer, Treasurer and

Corporate Secretary (Principal Financial Officer)