METABASIS THERAPEUTICS INC
Form 10-Q
August 06, 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 June 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 (State or other jurisdiction of incorporation or organization)	**33-0753322** (I.R.S. Employer Identification No.)
11119 North Torrey Pines Road, La Jolla, CA (Address of principal executive offices)	**92037** (Zip code)

(858) 587-2770

(Registrant s telephone number, including area code)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. 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 July 31, 2007 was 30,642,271.

METABASIS THERAPEUTICS, INC.

FORM 10-Q
FOR THE QUARTERLY PERIOD ENDED June 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)

	June 30, 2007 (Unaudited)	December 31, 2006
Assets		
Current assets:		
Cash and cash equivalents	$ 14,529	$ 12,052
Securities available-for-sale	47,226	65,871
Trade accounts receivable	450	187
Prepaids and other current assets	1,231	1,303
Total current assets	63,436	79,413
Property and equipment, net	6,920	6,263
Other assets	175	179
Total assets	$ 70,531	$ 85,855
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	$ 1,706	$ 1,053
Accrued liabilities	6,145	3,999
Deferred revenue, current portion	3,155	3,192
Current portion of long-term debt	1,896	1,761
Current portion of capital lease obligations	21	20
Total current liabilities	12,923	10,025
Deferred revenue, net of current portion	333	1,630
Deferred rent	2,131	1,566
Long-term debt	3,981	3,908
Capital lease obligations, net of current portion	60	71
Other long-term liabilities	287	517
Total liabilities	19,715	17,717
Stockholders equity:		
Preferred stock, $0.001 par value; 5,000 shares authorized at June 30, 2007 and December 31, 2006, no shares issued or outstanding		
Common stock, $0.001 par value; 100,000 shares authorized at June 30, 2007 and December 31, 2006; 30,642 and 30,493 shares issued and outstanding at June 30, 2007 and December 31, 2006, respectively	31	30
Additional paid-in capital	179,395	176,298
Accumulated deficit	(128,654)	(108,213)
Accumulated other comprehensive loss	44	23
Total stockholders equity	50,816	68,138
Total liabilities and stockholders equity	$ 70,531	$ 85,855

See accompanying notes.

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

	Three Months Ended June 30, 2007	Three Months Ended June 30, 2006	Six Months Ended June 30, 2007	Six Months Ended June 30, 2006
Revenues:				
Sponsored research	$ 938	$ 525	$ 1,876	$ 1,050
License fees	666	417	3,133	834
Other revenue			21	31
Total revenues	1,604	942	5,030	1,915
Operating expenses:				
Research and development	11,065	6,820	20,571	13,611
General and administrative	3,186	2,725	6,450	4,973
Total operating expenses	14,251	9,545	27,021	18,584
Loss from operations	(12,647)	(8,603)	(21,991)	(16,669)
Other income (expense):				
Interest income	842	1,072	1,814	1,745
Interest expense	(130)	(114)	(264)	(187)
Total other income, net	712	958	1,550	1,558
Net loss	$ (11,935)	$ (7,645)	$ (20,441)	$ (15,111)
Basic and diluted net loss per share	$ (0.40)	$ (0.25)	$ (0.67)	$ (0.55)
Shares used to compute basic and diluted net loss per share	30,213	30,155	30,502	27,717

See accompanying notes.

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

	Six Months Ended June 30, 2007	2006
Operating activities		
Net loss	$ (20,441)	$ (15,111)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	2,694	1,602
Depreciation and amortization	978	708
Deferred rent	565	656
Amortization of discount and premium on securities available-for-sale	(1,351)	118
Change in operating assets and liabilities:		
Trade accounts receivable	(263)	609
Other current assets	72	27
Other assets	4	
Deferred revenue	(1,334)	(833)
Accounts payable	653	(1,014)
Accrued liabilities and other long-term liabilities	1,916	(877)
Net cash flows used in operating activities	(16,507)	(14,115)
Investing activities		
Purchases of securities available-for-sale	(50,441)	(41,260)
Sales/maturities of securities available-for-sale	70,458	31,421
Purchases of property and equipment	(1,635)	(2,003)
Net cash flows provided by (used in) investing activities	18,382	(11,842)
Financing activities		
Issuance of common stock, net	404	37,651
Principal payments on debt and capital lease obligations	(936)	(662)
Proceeds received from debt and capital lease obligations	1,134	2,356
Net cash flows provided by financing activities	602	39,345
Increase in cash and cash equivalents	2,477	13,388
Cash and cash equivalents at beginning of year	12,052	32,597
Cash and cash equivalents at end of period	$ 14,529	$ 45,985
Supplemental schedule of noncash investing and financing activities:		
Net-share settlement of warrant	$ 56	$
Unrealized gain (loss) on short-term investments	$ 21	$ 28

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.

Operating results for the three and six months ended June 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 Months Ended June 30,		Six Months Ended June 30,	
	2007	2006	2007	2006
Net loss	$ (11,935)	$ (7,645)	$ (20,441)	$ (15,111)
Unrealized gain (loss) on available-for-sale investments	26	27	21	28
Comprehensive loss	$ (11,909)	$ (7,618)	$ (20,420)	$ (15,083)

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 7,523,754 and 5,746,633 for the three months ended June 30, 2007 and 2006, respectively, and 7,145,040 and 5,546,552 for the six months ended June 30, 2007 and 2006, respectively.

	Three Months Ended June 30, 2007	2006	Six Months Ended June 30, 2007	2006
	(in thousands, except per share amounts)			
Actual:				
Numerator:				
Net loss	$ (11,935)	$ (7,645)	$ (20,441)	$ (15,111)
Denominator:				
Weighted average common shares	30,228	30,304	30,533	27,883
Weighted average unvested common shares subject to repurchase	(15)	(149)	(31)	(166)
Denominator for basic and diluted net loss per share	30,213	30,155	30,502	27,717
Basic and diluted net loss per share	$ (0.40)	$ (0.25)	$ (0.67)	$ (0.55)

4. New Accounting Pronouncements

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 Section 382 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 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 it s 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 (beginning with the Company s 2008 fiscal year), although earlier application is encouraged. 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. The provisions of SFAS No. 159 will be effective for the Company beginning with the first quarter of fiscal 2008. 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.

5. Subsequent Events

In July 2007, the Company was informed by Schering-Plough Corporation of its intention to terminate the agreements it entered into with the Company and Valeant Pharmaceuticals 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 does not expect to receive any additional payments related to these agreements and upon termination of these agreements, all rights to pradefovir will be returned to the Company.

In July 2007, the Company was informed by Idenix Inc. that it planned to end the sponsored research term of the collaboration agreement 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 $2.6 million in license fees and sponsored research funding through June 30, 2007 and is entitled to receive an additional $688,000 in sponsored research funding through the effective termination date of the sponsored research term of the agreement in October 2007.

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In July 2007, the Company was informed by Idenix Inc. that it planned to end the sponsored research term of the co

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. These diseases include metabolic diseases such as diabetes, hyperlipidemia and obesity, among others, and liver diseases such as hepatitis and primary liver cancer. 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 five product candidates at the clinical stage of development. These five product candidates, by category, and in order from the most advanced stage of clinical development reached to date by each product candidate within each category, are as follows:

Product Candidate	**Disease Indication**
Metabolic Diseases	
CS-917	type 2 diabetes
MB07803	type 2 diabetes
MB07811	hyperlipidemia
Liver Diseases	
pradefovir	hepatitis B
MB07133	primary liver cancer

In July 2007, we were informed by Daiichi Sankyo, Co. Ltd., our collaborative partner on CS-917, that results from a recently completed Phase 2b clinical trial showed that this product candidate failed to achieve the primary endpoint of the study, a statistically significant reduction in the placebo-adjusted level of gylcosolated hemoglobin (HbA1c), a measure of blood glucose levels, at either of the two doses tested. Also in July we were informed by Schering-Plough Corporation that it intended to terminate the agreements previously entered into with us and Valeant Pharmaceuticals International for the development and commercialization of pradefovir. As a result of these events, we have taken certain actions to control costs and may institute others and are unable at this time to determine what overall impact these events will have on our ongoing business strategy.

We have incurred annual net losses since inception. As of June 30, 2007, our accumulated deficit was approximately $128.7 million. We may incur substantial and potentially increasing losses for the next several years should we:

- continue to develop current and future clinical development candidates,
- commercialize our product candidates, if any, that receive regulatory approval,
- continue and 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 our collaborative partners and, to a lesser extent, the sale of common stock through our stockholder approved equity incentive plans.

Our agreements with collaborators may include joint marketing or promotion arrangements of our products. For example, we have retained co-promotion rights for CS-917 in North America with Daiichi Sankyo. Alternatively, we may grant exclusive marketing rights to our collaborators in exchange for up-front fees, milestones and royalties on future sales, if any.

As a result of Schering-Plough s decision to terminate our pradefovir collaboration, we will no longer have an ongoing collaborative partnership for pradefovir and we expect that all commercial rights to this product candidate will be returned to us. At this time, we do not intend to independently develop pradefovir and will likely seek a new collaborative partnership for the further development and commercialization of this product candidate should we ultimately determine that such future development and commercialization is feasible. We do not have collaborative partnerships for MB07803, MB07811 or MB07133 and are currently independently developing these product candidates. We retain worldwide commercialization rights to all of the compounds generated from our current research programs, with the exception of any potential future product candidates covered by our collaborations with Merck & Co., Inc. and Idenix Pharmaceuticals, Inc. We intend to eventually market one or more of the product candidates for which we retain commercialization rights through our own sales force or with a co-promotion partner in the U.S. and through strategic collaborations abroad.

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

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 research and development activities are primarily focused on the clinical development of MB07803, MB07811 and MB07133. Daiichi Sankyo is currently responsible for the costs of clinical development of CS-917. In addition, research and development activities include work on a variety of compounds in our other discovery research programs. We are responsible for all costs incurred for these product and clinical candidates and in our discovery research programs with the exception of the AMPK and hepatitis C programs partnered with Merck and our hepatitis C program partnered with Idenix. Under the terms of our collaboration agreements with Merck, we had received approximately $7.5 million in sponsored research funding through June 30, 2007. In July 2007, we were informed by Idenix Inc. that it planned to end the sponsored research term of the collaboration agreement upon the first anniversary of the agreement in accordance with its terms. Under the terms of our collaboration agreement with Idenix, we had received approximately $2.6 million in license fees and sponsored research funding through June 30, 2007 and are entitled to receive approximately $688,000 in cumulative sponsored research funding through the one-year sponsored research term ending in October 2007.

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 if 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, MB07811 and MB07133 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 considering 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 downstream milestones and royalties. All fees are nonrefundable. Revenue from milestones is recognized when earned, provided that:

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

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

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

revenue as the services are provided, as long as the amounts received are not refundable regardless of the results of the research project.

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

Stock-Based Compensation. We grant equity based awards under three stockholder-approved share-based compensation plans. We may grant options and restricted stock awards to employees, directors and consultants under our Amended and Restated 2001 Equity Incentive Plan. We also grant awards to non-employee directors under our 2004 Non-Employee Directors Stock Option Plan. All of our employees are eligible to participate in our 2004 Employee Stock Purchase Plan which provides a means for employees to purchase common stock at a discount through payroll deductions. The benefits provided under all of these plans are subject to the provisions of 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, 2007 (beginning with our 2008 fiscal year), although earlier application is encouraged. 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. The provisions of SFAS No. 159 will be effective in our first quarter of fiscal 2008. 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.

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Results of Operations

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

Revenues. Revenues were $1.6 million for the three months ended June 30, 2007, compared with $942,000 for the three months ended June 30, 2006. The $662,000 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 $11.1 million for the three months ended June 30, 2007, compared with $6.8 million for the three months ended June 30, 2006. The $4.3 million increase was mainly due to increased spending of $2.8 million in development expense for the MB07803, MB07811 and MB07133 programs, an increase of $1.0 in payroll and related benefits as a result of a higher average number of employees in the second quarter of 2007 as compared to the second quarter of 2006 and an increase of approximately $430,000 in stock-based compensation expense.

General and Administrative Expenses. General and administrative expenses were $3.2 million for the three months ended June 30, 2007, compared with $2.7 million for the three months ended June 30, 2006. The $461,000 increase was mainly due to an increase of $240,000 in payroll and related benefits as a result of a higher average number of employees in the second quarter of 2007 as compared to the second quarter of 2006 and a $190,000 increase in stock-based compensation.

Other Income (Expense). Net interest income was $712,000 for the three months ended June 30, 2007, compared to net interest income of $1.0 million for the three months ended June 30, 2006. The $246,000 decrease was a result of lower cash balances in the second quarter of 2007 as compared to the second quarter of 2006.

Comparison of the Six Months Ended June 30, 2007 and 2006

Revenues. Revenues were $5.0 million for the six months ended June 30, 2007, compared with $1.9 million for the six months ended June 30, 2006. The $3.1 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-Plough and license fee and sponsored research revenue from our hepatitis C collaboration with Idenix.

Research and Development Expenses. Research and development expenses were $20.6 million for the six months ended June 30, 2007, compared with $13.6 million for the six months ended June 30, 2006. The $7.0 million increase was mainly due to increased spending of $3.8 million in development costs for the MB07803, MB07811 and MB07133 programs, an increase of $2.3 million in payroll and related benefits as a result of a higher average number of employees in the first six months of 2007 as compared to the first six months of 2006 and an increase of $800,000 in stock-based compensation expense.

General and Administrative Expenses. General and administrative expenses were $6.5 million for the six months ended June 30, 2007, compared with $5.0 million for the six months ended June 30, 2006. The $1.5 million increase was mainly due to an increase of $465,000 in professional services related to legal costs associated with patent and corporate related matters and consulting services, an increase of $450,000 in payroll and related benefits as a result of a higher average number of employees in the first six months of 2007 compared to the first six months of 2006, an increase of $350,000 in stock-based compensation and an increase of $200,000 in occupancy related costs and depreciation expense.

Other Income (Expense). Net interest income was $1.6 million for both the six months ended June 30, 2007 and 2006 due to having similar average cash balances over the first six months of 2007 as compared to the first six months of

2006.

Liquidity and Capital Resources

Since our inception, we have funded our operations primarily with $55.8 million in 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.

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 over a three-year term 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.

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 June 30, 2007, we had $61.8 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 $16.1 million. The decrease was primarily due to our use of approximately $16.5 million in cash to fund ongoing operations.

As of June 30, 2007, we have financed through leases and loans the purchase of equipment and leasehold improvements totaling approximately $11.2 million, of which $6.0 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 June 30, 2007, we have not exercised our option to sell shares under the CEFF agreement. In the event we determine that the need for an equity financing is necessary to pursue specific strategic initiatives, and we determine 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 we determine 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. Due mainly to recent unfavorable clinical trial results related to CS-917 and Schering-Plough s decision to terminate our strategic collaboration for the development and commercialization of pradefovir, we have taken certain actions to control costs and may institute others. We are unable at this time to determine what overall impact these events will have on our net spending for the remainder of 2007 and on our ongoing business strategy. In addition, because of these events and their subsequent impact on the price of our common stock and our cost of capital, we are also unable at this time to determine their overall impact on our financing strategy. Until we can generate significant cash from our operations, we expect to continue to fund our operations with existing cash resources that were primarily generated from the proceeds of prior offerings of our equity securities and cash payments under our strategic collaborations.

We will continue to evaluate opportunities to finance future cash needs through our CEFF, debt financing arrangements, the sale of other equity securities and by entering into additional strategic collaboration agreements. However, we may not be successful in obtaining additional collaboration agreements, or in receiving milestone or royalty payments under current or future agreements. In addition, we cannot be sure that our existing cash, cash equivalents and securities

available-for-sale 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 June 30, 2007 (in thousands):

		Payments Due by Period			
	Total	Less than 1 Year	1 to 3 Years	4 to 5 Years	After 5 Years
Operating leases	$ 25,472	$ 2,102	$ 5,547	$ 6,359	$ 11,464
Equipment financing	5,877	1,895	3,287	567	128
Purchase commitments	2,764	2,764			
Capital leases	81	21	47	13	
Total	$ 34,194	$ 6,782	$ 8,881	$ 6,939	$ 11,592

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 June 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,
- the scope, prioritization and number of clinical development and research programs we pursue,
- the costs of expanding or potentially restructuring our operations,
- 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,
- the effect of competing technological and market developments, and
- the extent to which we acquire or in-license new products, technologies or businesses.

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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, 2006. 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. 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 bears 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 Exchange Act of 1934 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.

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

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

PART II - OTHER INFORMATION

Item 1. Legal Proceedings

None.

Item 1A. Risk Factors

You should consider carefully the following information about the risks described below, together with the other information contained in this quarterly report on Form 10-Q and in our other filings with the Securities and Exchange Commission, before you decide to buy or maintain an investment in our common stock. We believe the risks described below are the risks that are material to us as of the date of this quarterly report. If any of the following risks actually occur, our business, financial condition, results of operations and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our common stock could decline, and you may lose all or part of the money you paid to buy our common stock. The risks described below include certain revisions to the risks set forth in our annual report on Form 10-K for the fiscal year ended December 31,2006 and our subsequent filings with the Securities and Exchange Commission.

Risks Related to our Business

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

We have expended significant time, money and effort in the development of our metabolic disease product candidates, CS-917, MB07803 and MB07811, and our liver disease product candidates, pradefovir and MB07133. Clinical trials conducted to date in patients treated with CS-917 and pradefovir have provided evidence of efficacy as measured by various parameters that we believe to be clinically and statistically significant. However, in July 2007 we were informed that results from the most recently completed Phase 2b clinical trial of CS-917 showed that the product candidate failed to achieve the primary endpoint of the study. The impact of this finding on CS-917 and MB07803, a second-generation gluconeogenesis inhibitor, is currently being assessed. 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 partners, as applicable, may be unable to commercialize them successfully for a variety of reasons. These include, for example, the availability of alternative treatments, lack of cost effectiveness, the cost of manufacturing the product on a commercial scale and the effect of competition with other drugs. The success of our product candidates may also be limited by the prevalence and severity of any adverse side effects. If we fail to commercialize one or more of our current product candidates, we may be unable to generate sufficient revenues to attain or maintain profitability, and our reputation in our industry and the investment community may be damaged.

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

To receive regulatory approval for the commercialization of our metabolic disease product candidates CS-917, MB07803 and MB07811, our liver disease product candidates 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 Food and Drug Administration, or FDA, in the U.S. and other regulatory agencies elsewhere in the

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world. In order to support marketing approval, these agencies typically require successful results in one or more Phase 3 clinical trials, which our current product candidates have not yet reached and may never reach. In addition, regulatory approval of our product candidates may be affected by adverse results in animal studies conducted during clinical development to, among other things, evaluate their toxicology, carcinogenicity and pharmacokinetics and optimize their formulation.

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

- clinical trials may produce negative or inconclusive results,
- animal studies conducted on product candidates during clinical development to, among other things, evaluate their toxicology and pharmacokinetics and optimize their formulation may produce unfavorable results,
- patient recruitment and enrollment in clinical trials may be slower than we anticipate,
- costs of development may be greater than we anticipate,
- our product candidates may cause undesirable side effects that delay or preclude regulatory approval or limit their commercial use or market acceptance if approved,
- collaborators who are responsible for development of our product candidates may not devote sufficient resources to these clinical trials or other studies of these candidates or conduct them in a timely manner, or
- we may face delays in obtaining regulatory approvals to commence a clinical trial.

Success in early development does not mean that later development will be successful because, for example, product candidates in later-stage clinical trials may fail to demonstrate sufficient safety and efficacy despite having progressed through initial clinical testing. Our clinical experience with our product candidates is limited, and to date our product candidates have been tested in less than the number of patients that will likely need to be studied to gain regulatory approval. The data collected from clinical trials with larger patient populations may not demonstrate sufficient safety and efficacy to support regulatory approval of these product candidates. For example, in July 2007 we were informed that results from the most recently completed Phase 2b clinical trial of CS-917 showed that the product candidate failed to achieve the primary endpoint of the study.

The targeted endpoints and goals for development of CS-917 have been, and will continue to be, primarily established by Daiichi Sankyo. The current targeted endpoints and goals for development of pradefovir have been primarily established by Valeant and Schering-Plough. However, as a result of Schering-Plough s decision to terminate our pradefovir collaboration, we will no longer have an ongoing collaborative partnership for pradefovir and we expect that all commercial rights to this product candidate will be returned to us. Therefore, in the future, should we determine that further development and commercialization of pradefovir is feasible, we and/or any potential future collaborative partner will be responsible for establishing the targeted endpoints and goals for development of pradefovir. We are also solely responsible for establishing the targeted endpoints and goals for development of MB07803, MB07811 and MB07133. 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.

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 caused by 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

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authorities for any or all targeted indications or adversely affect the marketability of any such product candidates that receive regulatory approval. In turn, this could eliminate or limit our ability to commercialize our product candidates and generate revenues from their sale.

For example, data from 24-month oral carcinogenicity studies of pradefovir in rats and mice showed that the incidence of rats or mice with tumors was increased in the animals dosed with the highest dose levels tested and was slightly increased at the intermediate dose levels. The low dose levels were considered no-effect dose levels in both studies. Based on these findings, Schering-Plough and Valeant discontinued dosing of all patients in the single ongoing pradefovir Phase 2 extension study as a precautionary measure. This was considered a prudent course of action given the understanding of these findings and until the relevance of the rodent studies to man can be more fully evaluated. As a result of these findings and other considerations, Schering-Plough recently informed us that it is terminating its collaboration with us for the development and commercialization of pradefovir, and we expect that all commercial rights to pradefovir will be returned to us.

As another example, the inhibition of gluconeogenesis can cause elevated levels of lactic acid, or lactate, which, if high and sustained under certain conditions, could lead to lactic acidosis, a serious and potentially fatal condition. Certain preclinical animal studies have shown that CS-917 raises lactate levels two- to three-fold in some but not all animal models. Elevated lactate levels have also been observed in certain human clinical trials of CS-917. For example, in a 28-day Phase 2 clinical trial of CS-917, isolated instances of lactate elevation significantly above the normal range were seen in some patients in both CS-917 and placebo treated groups over the course of the 28 days. No patient exhibited sustained lactate levels significantly above the normal range over a period of consecutive days during the clinical trial. However, one patient who received 200 milligrams of CS-917 twice a day was withdrawn from the clinical trial by the investigator on day 15 due to concerns over consistently elevated lactate levels measured the previous day. Other incidences of elevated lactate levels have been observed and will likely occur in the future.

Our product candidates could also exhibit adverse interactions with other drugs. For instance, in March 2005 we were notified by Daiichi Sankyo that two serious adverse events involving lactic acidosis had occurred in two patients in a Phase 1 clinical trial evaluating the interaction of CS-917 with metformin. The serious adverse events were resolved after medical intervention. After the adverse events occurred, the three clinical trials that were ongoing at the time were stopped while one Phase 1 clinical trial which did not combine CS-917 with metformin continued and was completed. After extensive analysis Daiichi Sankyo concluded that the lactic acidosis observed in the two patients was likely due to significantly increased blood levels of metformin. The reason for the increase in metformin blood levels observed in these two patients has not been determined. At high blood levels, metformin is believed to cause a form of cellular toxicity known as mitochondrial toxicity which can cause lactic acidosis. Subsequently, Daiichi Sankyo decided that clinical trials of CS-917 could safely resume.

Daiichi Sankyo has conducted and may conduct additional studies combining CS-917 with other diabetes drugs to assess both the safety and eventually the potential for enhanced efficacy with the combination. However, further use of CS-917 in combination with metformin will be avoided unless additional data suggests that the elevation of metformin blood levels as seen in the two patients can be avoided through patient exclusion or through the administration of CS-917 at lower doses or through other means. Should CS-917 eventually be approved and the use of CS-917 in combination with metformin remains an issue, the FDA may require additional measures be taken during marketing, such as prominent warning labels known as black-box warnings, physician education programs and/or other steps regarding concomitant use of CS-917 and metformin.

In February 2006, we initiated Phase 1 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 described previously for CS-917.

It is also possible that CS-917 and MB07803 may cause other side effects. In certain preclinical studies, as expected based on the mechanism of these compounds, fasted animals treated with CS-917 showed pronounced hypoglycemia, a condition involving abnormally low blood glucose levels that can lead to coma or death. Hypoglycemia has been observed in one patient participating in a clinical trial that involved multi-day administration of the highest dose of CS-917 tested to date in patients (400 milligrams twice a day). This dose is above what is expected to be used in Phase 3 clinical trials if warranted. However, we cannot yet rule out the possibility that CS-917 may increase a patient s susceptibility to hypoglycemia, including the potential for severe hypoglycemia, by inhibiting gluconeogenesis, especially in elderly patients who are already prone to develop this condition. Some rodent models of diabetes studied in preclinical trials of CS-917 demonstrated, at glucose lowering doses, increased levels of fat molecules known as triglycerides, which are associated with an increased risk

of cardiovascular disease. Elevated triglyceride levels have not been observed in human clinical trials to date. Other side effects observed during early clinical trials of CS-917 included nausea and vomiting.

We apply our HepDirect technology to make liver-specific prodrugs of certain compounds. A prodrug is a drug to which a chemical modification has been made that renders it inactive until enzymes in the body convert it to its active form. When converted by the body to their active forms, HepDirect prodrugs produce a byproduct that is within a class of compounds that have the potential of causing toxicity, genetic mutations and cancer. We are unaware of any byproduct-related toxicities demonstrated to date in clinical trials of any of pradefovir, MB07133 or MB07811. However, we cannot be certain that this byproduct will not cause adverse effects in current or future clinical trials of these product candidates or other HepDirect prodrugs we may develop. In addition, because our current product candidates are in early stages of development and have been tested in relatively small populations, additional side effects may be observed as their development progresses.

MB07811 is a HepDirect prodrug of a potent TRß agonist discovered by us. Thyroid hormone and thyroid hormone mimetics are known to exhibit a wide array of physiological actions involving a variety of organs that can be assessed in preclinical animal studies. Both beneficial and undesirable effects can be inferred from studies of humans with hyperthyroidism (elevated thyroid hormone). The development of liver-selective thyroid receptor modulators for the treatment of hyperlipidemia is a novel approach seeking to exploit the beneficial hepatic effects while avoiding toxicities related to systemic exposure of thyromimetic agents. Successful development of MB07811 will require finding a dose range in humans that provides adequate benefit and an acceptable safety profile.

In addition, undesirable side effects involving of our product candidates may have other significant adverse implications on our business, for example:

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

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

- regulatory authorities may withdraw their approval of the product, or we may decide to cease marketing and sale of the product voluntarily,
- we may be required to change the way the product is administered, conduct additional studies, change the labeling of the product, or change the product s manufacturing facilities, and
- our reputation may suffer.

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

We are currently dependent on our collaboration with Daiichi Sankyo for development of CS-917, and events involving this collaboration, our collaborations with Merck and Idenix, or any future collaborations could prevent us from developing and commercializing our product candidates and achieving or sustaining profitability.

We have entered into a collaboration with Daiichi Sankyo for the development and commercialization of CS-917. Daiichi Sankyo has agreed to finance the development of CS-917 and, if it is approved, manufacture and market CS-917. Accordingly, we are currently dependent on Daiichi Sankyo to gain FDA and other foreign regulatory agency approval of, and to commercialize, CS-917. Recent unfavorable clinical trial results related to CS-917 may impact the potential further future development of this product candidate. In addition, our agreement with Daiichi Sankyo contains certain rights and restrictions regarding our access to and use of confidential data and information generated by Daiichi Sankyo. We have initiated clinical trials of MB07803, a second-generation gluconeogenesis inhibitor that may be a direct competitor to CS-917. Because of this competitive situation and with our consent, the transfer to us of confidential information was reduced. However, as a result of recent findings in a Phase 2b clinical trial of CS-917, we will likely need to review detailed data and information related to these findings. The prior transfer of confidential information and any further future transfer of data and information related to these findings may increase the risk of claims based on our access to this information and data. It is possible that Daiichi Sankyo could challenge our rights to independently develop second generation gluconeogenesis inhibitors, including MB07803, which may delay or prevent the development, partnering and/or commercialization of such product candidates.

We have also entered into two collaborations with Merck and a collaboration with Idenix. The first collaboration with Merck seeks to develop and commercialize new products for the treatment of hepatitis C infection and the second seeks to develop and commercialize new products to treat several metabolic diseases including type 2 diabetes, hyperlipidemia and non-alcoholic steatohepatitis, or NASH. Our collaboration with Idenix seeks to develop and commercialize new products for the treatment of hepatitis C infection. Although our collaborations with Merck and Idenix have not yet yielded any product candidates, should they ultimately be successful, we will be dependent on Merck and/or Idenix, as applicable, for further development and commercialization of any resulting product candidates. In addition, since we do not currently possess the resources necessary to independently develop and commercialize all of the potential products that may be based upon our technologies, including pradefovir, MB07803, MB07811 and MB07133, we may need to enter into additional collaborative agreements to assist in the development and commercialization of some or all of these product candidates. However, our discussions with potential collaborators may not lead to the establishment of new collaborations on acceptable terms, if at all, or it may take longer than expected to establish new collaborations, leading to development and commercialization delays.

We have limited control over the amount and timing of resources that Daiichi Sankyo, Merck, Idenix or any future collaborators devote to our programs or potential products. These collaborators may breach or terminate their agreements with us or otherwise fail to conduct their collaborative activities successfully and in a timely manner. For example, we were recently informed that Schering-Plough is terminating its collaboration with us for the development and commercialization of pradefovir, and returning all rights to pradefovir to us. Further, our collaborators may not develop products 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 did not already have those rights. We would then determine whether to continue the development or commercialization of the product candidate or drug compound independently or together with a new collaborator. However, in the event that we do not have sufficient resources to independently develop or commercialize the product candidate or drug compound, and we cannot establish a new collaboration on acceptable terms, we would be forced to discontinue its development or commercialization. For example, at this time, we do not intend to independently develop pradefovir and will seek a new collaborative partnership for the further development and commercialization of this product candidate should we ultimately determine that such future development and commercialization is feasible.

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,

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

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

Our agreement with Merck to develop and commercialize new products to treat several metabolic diseases including type 2 diabetes, hyperlipidemia and NASH may include the development of compounds owned or controlled by Merck. Accordingly, if Merck terminates this collaboration it may prove difficult for us to continue development of such compounds. Similarly, our agreement with Idenix to develop and commercialize new products to treat hepatitis C infection may include the development of compounds owned or controlled by Idenix. Accordingly, if Idenix terminates this collaboration it may prove difficult for us to continue development of such compounds.

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 Daiichi Sankyo, Merck, Idenix 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,

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

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

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

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

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

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

- obtaining regulatory approval to commence a clinical trial,

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

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

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

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

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

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

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

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

- unforeseen safety issues, or

- lack of adequate funding to continue the clinical trial.

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

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significant revenues may be delayed. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate.

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

Daiichi Sankyo is currently responsible for conducting all potential future development of CS-917. Recent unfavorable clinical trial results related to CS-917 may impact the potential further future development of this product candidate. Although our collaborations with Merck and Idenix have not yet yielded product candidates, should they be successful, we will be dependent on Merck and/or Idenix, as applicable, to conduct the development of any resulting product candidates. At this time, we do not intend to independently develop pradefovir and will likely seek, and may therefore ultimately be dependent upon, a new collaborative partner for the further development and commercialization of this product candidate should we ultimately determine that such future development and commercialization is feasible. We intend to rely on other third parties, such as contract research organizations, medical institutions, clinical investigators and contract laboratories, to assist in the development of MB07803, MB07811, MB07133 and any other product candidates that we may develop for which a collaborator is not responsible for development. If Daiichi Sankyo, Merck, Idenix or these other third parties do not successfully meet their obligations under our agreements, or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to applicable protocols or for other reasons, clinical trials or other studies may be extended, delayed or terminated, and these product candidates may not receive regulatory approval or be successfully commercialized.

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

We used our NuMimetic technology to identify CS-917 and MB07803. We used our HepDirect technology to discover pradefovir, MB07811, MB07133 and have applied it in certain other programs as well. We intend to use these and future proprietary technologies to expand our product pipeline in the future. We also may leverage our HepDirect and other liver-targeting technology through strategic alliances and collaborations with other companies, such as our hepatitis C collaborations with Merck and Idenix in which we are applying our technology to certain Merck and Idenix compounds. Our proprietary technologies are subject to many of the same risks as our product candidates, including risks related to:

- obtaining and maintaining patent and trade secret protection for these technologies,
- avoiding infringement of the proprietary rights of third parties,
- the development of competing technologies by others, and
- in HepDirect s case, the safety and effectiveness of this technology in humans.

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

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

The clinical development, manufacturing, labeling, storage, record-keeping, advertising, promotion, export, marketing and distribution of our product candidates are subject to extensive regulation by the FDA and other regulatory agencies in the U.S. and by comparable governmental authorities in foreign markets. In the U.S., neither we, nor our collaborators, are permitted to market our product candidates until we or our collaborators receive approval of a New Drug Application, or NDA, from the FDA or receive similar approvals abroad. The process of obtaining these approvals is expensive, often takes many years, and can vary substantially based upon the type, complexity and novelty of the product candidates involved. Approval policies or regulations may change. In addition, as a company, we have not previously filed NDAs with the FDA or filed similar applications with other foreign regulatory agencies. This lack of experience may impede

our ability to obtain FDA or other foreign regulatory agency approval in a timely manner, if at all, for our product candidates for which development and commercialization is our responsibility.

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

- a product candidate may not be safe and effective,
- FDA or other foreign regulatory agency officials may not find the data from preclinical testing and clinical trials generated during development sufficient,
- the FDA or other foreign regulatory agency may not approve of our third-party manufacturers processes or facilities, or
- the FDA or other foreign regulatory agency may change its approval policies or adopt new regulations.

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

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

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

- issue warning letters or other notices of possible violations,
- impose civil or criminal penalties or seek disgorgement of revenue or profits,
- suspend regulatory approval,
- suspend any ongoing clinical trials,
- refuse to approve pending applications or supplements to approved applications filed by us or our collaborators,
- impose restrictions on operations, including costly new manufacturing requirements, or
- seize or detain products or require a product recall.

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

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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 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 CS-917 and/or MB07803 are ultimately determined safe and effective and approved for marketing, these products may compete for market share with established therapies from a number of competitors, including large pharmaceutical companies. Such marketed products include, but are not limited to the following classes:

- metformin a member of the biguanide drug class, related to guanidine and currently is the most widely prescribed first line therapy for type 2 diabetes,

- sulfonylureas increase the secretion of insulin by the pancreas, thereby lowering the level of the sugar glucose in the blood,

- insulins mimic insulin, the naturally occurring hormone made by the pancreas to control blood glucose levels,

- PPARs improve insulin sensitivity by activating certain genes involved in fat synthesis and carbohydrate metabolism,

- incretin mimetics lower glucose levels by increasing the levels of certain naturally occurring hormones from the pancreas, including glucagon-like peptide-1 or GLP-1, a peptide that facilitates the response of the pancreas and liver to fluctuations in glucose levels by its action on pancreatic beta and alpha cells. Compounds in this class include dipeptidyl peptidase IV or DPP-IV inhibitors, and BYETTA ® (exenatide) injection. DPP-IV is an enzyme in the bloodstream that cleaves and inactivates GLP-1. Inhibition of DPP-IV thus increases the half-life of endogenous GLP-1 by preventing cleavage and inactivation of GLP-1. BYETTA is an injectable medication that exhibits many of the same glucose regulating actions of GLP-1. The overall effect of these compounds is to enhance glucose-dependent insulin secretion and suppress inappropriate glucagon secretion,

- alpha-glucosidase inhibitors decrease the absorption of carbohydrates from the intestine, resulting in a slower and lower rise in blood glucose throughout the day,

- glinides stimulate the pancreas beta-cells to produce insulin, and

- combination therapies combines metformin with members of several of the above-mentioned classes, particularly sulfonylureas and PPARs.

Metformin is a drug that inhibits liver glucose production like CS-917 and MB07803 but does so through an unknown mechanism. Because it does not cause weight gain, metformin is often prescribed as a first line therapy to obese patients with type 2 diabetes, who are reported to comprise more than 90% of patients newly diagnosed with type 2 diabetes. Generic forms of metformin have recently become available. Accordingly, unless CS-917 and MB07803 demonstrate significant benefits when compared to metformin or demonstrate that they can be used in the patient population who do not tolerate and/or adequately respond to metformin treatment, the price required to effectively compete with

the generic form of metformin may be so low that it becomes uneconomical to market CS-917 or MB07803. Moreover, if the combination of

CS-917 with metformin is contraindicated for safety reasons the market potential of CS-917 could be reduced and/or selling expenses could be increased. Should CS 917 eventually be approved and combination with metformin remains an issue, the FDA may require additional measures be taken during marketing, such as prominent warning labels known as black-box warnings, physician education programs and/or other steps to restrict concomitant use of CS-917 and metformin.

In addition, many companies are developing novel therapies that target diabetes. These companies may develop and introduce products competitive with or superior to CS-917 and/or MB07803.

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 mimic interferon, the naturally occurring infection-fighting immune substance produced by the body,
- nucleoside analogues chemically engineered nucleoside compounds that are converted inside cells into other compounds that are structurally similar to the building blocks of DNA and RNA that interfere with the replication of HBV, and
- nucleotide analogues chemically engineered nucleotide compounds that are converted inside cells into other compounds that are structurally similar to the building blocks of DNA and RNA that interfere with the replication of HBV.

A competitor to pradefovir may be Hepsera (adefovir dipivoxil), which is a nucleotide analogue currently marketed in the U.S. and Europe by Gilead Sciences, Inc. Pradefovir and Hepsera are prodrugs of the same active drug, and therefore may directly compete. In order to effectively compete with Hepsera, pradefovir may have to be significantly more beneficial or less expensive than Hepsera. In addition, marketed products approved to treat HIV infections are being evaluated for their effectiveness in treating hepatitis B infections.

There are no currently approved drugs for primary liver cancer. However, some companies are developing novel therapies specifically for primary liver cancer. Nexavar (sorafenib), a chemotherapy approved for the treatment of kidney cancer, has been submitted for approval for the treatment of patients with primary liver cancer and it may experience off-label use prior to its approval.

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.

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 reduce serum cholesterol levels by inhibiting a key enzyme involved in the biosynthesis of cholesterol,
- fibrates reduce the amount of cholesterol and triglycerides (fatty substances) in blood,
- nicotinic acid derivatives lower cholesterol, triglycerides and low density lipoproteins and increase high density lipoproteins,
- CAIs inhibit the absorption of dietary and biliary cholesterol,
- bile acid sequestrants bind with cholesterol-containing bile acids in the intestines and remove them in bowel movements, and
- statin combination therapies combine statins with members of the above-mentioned classes, particularly CAIs.

Several large pharmaceutical companies are also developing novel therapies that target hyperlipidemia. These companies may develop and introduce products competitive with or superior to MB07811. Lipitor (atorvastatin; a statin

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

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

Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, clinical trials, regulatory approvals and marketing approved products than we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Our competitors may succeed in developing technologies and therapies that are more effective, better tolerated or less costly than any which we are developing, or that would render our product candidates obsolete and noncompetitive. Our competitors may succeed in obtaining approvals from the FDA and foreign regulatory authorities for their products sooner than we do for ours. We will also face competition from these third parties in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, and in acquiring and in-licensing technologies and products complementary to our programs or advantageous to our business.

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

Our ability to develop and commercialize our products depends in part on our ability to manufacture, or arrange for collaborators or other third parties to manufacture, our products at a competitive cost, in accordance with regulatory requirements and in sufficient quantities for development and eventual commercialization. Daiichi Sankyo is currently responsible for all clinical and commercial manufacturing of CS-917. Recent unfavorable clinical trial results related to CS-917 may impact the potential further future development and ultimate manufacture, marketing and commercialization of this product candidate. At this time, we do not intend to independently develop pradefovir and will likely seek, and may therefore ultimately be dependent upon, a new collaborative partner for the clinical and commercial manufacture of this product candidate should we ultimately determine that future development and commercialization is feasible. We have relied on a number of suppliers to manufacture sufficient quantities of MB07803, MB07811 and MB07133 for use in our current 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 collaborators and third-party manufacturers may encounter difficulties with the small- and large-scale formulation and manufacturing processes required to manufacture our product candidates, resulting in delays in our clinical trials development and regulatory submissions, in the commercialization of our product candidates or, if any of our product candidates is approved, in the recall or withdrawal of the product from the market. Further, development of large-scale manufacturing processes may require additional validation studies, which the FDA and other foreign regulatory agencies must review and approve. Our inability to enter into or maintain agreements with collaborators or capable third-party manufacturers on acceptable terms could delay or prevent the commercialization of our products, which would adversely affect our ability to generate revenues and could prevent us from achieving or maintaining profitability.

We currently expect that in any future development activities related to MB07803, MB07811 and MB07133, we will rely on our current suppliers to manufacture these compounds. However, we do not have long-term supply agreements with these third parties, and we may not be able to enter into new supply agreements with them in a timely manner or on acceptable terms, if at all. These third parties may also be subject to capacity constraints that would cause them to limit the amount of these compounds that we can purchase. While we believe alternative sources to manufacture these compounds are readily available, in the event we have to seek such alternative sources we will incur costs associated with identifying and qualifying one or more alternate suppliers. In addition, any resulting interruption or delay we experience in the supply of MB07803, MB07811 or MB07133 may impede the development of these compounds.

In addition, we, our collaborators or other third-party manufacturers of our products must comply with current good manufacturing practices, or CGMP, requirements enforced by the FDA and other foreign regulatory agencies through their facilities inspection programs. These requirements include quality control, quality assurance and the maintenance of records and documentation. In addition, product manufacturing facilities in California are subject to licensing requirements of the California Department of Health Services and may be inspected by the California Department of Health Services, and other applicable regulatory authorities, at any time. We, our collaborators or other third-party manufacturers of our products may be unable to comply with these CGMP requirements and with other FDA, state and foreign regulatory requirements. We have

little control over third-party manufacturers compliance with these regulations and standards. A failure to comply with these requirements may result in fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure or recall, or withdrawal of product approval.

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

We do not have a sales and marketing organization, and we have no experience as a company in the sales, marketing and distribution of pharmaceutical products. Daiichi Sankyo is currently responsible for worldwide marketing and commercialization for CS-917, although we have an option to co-promote CS-917 in North America with Daiichi Sankyo. Recent unfavorable clinical trial results related to CS-917 may impact the potential further future development and ultimate manufacture, marketing and commercialization of this product candidate. At this time, we do not intend to independently develop pradefovir and will likely seek, and may therefore ultimately be dependent upon, a new collaborative partner for the worldwide marketing and commercialization of this product candidate should we ultimately determine that future development and commercialization is feasible. Although our hepatitis C and metabolic disease collaborations with Merck have not yet yielded product candidates, should they be successful, Merck will be responsible for worldwide marketing and commercialization of any resulting product candidates (subject to, in the case of our metabolic disease collaboration, our option to co-promote the product in the U.S. with certain financial assistance from Merck). Similarly, should our hepatitis C collaboration with Idenix be successful, Idenix will be responsible for worldwide marketing and commercialization of any resulting product candidates. In order to co-promote any of these products, or to commercialize MB07803, MB07811, MB07133 or any future product candidates, we must develop our sales, marketing and distribution capabilities, or make arrangements with a third party to perform these services. Even though we may receive financial assistance from Merck if we exercise our U.S. co-promotion option under the metabolic disease collaboration, developing a sales force for any resulting product or any product resulting from any of our other product candidates is expensive and time consuming and could delay any product launch. We may be unable to establish and manage an effective sales force in a timely or cost-effective manner, if at all, and any sales force we do establish may not be capable of generating sufficient demand for our product candidates. To the extent that we enter into arrangements with collaborators or other third parties to perform sales and marketing services, our product revenues are likely to be lower than if we directly marketed and sold our product candidates. If we are unable to establish adequate sales and marketing capabilities, independently or with others, we may not be able to generate significant revenues and may not become profitable.

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,

- effectiveness of our or our partners sales and marketing strategy, and
- our ability to obtain sufficient third-party coverage or reimbursement.

If approved, CS-917 may have to be administered several times daily. Additionally, it may result in variable drug levels in different patient populations, which could complicate its use and limit its marketability. Since CS-917 is eliminated

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from the body through the kidney, it may be of limited use in type 2 diabetes patients with kidney dysfunction. In addition, CS-917 and HepDirect prodrugs such as pradefovir, MB07133 and MB07811 may also exhibit interactions with other marketed drugs that could limit their combination with those drugs. Serious adverse events observed in early 2005 in a Phase 1 clinical trial of CS-917 in combination with metformin have raised questions about the safety of the potential use of CS-917 and metformin in combination. Therefore, even if CS-917 receives regulatory approval, its combination with metformin may be restricted which may reduce its market potential. In addition, various risk management strategies may be required to minimize inadvertent use with metformin including prominent warning labels known as black-box warnings, physician education programs and/or other steps designed to more tightly control the sale and use of CS-917. Such strategies and programs, if required, will likely adversely impact the sales of CS-917 and may incur additional selling expenses thereby reducing profits. While MB07803 has not demonstrated the same metformin interaction risk in clinical trials to date, it may exhibit the same metformin interaction risk and thus may be subject to the same market potential limitations as CS-917. In addition, primarily because the number of treatable patients in the U.S. with primary liver cancer is relatively small, we expect to market MB07133, if approved, at a relatively high price in the U.S. in order to generate sufficient revenues to recoup our costs and provide a return on our investment. This could limit or prevent us from achieving the market acceptance of MB07133 in the U.S. The number of treatable patients outside of the U.S. is much larger than the number of treatable patients in the U.S. However, because third party reimbursement in many of these countries is uncertain, we may be unable to recoup our costs or generate sufficient returns on our investment in these countries. If any of our product candidates is approved but does not achieve an adequate level of acceptance by physicians, healthcare payors and patients, we may not generate sufficient revenue from this product candidate and we may not become or remain profitable.

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

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

- our ability to set a price we believe is fair for our products,
- our ability to generate revenues and achieve or maintain profitability,
- the future revenues and profitability of our potential customers, suppliers and collaborators, and
- the availability of capital.

In certain foreign markets, the pricing of prescription drugs is subject to government control. In the U.S., given recent federal and state government initiatives directed at lowering the total cost of health care, Congress and state legislatures will likely continue to focus on health care reform, the cost of prescription drugs and the reform of the Medicare and Medicaid systems. For example, 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 this legislation, it is possible that the new Medicare prescription drug benefit, which will be managed by private health insurers and other managed care organizations, will result in decreased reimbursement for prescription drugs, which may further exacerbate industry-wide pressure to reduce prescription drug prices. This could harm our ability to market our products and generate revenues. It is also possible that other similar proposals will be adopted.

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

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

Since we became an independent company in 1999, we have increased the number of our full-time employees from 50 to 129 as of June 30, 2007. We may need to decrease the number of our full-time employees in the future in response to adverse business events. Reducing our workforce may lead to additional unanticipated attrition. If our future staffing is inadequate because of additional unanticipated attrition or because we failed to retain the staffing level required to accomplish our business objectives we may be delayed or unable to continue the development or commercialization of our product candidates, which could impede our ability to generate revenues and achieve or maintain profitability.

Alternatively, we may need to continue to expand our managerial, operational, financial and other resources in order to manage and fund our operations and clinical trials, continue our research and development and collaborative activities, and commercialize our product candidates. It is possible that our management and scientific personnel, systems and facilities currently in place may not be adequate to support this potential future growth. Our need to effectively manage our operations, potential future growth and various projects requires that we continue to improve our operational, financial and management controls, reporting systems and procedures and to attract and retain sufficient numbers of talented employees. We may be unable to successfully implement these tasks on a larger scale and, accordingly, may not achieve our research, development and commercialization goals.

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

Our success depends on our continued ability to attract, retain and motivate highly qualified management and scientific personnel. The loss of the services of certain principal members of our management or scientific staff could delay or prevent the commercialization of our product candidates. We employ these individuals on an at-will basis and their employment can be terminated by us or them at any time, for any reason and with or without notice, subject to the terms of their stock restriction agreements and severance agreements.

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

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

We have limited experience in identifying, completing and integrating acquisition targets, and if we do not successfully integrate any future acquisitions, we may incur unexpected costs and disruptions to our business.

An important part of our business strategy is to continue to develop a broad pipeline of product candidates. In addition to our internal drug development efforts, we may seek to expand our product pipeline, at the appropriate time and as resources allow, by acquiring products or businesses or in-licensing technologies that we believe are a strategic fit with our business and complement our existing product candidates and research programs. Future acquisitions, however, may entail numerous operational and financial risks including:

- exposure to unknown liabilities,
- disruption of our business and diversion of our management s time and attention to developing acquired products or technologies,
- incurrence of substantial debt or dilutive issuances of securities to pay for acquisitions,
- higher than expected acquisition and integration costs,

- increased amortization expenses,
- difficulty and cost in combining the operations and personnel of any acquired businesses with our operations and personnel,
- impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership, and
- inability to retain key employees of any acquired businesses.

We have limited experience in identifying acquisition targets, successfully completing potential acquisitions and integrating any acquired products, businesses or technologies into our current infrastructure. Moreover, we may devote resources to potential acquisitions that are never completed or fail to realize the anticipated benefits of any acquisition.

Risks Related to our Finances and Capital Requirements

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

We have incurred net losses from our inception. As of June 30, 2007, we had an accumulated deficit of approximately $128.7 million. Due to recent unfavorable clinical trial results related to CS-917 and Schering-Plough s decision to terminate our strategic collaboration for the development and commercialization of pradefovir, we have taken certain actions to control costs and may institute others. We are unable at this time to determine what overall impact these events will have on our ongoing business strategy.

Should we ultimately determine it is in our stockholders interests to do so, we may need to increase our operating expenses over the next several years if we continue and expand our research and development activities, including conducting clinical trials for our product candidates and further developing our product pipeline, acquiring or in-licensing products, technologies or businesses, and funding other working capital and general corporate purposes. As a result, we may incur significant and increasing operating losses for the foreseeable future. Because of the numerous risks and uncertainties associated with our product development efforts, we are unable to predict the extent of any future losses or when we will become profitable, if ever.

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

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

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

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

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

We 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 12 months. 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 costs of expanding our operations,
- the terms and timing of any collaborative, licensing and other arrangements that we may establish,
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights,
- the costs and timing of regulatory approvals,
- the costs of establishing or contracting for sales and marketing capabilities,
- the effect of competing technological and market developments, and
- the extent to which we acquire or in-license new products, technologies or businesses.

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

We cannot be certain that additional funding will be available on acceptable terms, or at all. If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate one or more of our research and development programs or our commercialization efforts and we may be unable to continue as a going concern.

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

We may raise additional funds through public or private equity offerings, our CEFF with Kingsbridge Capital Limited, debt financings, grants or corporate collaboration and licensing arrangements. For example, we have effective shelf registration statements on file with the Securities and Exchange Commission which allow us to issue shares of our common stock and warrants to purchase our common stock in the future for an aggregate initial offering price of up to $75 million.

We have also filed a registration statement with the Securities and Exchange Commission covering the resale of shares issuable under the CEFF though to date, no shares have been issued under this resale registration statement. We may sell additional securities from time to time in one or more offerings in amounts, at prices and on terms that we will determine at the time of the offering. To the extent that we raise additional capital by issuing equity securities, pursuant to our effective shelf registration statements or otherwise, our existing stockholders ownership will be diluted.

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

Our quarterly operating results and stock price may fluctuate significantly.

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

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

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

Our committed equity financing facility with Kingsbridge 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 Kingsbridge and may result in dilution to our stockholders.

In November 2006, we entered into the CEFF with Kingsbridge. The CEFF entitles us to sell and obligates Kingsbridge to purchase, from time to time over a period of 36 months, shares of our common stock for cash consideration up to an aggregate of $50.0 million, subject to specified conditions and restrictions. Kingsbridge will not be obligated to purchase shares under the CEFF unless specified conditions are met, which include a minimum price for our common stock; the accuracy of representations and warranties made to Kingsbridge; 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, Kingsbridge is permitted to terminate the CEFF by providing written notice to us within 10 business days after it obtains actual knowledge that an event has occurred resulting in a material and adverse effect on our business, operations, properties or financial condition (subject to specified exceptions, including conditions or events that are reasonably expected to occur in the ordinary course of our business). If we are unable to access funds through the CEFF, or if Kingsbridge 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 Kingsbridge to suspend the use of the prospectus covering the shares of common stock issued in connection with the CEFF and prohibit Kingsbridge 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 Kingsbridge, then we must make a payment to Kingsbridge, or issue Kingsbridge additional shares in lieu of this payment, calculated on the basis of a specified number of shares held by Kingsbridge 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 Kingsbridge 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 and may result in downward pressure on the price of our common stock. If we draw down amounts under the CEFF, we will issue shares to Kingsbridge at a discount of up to 10% from the volume weighted average price of our common stock. If we draw down amounts under the CEFF when our stock price is decreasing, we will need to issue more shares to raise the same amount than if our stock price was higher. Issuances in the face of a declining stock price will have an even greater dilutive effect than if our stock price were stable or increasing and may further decrease our stock price.

Risks Related to our Intellectual Property

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

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

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

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

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

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

- we might not have been the first to make the inventions covered by each of our pending patent applications and issued patents,
- we might not have been the first to file patent applications for these inventions,
- others may independently develop similar or alternative technologies or duplicate any of our technologies,
- it is possible that none of our pending patent applications will result in issued patents,
- our issued patents may not provide a basis for commercially viable products, may not provide us with any competitive advantages, or may be challenged by third parties,
- our issued patents may not be valid or enforceable,
- we may not develop additional proprietary technologies that are patentable, or
- the patents of others may have an adverse effect on our business.

Proprietary trade secrets and unpatented know-how are also very important to our business. Although we have taken steps to protect our trade secrets and unpatented know-how, including entering into proprietary information and inventions agreements with our employees and consultants and entering into confidentiality agreements with other third parties to whom

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we disclose our proprietary information, third parties may still obtain this information without our knowledge and consent. Enforcing a claim that a third party illegally obtained and is using our trade secrets or unpatented know-how is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the U.S. may be less willing to protect this information. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

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

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

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

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

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

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

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

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

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

We have conducted searches of U.S. and foreign patents, but cannot guarantee that the searches were comprehensive and therefore whether any of our product candidates or the methods of using, making or identifying our product candidates infringe the patents searched, or that other patents do not exist that cover our product candidates or these methods. There may also be pending patent applications that are unknown to us and may prevent us from marketing our product candidates. Other product candidates that we may develop, either internally or in collaboration with others, could be subject to similar delays and uncertainties.

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

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

Risks Related to Other Legal Matters

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

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

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

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials, and will face an even greater risk if we sell our product candidates commercially. For example, in March 2005 two cases of lactic acidosis were observed in a clinical trial combining CS-917 with metformin. As a result, unless further data changes the situation, the combination of CS-917 and metformin is contraindicated and the inadvertent combination of the drugs could put patients at risk for lactic acidosis. Therefore, even if CS-917 receives regulatory approval the FDA may require that additional measures be taken during marketing, such as prominent warning labels known as black-box warnings, physician education programs and/or other steps to restrict concomitant use of metformin and CS-917. However, none of these programs can be assured of eliminating the possibility of the inadvertent use of CS-917 with metformin and the consequent risk of lactic acidosis. Therefore, these programs may not effectively protect us from a liability claim.

An individual may bring a liability claim against us if one of our product candidates causes, or merely appears to have caused, an injury. If we cannot successfully defend ourselves against the product liability claim, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for our product candidates,
- injury to our reputation,
- withdrawal of clinical trial participants,
- costs of related litigation,
- substantial monetary awards to patients or other claimants,
- loss of revenues, and
- the inability to commercialize our product candidates.

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

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

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

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

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

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

- changes in the regulatory status of our product candidates, including the status and results of our development activities,
- events affecting Daiichi Sankyo, Merck, Idenix or any future collaborators,
- announcements of new products or technologies, commercial relationships or other events by us or our competitors,
- regulatory developments in the U.S. and foreign countries,
- fluctuations in stock market prices and trading volumes of similar companies,
- variations in our quarterly operating results,
- changes in securities analysts estimates of our financial performance,
- changes in accounting principles,
- issuances of new equity securities by us, pursuant to our effective shelf registration statements or otherwise,
- sales of large blocks of our common stock, including sales by our executive officers, directors and significant stockholders,
- additions or departures of key personnel, and
- discussion of us or our stock price by the financial and scientific press and in online investor communities.

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

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

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

There are numerous regulatory requirements for public companies, including the provisions of the Sarbanes-Oxley Act of 2002 and rules adopted or proposed by the Securities and Exchange Commission and by the Nasdaq Stock Market. With regard to the Sarbanes-Oxley Act, we have and will continue to incur significant expense as we continue to address the implications of applicable rules and our operations relative thereto, and as we work to respond to and comply with applicable requirements. Section 404 requires management to report on, and our independent auditors to attest to, our internal controls. These laws and regulations could make it more difficult or more costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers. We are presently evaluating and monitoring developments with respect to these laws and regulations and cannot predict or estimate the amount or timing of additional costs we may incur to respond to their requirements. Compliance with these rules could also result in continued diversion of management s time and attention, which could be disruptive to normal business operations. If we do not satisfactorily or timely comply with these requirements, possible consequences could include sanction or investigation by regulatory authorities such as the Securities and Exchange Commission or the Nasdaq Stock Market; fines and penalties; incomplete or late filing of our periodic reports, including our annual report on Form 10-K; or civil or criminal liability. Our stock price and business could also be adversely affected.

If our executive officers, directors and largest stockholders choose to act together, they may be able to control our operations and act in a manner that advances their best interests and not necessarily those of other stockholders.

Our executive officers, directors and holders of 5% or more of our outstanding common stock, beneficially owned approximately 67% of our common stock as of June 30, 2007. As a result, these stockholders, acting together, are able to control all matters requiring approval by our stockholders, including the election of directors and the approval of mergers or other business combination transactions. The interests of this group of stockholders may not always coincide with our interests or the interests of other stockholders, and they may act in a manner that advances their best interests and not necessarily those of other stockholders.

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 4,057,176 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, Kingsbridge is committed to purchase up to $50 million of our common stock over a 36 month period. Sales by these current and potential future stockholders or warrant holders of a substantial number of shares could significantly reduce the market price of our common stock.

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

None.

Item 3. Defaults Upon Senior Securities

None.

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

We held our 2007 Annual Meeting of Stockholders on June 1, 2007. As of the close of business on April 11, 2007, the record date for the Annual Meeting, there were 30,517,459 shares of our common stock entitled to vote, of which there were 20,059,362 shares present at the Annual Meeting in person or by proxy. At the Annual Meeting, our stockholders approved the following matters:

Proposal 1. Election of three directors to serve as Class III directors until our 2010 Annual Meeting of Stockholders. The vote for the nominees for Class III director was as follows:

David F. Hale. 19,948,468 shares were voted in favor of the nominee; 110,894 shares withheld their vote.

Paul K. Laikind, Ph.D. 20,040,054 shares were voted in favor of the nominee; 19,308 shares withheld their vote.

George F. Schreiner, M.D., Ph.D. 20,041,952 shares were voted in favor of the nominee; 17,410 shares withheld their vote.

Our Class I directors, Daniel D. Burgess, M.B.A. and Luke B. Evnin, Ph.D., continue in office until our 2008 Annual Meeting of Stockholders. Our Class II directors, Mark D. Erion, Ph.D., Arnold L. Oronsky, Ph.D. and William R. Rohn, continue in office until our 2009 Annual Meeting of Stockholders.

Proposal 2. Ratification of the selection by the Audit Committee of our Board of Directors of Ernst & Young LLP as our independent registered public accounting firm for the fiscal year ending December 31, 2007. 20,046,336 shares voted in favor of the proposal; 12,892 shares voted against the proposal; and 134 votes abstained.

Item 5. Other Information

None.

Item 6. Exhibits

Exhibit Number	**Description**
3.1(1)	Amended and Restated Certificate of Incorporation of the Company.
3.2(1)	Amended and Restated Bylaws of the Company.
4.1(1)	Form of Common Stock Certificate.
10.1	First Amendment dated April 27, 2007 to Amended and Restated Severance Agreement dated July 19, 2006 between Paul K. Laikind and the Company.
10.2	Severance Agreement dated April 27, 2007 between Edgardo Baracchini and the Company.
10.3	Severance Agreement dated April 27, 2007 between Howard Foyt and the Company.
10.4	Severance Agreement dated April 27, 2007 between Mark D. Erion and the Company.
10.5	Severance Agreement dated April 27, 2007 between John W. Beck and the Company.

31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

Indicates management contract or compensatory plan.

(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.

SIGNATURES

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

Date: August 3, 2007

By: /s/ John W. Beck

John W. Beck, C.P.A., Senior Vice President of Finance, Chief Financial Officer and Treasurer (Principal Financial and Accounting Officer)