METABASIS THERAPEUTICS INC Form 10-Q November 07, 2007

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended September 30, 2007.

OR

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

For the transition period from

to

Commission file number 000-50785

METABASIS THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware

33-0753322

(State or other jurisdiction of incorporation or organization)

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

11119 North Torrey Pines Road,

La Jolla, CA

92037

(Address of principal executive offices)

(Zip code)

(858) 587-2770

(Registrant s telephone number, including area code)

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

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

Large Accelerated Filer O

Accelerated Filer x

Non-Accelerated Filer o

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

The number of outstanding shares of the registrant s common stock, par value \$0.001 per share, as of November 1, 2007 was 30,657,305

| METABASIS | THERAPEUTICS | , INC. |
|------------------|--------------|--------|
|------------------|--------------|--------|

FORM 10-Q

FOR THE QUARTERLY PERIOD ENDED September 30, 2007

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PART I - FINANCIAL INFORMATION

Item 1. Financial Statements

Metabasis Therapeutics, Inc.

Balance Sheets

(In thousands, except par value data)

| Assets Current assets: Cash and cash equivalents \$ 13,194 \$ 12,05 Securities available-for-sale 38,079 65,87 Trade accounts receivable 412 18 Prepaids and other current assets 1,397 1,30 Total current assets 53,082 79,41 |
|--|
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| Trade accounts receivable41218Prepaids and other current assets1,3971,30Total current assets53,08279,41 |
| Prepaids and other current assets 1,397 1,30 Total current assets 53,082 79,41 |
| Total current assets 53,082 79,41 |
| , |
| |
| Property and equipment, net 6,861 6,26 |
| Other assets 174 17 |
| Total assets \$ 60,117 \$ 85,85 |
| Liabilities and stockholders' equity |
| Current liabilities: |
| Accounts payable \$ 551 \$ 105 |
| Accrued compensation 2,915 1,77 |
| Accrued liabilities 3,902 2,28 |
| Deferred revenue, current portion 2,071 3,19 |
| Current portion of long-term debt 1,692 1,76 |
| Current portion of capital lease obligations 22 |
| Total current liabilities 11,153 10,02 |
| Deferred revenue, net of current portion 1,63 |
| Deferred rent 2,413 1,50 |
| Long-term debt 4,591 3,90 |
| Capital lease obligations, net of current portion 55 |
| Other long-term liabilities 270 5: |
| Total liabilities 18,482 17,77 |
| Stockholders' equity: |
| Preferred stock, \$0.001 par value; 5,000 shares authorized at September 30, 2007 |
| and December 31, 2006, no shares issued or outstanding |
| Common stock, \$0.001 par value; 100,000 shares authorized at September 30, |
| 2007 and December 31, 2006; 30,657 and 30,493 shares issued and outstanding at |
| September 30, 2007 and December 31, 2006, res ectivel |
| Additional paid-in capital 180,660 176,29 |
| Accumulated deficit (139,134) (108,2 |
| Accumulated other comprehensive loss 78 |
| Total stockholders' equity 41,635 68,13 |
| Total liabilities and stockholders' equity \$ 60,117 \$ 85,85 |

See accompanying notes.

Metabasis Therapeutics, Inc.

Statements of Operations

(In thousands, except per share data)

(Unaudited)

| | Three Mon Septem |), | Nine Months Ended September 30, | | | | |
|--|---------------------|------------------|------------------------------------|----|----------|--|--|
| | 2007 | 2006 | 2007 | | 2006 | | |
| Revenues: | | | | | | | |
| Sponsored research | \$ 937 | \$ 525 \$ | 2,813 | \$ | 1,575 | | |
| License fees | 1,417 | 530 | 4,550 | | 1,364 | | |
| Other revenue | 299 | | 320 | | 31 | | |
| Total revenues | 2,653 | 1,055 | 7,683 | | 2,970 | | |
| | | | | | | | |
| Operating expenses: | | | | | | | |
| Research and development | 10,866 | 7,614 | 31,437 | | 21,058 | | |
| General and administrative | 2,834 | 2,880 | 9,284 | | 8,020 | | |
| Total operating expenses | 13,700 | 10,494 | 40,721 | | 29,078 | | |
| | | | | | | | |
| Loss from operations | (11,047) | (9,439) | (33,038) | | (26,108) | | |
| Other income (expense): | | | | | | | |
| Interest income | 708 | 1,115 | 2,522 | | 2,860 | | |
| Interest expense | (141) | (86) | (405) | | (273) | | |
| Total other income | 567 | 1,029 | 2,117 | | 2,587 | | |
| | | | | | | | |
| Net loss | \$ (10,480) | \$ (8,410) \$ | (30,921) | \$ | (23,521) | | |
| | | | | | | | |
| Basic and diluted net loss per share | \$ (0.34) | \$ (0.28) \$ | (1.01) | \$ | (0.82) | | |
| Shares used to compute basic and diluted | | | | | | | |
| net loss per share | 30,650 | 30,263 | 30,552 | | 28,575 | | |

See accompanying notes.

Metabasis Therapeutics, Inc.

Statements of Cash Flows

(In thousands)

(Unaudited)

| | Nine Months Ended 2007 | d September 30, 2006 | | |
|---|------------------------|-------------------------|----------|--|
| Operating activities | | | | |
| Net loss | \$ (30,921) | \$ | (23,521) | |
| Adjustments to reconcile net loss to net cash used in operating activities: | | | | |
| Stock-based compensation | 3,938 | | 2,699 | |
| Depreciation and amortization | 1,496 | | 1,141 | |
| Deferred rent | 847 | | 950 | |
| Amortization of discount and premium on securities available-for-sale | (1,883) | | (265) | |
| Change in operating assets and liabilities: | | | | |
| Trade accounts receivable | (225) | | 241 | |
| Other current assets | (94) | | (85) | |
| Other assets | 5 | | | |
| Deferred revenue | (2,751) | | (1,213) | |
| Accounts payable | (502) | | (1,068) | |
| Accrued compensation and other liabilities | 2,571 | | (8) | |
| Net cash flows used in operating activities | (27,519) | | (21,129) | |
| Investing activities | | | | |
| Purchases of securities available-for-sale | (63,977) | | (84,986) | |
| Sales/maturities of securities available-for-sale | 93,707 | | 66,577 | |
| Purchases of property and equipment | (2,094) | | (2,611) | |
| Net cash flows provided by (used in) investing activities | 27,636 | | (21,020) | |
| Financing activities | | | | |
| Issuance of common stock, net | 425 | | 37,665 | |
| Principal payments on debt and capital lease obligations | (1,447) | | (1,051) | |
| Proceeds received from debt and capital lease obligations | 2,047 | | 3,126 | |
| Net cash flows provided by financing activities | 1,025 | | 39,740 | |
| Increase (decrease) in cash and cash equivalents | 1,142 | | (2,409) | |
| Cash and cash equivalents at beginning of year | 12,052 | | 32,597 | |
| Cash and cash equivalents at end of period | \$ 13,194 | \$ | 30,188 | |
| Supplemental schedule of noncash investing and financing activities: | | | | |
| Net-share settlement of warrant | \$ 56 | \$ | | |
| Unrealized gain on short-term investments | \$ 55 | \$ | 89 | |
| Reclass of deferred compensation | \$ | \$ | 3,266 | |

See accompanying notes.

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, 2006 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.

Certain prior year amounts have been reclassified to be consistent with current year presentation.

Operating results for the three and nine months ended September 30, 2007 are not necessarily indicative of the results that may be expected for the year ending December 31, 2007. For further information, see the financial statements and notes thereto for the year ended December 31, 2006 included in our annual report on Form 10-K filed with the SEC.

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

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

2. Comprehensive Loss

Statement of Accounting Financial Standard (SFAS) No. 130, *Reporting Comprehensive Income*, requires that all components of comprehensive loss, including net loss, be reported in the financial statements in the period in which they are recognized. Comprehensive 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 Mon Septem | | | Nine Months Ended September 30, | | | |
|---------------------------------------|---------------------|------|------------|------------------------------------|------|----------|--|
| | 2007 | 2006 | | 2007 | 2006 | | |
| Net loss | \$ (10,480) | \$ | (8,410) \$ | (30,921) | \$ | (23,521) | |
| Unrealized gain on available-for-sale | | | | | | | |
| investments | 35 | | 61 | 55 | | 89 | |
| Comprehensive loss | \$ (10,445) | \$ | (8,349) \$ | (30,866) | \$ | (23,432) | |

3. Net Loss Per Share

The Company calculated net loss per share in accordance with SFAS No. 128, *Earnings Per Share*. Basic earnings per share (EPS) is calculated by dividing the net loss by the weighted average number of common shares outstanding for the period, without consideration for common stock equivalents. Diluted EPS is computed by dividing the net loss by the weighted average number of common share equivalents outstanding for the

period determined using the treasury-stock method. For purposes of this calculation, common stock subject to repurchase by the Company, options and warrants are considered to be common stock equivalents and are only included in the calculation of diluted EPS when their effect is dilutive. The total number of shares issuable upon exercise of stock options and warrants excluded from the calculation of diluted EPS since they are anti-dilutive were 7,575,946 and 6,112,787 for the three months ended September 30, 2007 and 2006, respectively, and 7,262,816 and 5,768,612 for the nine months ended September 30, 2007 and 2006, respectively.

| | Three Months Ended September 30, | | | | | Nine Months Ended September 30, | | | | |
|--------------------------------------|-------------------------------------|----------|--------|-----------------|-----|------------------------------------|----|----------|--|--|
| | | 2007 | 2006 | | | 2007 | | 2006 | | |
| | | | (in th | ousands, except | per | share amounts) | | | | |
| Actual: | | | | | | | | | | |
| Numerator: | | | | | | | | | | |
| Net loss | \$ | (10,480) | \$ | (8,410) | \$ | (30,921) | \$ | (23,521) | | |
| Denominator: | | | | | | | | | | |
| Weighted average common shares | | 30,652 | | 30,379 | | 30,573 | | 28,724 | | |
| Weighted average unvested common | | | | | | | | | | |
| shares subject to repurchase | | (2) | | (116) | | (21) | | (149) | | |
| Denominator for basic and dilutednet | | | | | | | | | | |
| loss per share | | 30,650 | | 30,263 | | 30,552 | | 28,575 | | |
| Basic and diluted net loss per share | \$ | (0.34) | \$ | (0.28) | \$ | (1.01) | \$ | (0.82) | | |

4. Collaboration Agreements

In September 2007, the Company, Schering Corporation and Valeant Pharmaceuticals North America entered into an agreement to terminate the agreements they entered into in December 2006 for the development and commercialization of pradefovir. The Company received a non-refundable \$1.8 million up-front license fee in the first quarter of 2007 when the agreements became effective. The Company will not receive any additional payments related to these agreements and all rights to pradefovir have been returned to the Company subject to certain milestone and royalty payments we may be required to make to Valeant should this product candidate be subsequently developed.

In October 2007, the sponsored research term of the Company s collaboration agreement with Idenix Pharmaceuticals, Inc. (Idenix) ended upon the first anniversary of the agreement in accordance with its terms. The remaining rights and obligations of the agreement will remain in effect. The Company received approximately \$3.0 million in license fees and sponsored research funding through September 30, 2007 and is entitled to receive an additional \$138,000 in sponsored research funding through the effective end of the sponsored research term of the agreement in October 2007.

New Accounting Pronouncements

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On July 13, 2006, the Financial Accounting Standards Board (FASB) issued Interpretation No. 48 (FIN 48), *Accounting for Uncertainty in Income Taxes*, an interpretation of FASB SFAS No. 109, *Accounting for Income Taxes*, to create a single model to address accounting for uncertainty in tax positions. FIN 48 clarifies the accounting for income taxes by prescribing a minimum recognition threshold in which a tax position be reached before financial statement recognition. FIN 48 also provides guidance on derecognition, measurement, classification, interest and penalties, accounting in interim periods, disclosure and transition. FIN 48 is effective for fiscal years beginning after December 15, 2006. The Company adopted FIN 48 as of January 1, 2007, as required. The adoption of this guidance did not have a material impact on the Company s results of operations or financial position.

At December 31, 2006, the Company had federal and California net operating loss (NOL) carryforwards of \$91.9 million and \$91.6 million, respectively, expiring at various dates through 2019 and federal and state research and development (R&D) carryforwards of \$3.7 million and \$3.2 million, respectively, expiring beginning in 2019. Utilization of the NOL and R&D carryforwards may be subject to a substantial annual limitation due to ownership changes that have occurred previously or that could occur in the future provided by Sections 382 and 383 of the Internal Revenue Code, as well as similar state and foreign provisions. The Company has not currently completed a study to assess whether a change in control has occurred or whether there have been multiple changes in control since the Company s formation due to the uncertainty as to whether the Company would realize a benefit from the NOL s and R&D credits, and the significant complexity and cost associated with such a study. The Company has not undergone an audit by the Internal Revenue Service or state of California. Further, until a study is completed and any limitation known, no amounts are being presented as an uncertain tax position under FIN 48. Accordingly, the Company cannot at this time determine whether its NOL s and R&D carryforwards are subject to limitation, the amount that may be subject to limitation and therefore the amount that should be presented as an uncertain tax position under FIN 48. However, based on the Company s history of financings and ownership changes these limitations could be significant.

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements*. This standard defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles, and expands disclosures about fair value measurements. This statement is effective for financial statements issued for fiscal years beginning after November 15, 2007, although earlier application is encouraged. Accordingly, this statement will be effective for the Company beginning with its 2008 fiscal year. The Company is in the process of determining the effect, if any, the adoption of SFAS No. 157 will have on its results of operations and financial position.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities*. SFAS No. 159 permits entities to choose to measure many financial instruments and certain other items at fair value. This statement is effective for financial statements issued for fiscal years beginning after November 15, 2007. Accordingly, this statement will be effective for the Company beginning with its 2008 fiscal year. The Company is in the process of determining the effect, if any, the adoption of SFAS No. 159 will have on its results of operations and financial position.

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, 2006 included in our annual report on Form 10-K filed with the Securities and Exchange Commission on March 13, 2007. This discussion contains forward-looking statements that involve risks and uncertainties. As a result of many factors, such as those set forth under Risk Factors and elsewhere in this quarterly report on Form 10-Q and in our other filings with the Securities and Exchange Commission, our actual results may differ materially from those anticipated in these forward-looking statements. Readers are cautioned not to place undue reliance on forward-looking statements. The forward-looking statements speak only as of the date on which they are made, and we undertake no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they are made.

Overview

We are a biopharmaceutical company focused on the discovery, development and commercialization of novel drugs by applying our proprietary technology, scientific expertise and unique capabilities for targeting the liver and liver pathways. Our primary focus is on drugs to treat metabolic diseases such as diabetes, hyperlipidemia and obesity, among others. In the past, we have also worked on drugs to treat liver diseases such as hepatitis and primary liver cancer, however, we are currently not seeking new drug candidates in that area. We have established a broad pipeline of product candidates and advanced research programs targeting large markets with significant unmet medical needs. We have discovered all of our product candidates internally using our proprietary technologies.

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

Revised Strategic Plan

We have conducted an extensive review of the results of the Phase 2b clinical trial of our previously most advanced clinical stage product candidate, CS-917, and have concluded that while it failed to achieve the trial sprimary endpoint there was evidence of efficacy observed in patients with more advanced disease. We also believe that the two dose groups evaluated in the trial were likely suboptimal. We believe that these results, combined with the extensive preclinical and clinical results previously generated with this class of drugs known as FBPase inhibitors, support their continued development as a potentially important new class of drugs for the treatment of diabetes. It is our expectation that we and Daiichi Sankyo, Co. Ltd. (Daiichi Sankyo), our collaborative partner on CS-917, will subsequently agree to terminate our strategic collaboration and return the rights to this product candidate to us. We believe that our second generation FBPase inhibitor, MB07803, has been designed with certain improvements which have the potential to address the shortcomings seen to date with CS-917. Accordingly, we have decided to concentrate our future internal clinical development efforts on MB07803 and not CS-917. Therefore, we plan to discontinue any further clinical development of CS-917.

In addition, in September 2007, we entered into an agreement with Schering Corporation and Valeant Pharmaceuticals North America to terminate our agreements for the development and commercialization of pradefovir, our product candidate for the treatment of hepatitis B. In connection with this agreement, all rights to pradefovir were transferred back to us subject to certain milestone and royalty payments we may be required to make to Valeant should this product candidate be subsequently developed. These agreements were terminated as a result of numerous factors, which may include recently reported adverse 24-month oral carcinogenicity studies of pradefovir in rats and mice. At this time, we do not intend to independently develop pradefovir and will seek a licensee to conduct the further development and commercialization of this product candidate should we ultimately determine that such future development and commercialization is feasible.

As a result of these events, we have re-evaluated our current business strategy and revised our strategic plan. Under our revised strategic plan we will focus our internal resources primarily on our clinical, preclinical and discovery stage core metabolic disease related programs. This includes funding the further clinical evaluation of our core metabolic disease product candidates, MB07803 and MB07811 with a focus on achieving key, near-term value-driving milestones. Continued development of these core metabolic disease related product candidates thereafter will require significant resources.

Therefore, we plan to establish strategic collaborations for these product candidates at appropriate times to secure additional resources, accelerate progress and share risk. In addition, we plan to advance additional metabolic disease product candidates discovered by our research group into clinical development either independently, or potentially with current or future strategic collaborators.

In order to reduce future expenses and to minimize the potential dilution associated with financing their internal development, we intend to immediately seek licensees to assume the further development of our non-core liver disease related product candidates, MB07133 and pradefovir.

By selectively funding only our core metabolic disease related product candidates, licensing our non-core liver disease related product candidates and by seeking to offset current and future discovery, preclinical and clinical costs via additional strategic collaborations on our core discovery, preclinical and clinical programs, our revised strategic plan has the potential to reduce current and future expenses and to provide additional financial resources from license fees, milestones and potential strategic equity investments should we be successful in establishing these additional collaborations and license agreements. We expect to reduce costs even further by minimizing the previously planned general growth of the company. We are also evaluating the potential for additional debt financing. We believe that these measures, if successful, along with our existing resources will be sufficient to execute our revised strategic plan.

History of Losses, Prior Funding

We have incurred annual net losses since inception. As of September 30, 2007, our accumulated deficit was approximately \$139.1 million. We expect to incur losses for the next several years as we:

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

participate in the commercialization of our product candidates, if any, that receive regulatory approval and for which we retain commercialization rights,

continue and potentially expand our research and development programs, and

acquire or in-license products, technologies or businesses that are complementary to our own.

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 and our registered direct offering of common stock in March 2006, 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 our core metabolic disease related product candidates, MB07803 or MB07811, and we are currently seeking license agreements related to our non-core liver disease related product candidates, pradefovir and MB07133. We retain worldwide commercialization rights to all of the compounds that we have generated from our past and current discovery and preclinical stage programs, with the exception of any potential future product candidates covered by our collaborations with Merck & Co., Inc. (Merck) and Idenix. Our potential future agreements with strategic collaborators may include joint marketing or promotion arrangements which may allow us to eventually co-market one or more of our product candidates through our own sales force or with a co-promotion partner. Alternatively, we may grant exclusive marketing rights to our collaborators in exchange for up-front fees, milestones and royalties on future sales, if any.

We will rely on our collaborators or third-party manufacturers to produce sufficient quantities of our product candidates for preclinical and clinical studies and large-scale commercialization upon their approval.

Since we do not currently possess the resources necessary to independently develop and commercialize all of the potential product candidates that may be based upon our technologies, we plan to enter into additional collaborative agreements to assist in the development and commercialization of some or all of our product candidates. However, our

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discussions with potential collaborators may not lead to the establishment of new collaborations on acceptable terms, if at all, or it may take longer than expected to establish new collaborations, leading to development and commercialization delays.

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

Research and Development

Our research and development expenses consist primarily of cash and stock-based compensation and other expenses for research and development personnel, costs associated with preclinical 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 clinical development of our core metabolic disease related product candidates MB07803 and MB07811. Our activities related to our non-core liver disease related product candidates pradefovir and MB07133 are currently limited to planning, consultation, design and other efforts preparatory to their potential future clinical development by licensees. In addition, our research activities include work on a variety of compounds in our other discovery and preclinical research programs. We are responsible for all costs incurred for our product candidates and our discovery and preclinical research programs with the exception of the AMPK program partnered with Merck and the hepatitis C program partnered with Idenix. Our collaboration with Merck seeks to develop and commercialize new products to treat several metabolic diseases including type 2 diabetes, hyperlipidemia and non-alcoholic steatohepatitis, or NASH. Under the terms of our AMPK collaboration agreement with Merck, we have received approximately \$5.3 million in sponsored research funding through September 30, 2007 and are entitled to receive approximately \$1.0 million through the remaining three year sponsored research term ending in July 2008. Our collaboration with Idenix seeks to develop and commercialize new products for the treatment of hepatitis C infection. Our efforts and internal costs related to the hepatitis C collaboration with Idenix ceased upon completion of its research term in October 2007. Under the terms of this agreement, we have received approximately \$3.0 million in license fees and sponsored research funding through September 30, 2007 and are entitled to receive approximately \$138,000 in additional sponsored research funding for the remaining portion of the sponsored research term that ended.

At this time, due to the risks inherent in the clinical trial process and given the early stage of development of our product candidates and lead compounds from our research programs, we are unable to estimate with any certainty the costs we will incur in the continued development of our product candidates for commercialization. Other than costs for outsourced services associated with our clinical programs, we generally do not track our research and development expenses by project; rather, we track such expenses by the type of cost incurred. Due to these same 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 and to potentially increase as we continue the development of our current product candidates and continue to expand our research programs.

Generally, Phase 1 clinical trials can be expected to last from 6 to 18 months, Phase 2 clinical trials can be expected to last from 12 to 24 months and Phase 3 clinical trials can be expected to last from 18 to 36 months. However, clinical development timelines vary widely, as do the total costs of clinical trials and the likelihood of success. Although we are currently focused primarily on advancing MB07803 and MB07811 through clinical development, we anticipate that we will make determinations as to which research and development projects to pursue and how much funding to direct to each project on an ongoing basis in response to the scientific and clinical success of each product candidate, our ongoing assessment of its market potential and consideration of our available financial resources.

The lengthy process of seeking regulatory approvals for our product candidates, and the compliance with applicable regulations, require the expenditure of substantial resources. Any failure by us to obtain, or any delay in obtaining, regulatory approvals could cause our research and development expenditures to increase and, in turn, have a material unfavorable effect on our results of operations. We cannot be certain when or if any net cash inflow due to sales of any of our current product candidates will commence.

General and Administrative

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

Other Income (Expense)

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

Critical Accounting Policies

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

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

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

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

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

Stock-Based Compensation. We grant equity based awards under three stockholder-approved share-based compensation plans. We may grant options and restricted stock awards to employees, directors and consultants under our Amended and Restated 2001 Equity Incentive Plan. We also grant awards to non-employee directors under our 2004 Non-Employee

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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, *Share-Based Payment*, which we adopted effective January 1, 2006 under the modified prospective application method. The valuation provisions of SFAS No. 123R apply to new awards and to awards that are outstanding on the adoption date and subsequently modified or cancelled.

We estimate the fair value of stock options granted using the Black-Scholes-Merton, or Black-Scholes, option valuation model. This fair value is then amortized over the requisite service periods of the awards. The Black-Scholes option valuation model requires the input of subjective assumptions, including the option s expected life and price volatility of the underlying stock. Expected volatility is based on the weighted average volatility of our stock factoring in daily share price observations and the historical price volatility of certain peers within our industry sector. In computing expected volatility, the length of the historical period used is equal to the length of the expected term of the option and the share purchase right. The expected life of employee stock options represents the average of the contractual term of the options and the weighted average vesting period, as permitted under the simplified method, under SAB No. 107, Share-Based Payments.

As stock-based compensation expense is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures. SFAS No. 123R requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Forfeitures were estimated based on historical experience. Changes in assumptions used under the Black-Scholes option valuation model could materially affect our net loss and net loss per share.

Recently Issued Accounting Pronouncements

In July 2006, the Financial Accounting Standards Board, or FASB, issued Interpretation No., or FIN, 48, *Accounting for Uncertainty in Income Taxes*. This interpretation requires that we recognize in our financial statements the impact of a tax position if that position is more likely than not of being sustained on audit, based on the technical merits of the position. The provisions of FIN 48 are effective for fiscal years beginning after December 15, 2006, with the cumulative effect of the change in accounting principle recorded as an adjustment to retained earnings. We have adopted FIN 48 as of January 1, 2007, and compliance with this guidance did not have a significant impact on our results of operations or financial position.

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements*. This standard defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles and expands disclosures about fair value measurements. This statement is effective for financial statements issued for fiscal years beginning after November 15, although earlier application is encouraged. Accordingly, this statement will be effective for the Company beginning with its 2008 fiscal year. We are in the process of determining the effect, if any, the adoption of SFAS No. 157 will have on our results of operations or financial position.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities*. SFAS No. 159 permits entities to choose to measure many financial instruments and certain other items at fair value. This statement is effective for financial statements issued for fiscal years beginning after November 15, 2007. Accordingly, this statement will be effective for the Company beginning with its 2008 fiscal year. We are in the process of determining the effect, if any, the adoption of SFAS No. 159 will have on our results of operations or financial position.

Results of Operations

Comparison of the Three Months Ended September 30, 2007 and 2006

Revenues. Revenues were \$2.7 million for the three months ended September 30, 2007, compared with \$1.1 million for the three months ended September 30, 2006. The \$1.6 million increase was mainly due to increased sponsored research and license fee revenue as a result of our hepatitis C collaboration with Idenix.

Research and Development Expenses. Research and development expenses were \$10.9 million for the three months ended September 30, 2007, compared with \$7.6 million for the three months ended September 30, 2006. The \$3.3 million increase was mainly due to increased spending of \$2.5 million in development expense for the MB07803, MB07811 and MB07133 programs, an increase of \$0.6 million in payroll and related benefits as a result of a higher average number of employees in the third quarter of 2007 as compared to the third quarter of 2006, an increase of \$0.1 million in non-cash

stock-based compensation expense and an increase of approximately \$0.1 million in occupancy related costs and depreciation expense.

General and Administrative Expenses. General and administrative expenses were \$2.8 million for the three months ended September 30, 2007, compared with \$2.9 million for the three months ended September 30, 2006. The \$0.1 million decrease was mainly due to a decrease of approximately \$0.3 million in professional fees and other miscellaneous expenses offset by an increase of approximately \$0.2 million in payroll and related benefits as a result of a higher average number of employees in the third quarter of 2007 as compared to the third quarter of 2006.

Other Income (Expense). Net interest income was \$0.6 million for the three months ended September 30, 2007, compared to net interest income of \$1.0 million for the three months ended September 30, 2006. The \$0.4 million decrease was a result of lower cash balances in the third quarter of 2007 as compared to the third quarter of 2006.

Comparison of the Nine Months Ended September 30, 2007 and 2006

Revenues. Revenues were \$7.7 million for the nine months ended September 30, 2007, compared with \$3.0 million for the nine months ended September 30, 2006. The \$4.7 million increase was mainly due to increased license fee revenue as a result of the \$1.8 million upfront license fee we received from Schering and license fee and sponsored research revenue from our hepatitis C collaboration with Idenix.

Research and Development Expenses. Research and development expenses were \$31.4 million for the nine months ended September 30, 2007, compared with \$21.1 million for the nine months ended September 30, 2006. The \$10.3 million increase was mainly due to increased spending of \$6.3 million in development costs for the MB07803, MB07811 and MB07133 programs, an increase of \$3.0 million in payroll and related benefits as a result of a higher average number of employees in the first nine months of 2007 as compared to the first nine months of 2006, an increase of \$0.9 million in non-cash stock-based compensation expense and an increase of approximately \$0.3 million in occupancy related costs and depreciation expense. The increase was offset by a decrease of approximately \$0.1 million in other expenses.

General and Administrative Expenses. General and administrative expenses were \$9.3 million for the nine months ended September 30, 2007, compared with \$8.0 million for the nine months ended September 30, 2006. The \$1.3 million increase was mainly due to an increase of \$0.6 million in payroll and related benefits as a result of a higher average number of employees in the first nine months of 2007 compared to the first nine months of 2006, an increase of approximately \$0.3 million in professional fees related to legal costs associated with patent and corporate related matters and consulting services, an increase of \$0.3 million in non-cash stock-based compensation and an increase of \$0.2 million in occupancy related costs and depreciation expense. These increases were offset by a decrease of approximately \$0.1 million in other expenses.

Other Income (Expense). Net interest income was \$2.1 million for the nine months ended September 30, 2007, compared to net interest income of \$2.6 million for the nine months ended September 30, 2006. The \$0.5 million decrease was a result of lower cash balances during the first nine months of 2007 as compared to the first nine months of 2006.

Liquidity and Capital Resources

Since our inception, we have funded our operations primarily with \$55.8 million in net proceeds from private equity financings and \$107.5 million in net proceeds from our initial public offering in June 2004, a private placement of common stock and warrants in October 2005 and a registered direct offering of common stock in March 2006 as well as from 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.

In April 2007, we filed an additional shelf registration statement to increase the amount of common stock and warrants available for issuance under our existing shelf registration statement by approximately \$40 million to a total of \$75 million. The additional shelf registration statement was declared effective in May 2007.

In November 2006, we entered into a Committed Equity Financing Facility, or CEFF, with an institutional investor. Under the terms of the CEFF, the investor is committed to providing us up to \$50 million in funding from time to time for a period up to 36 months that commenced in December 2006 through the purchase of newly-issued shares of our common stock. Subject to certain conditions, we may access capital under the CEFF in tranches of up to the lesser of \$10 million or:

0.75% of our market capitalization if, at the time of the draw down of such tranche, our market capitalization equals or exceeds \$65 million but is less than \$100 million,

1.00% of our market capitalization if, at the time of the draw down of such tranche, our market capitalization equals or exceeds \$100 million but is less than \$175 million, and

1.50% of our market capitalization if, at the time of the draw down of such tranche, our market capitalization exceeds \$175 million.

If our market capitalization is less than \$65 million, we will not have access to this capital.

The investor will purchase shares of our common stock pursuant to the CEFF at discounts ranging from 6% to 10%, depending on the average market price of our common stock during an eight-day pricing period, provided that the minimum acceptable purchase price for any shares to be issued to the investor during the eight-day pricing period is determined by the higher of \$2.25 or 90% of our share price the day before the commencement of each draw down. Pursuant to the agreement we filed a registration statement with the Securities and Exchange Commission for the resale of the shares of common stock issuable in connection with the CEFF and the shares of common stock underlying the warrant discussed below which became effective on December 22, 2006.

As of September 30, 2007, we had \$51.3 million in cash and cash equivalents and securities available-for-sale as compared to \$77.9 million as of December 31, 2006, a decrease of \$26.6 million. The decrease was primarily due to our use of approximately \$27.6 million in cash to fund ongoing operations.

As of September 30, 2007, we have financed through leases and loans the purchase of equipment and leasehold improvements totaling approximately \$12.1 million, of which \$6.4 million was outstanding at that date. The loans are collateralized with the purchased equipment, bear interest at rates ranging from approximately 8.0% to 12.85% and are due in monthly installments through October 2015. We expect to continue to finance our capital expenditures through the use of debt.

As of September 30, 2007, we have not exercised our option to sell shares under the CEFF. In the event we determine that the need for an equity financing is necessary to pursue specific strategic initiatives, that an equity offering under this agreement provides for more favorable terms and results than what may be available through other financing vehicles at the time, and that the market will favorably support the additional equity available, we may utilize our option to sell shares of common stock under this agreement.

We believe that our existing cash, cash equivalents and short-term investments will be sufficient to meet our projected operating requirements through at least the next twelve months. Under our revised strategic plan we will focus our internal resources primarily on our clinical, preclinical and discovery stage core metabolic disease related programs. This includes funding the further clinical evaluation of our core metabolic disease product candidates, MB07803 and MB07811, with a focus on achieving key, near-term value-driving milestones. Continued development of these core metabolic disease related product candidates thereafter will require significant resources. Therefore, we plan to establish strategic collaborations for these product candidates at appropriate times to secure additional resources, accelerate progress and share risk. In addition, we plan to advance additional metabolic disease product candidates discovered by our research group into clinical development either independently, or potentially with current or future strategic collaborators

In order to reduce future expenses and to minimize the potential dilution associated with financing their internal development, we intend to immediately seek licensees to assume the further development of our non-core liver disease related product candidates, MB07133 and pradefovir.

By selectively funding only our core metabolic disease related product candidates, licensing our non-core liver disease related product candidates and by seeking to offset current and future discovery, preclinical and clinical costs via additional strategic collaborations on our core discovery, preclinical and clinical programs, our revised strategic plan has the potential to significantly reduce current and future expenses and to provide additional financial resources from license fees, milestones and potential strategic equity investments should we be successful in establishing these additional collaborations and license agreements. We expect to reduce costs even further by minimizing the previously planned general growth of the company. We are also evaluating the potential for additional debt financings. We believe that these measures, if

successful, along with our existing resources will be sufficient to execute our revised strategic plan.

However, we may not be successful in entering into additional collaboration agreements at the appropriate times or at all, in receiving milestone or royalty payments under current or future agreements, or in entering into additional debt financing arrangements. Accordingly, we may need to augment the funding of our revised strategic plan with additional offerings of our equity securities (including our CEFF). We cannot be sure that funding will be adequate or that additional financing will be available when needed or that, if available, financing will be obtained on terms favorable to us or our stockholders. Having insufficient funds may require us to delay, scale back or eliminate some or all of our research or development programs or to relinquish greater or all rights to product candidates at an earlier stage of development or on less favorable terms than we would otherwise choose. Failure to obtain adequate financing also may adversely affect our ability to operate as a going concern.

To the extent that we raise additional capital by issuing equity securities, our existing stockholders—ownership will be diluted. Any future 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 rights to our potential products or proprietary technologies, or grant licenses on terms that are not favorable to us.

The following summarizes our long-term contractual obligations as of September 30, 2007 (in thousands):

| | Payments Due by Period | | | | | | | |
|----------------------|------------------------|-------|-----------------|-------|-----------------|-------|------------------|--------|
| | Less than Total 1 Year | | 1 to 3 Years | | 4 to 5 Years | | After 5 Years | |
| Operating leases | \$ 25,062 \$ | 2,283 | \$ | 5,725 | \$ | 6,405 | \$ | 10,649 |
| Equipment financing | 6,283 | 1,692 | | 3,916 | | 552 | | 123 |
| Purchase commitments | 2,121 | 2,121 | | | | | | |
| Capital leases | 77 | 22 | | 46 | | 9 | | |
| Total | \$ 33,543 \$ | 6,118 | \$ | 9,687 | \$ | 6,966 | \$ | 10,772 |

We also enter into agreements with clinical sites and contract research organizations to conduct 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 if terminated for reasons other than cause, as defined in those agreements. These agreements generally expire upon termination for cause or when we have met our obligations under these agreements. As of September 30, 2007, no events have occurred resulting in the obligation of such payments.

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

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