METABASIS THERAPEUTICS INC
Form 10-Q
November 15, 2004

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended September 30, 2004.

OR

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

For the transition period from to .

Commission file number 000-50785

METABASIS THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**33-0753322**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

9390 Towne Centre Drive, **Building 300, San Diego, CA** (Address of principal executive offices)	**92121** (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. ý Yes o No

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Securities Exchange Act of 1934). o Yes ý No

The number of outstanding shares of the registrant s common stock, par value $0.001 per share, as of November 5, 2004 was 18,138,163

METABASIS THERAPEUTICS, INC.

FORM 10-Q

FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2004

TABLE OF CONTENTS

PART I - FINANCIAL INFORMATION

Item 1. Financial Statements

Metabasis Therapeutics, Inc.

Condensed Balance Sheets

(In thousands, except share and par value data)

	September 30, 2004 (Unaudited)	December 31, 2003 (Note)
Assets		
Current assets:		
Cash and cash equivalents	$ 32,811	$ 11,017
Short-term investments, available-for-sale	16,220	14,240
Accounts receivable	442	957
Other current assets	1,194	466
Total current assets	50,667	26,680
Property and equipment, net	2,225	1,727
Prepaid offering costs		504
Other assets	50	199
Total assets	$ 52,942	$ 29,110
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	$ 840	$ 767
Accrued liabilities	2,376	2,502
Deferred rent	81	
Deferred revenue, current portion	427	458
Current portion of capital lease obligations, net of discount	804	611
Total current liabilities	4,528	4,338
Deferred rent		122
Other long-term liabilities	3	4
Capital lease obligations, net of current portion and discount	1,392	1,209
Stockholders equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized:		
Convertible preferred stock, $.001 par value; 5,000,000 and 74,765,759 shares authorized at September 30, 2004 (unaudited) and December 31, 2003, respectively; 0 and 63,631,738 shares issued and outstanding at September 30, 2004 (unaudited) and December 31, 2003, respectively.		64
Common stock, $.001 par value; 100,000,000 and 129,840,390 shares shares authorized at September 30, 2004 (unaudited) and December 31, 2003, respectively; 18,138,163 and 1,772,608 shares issued and oustanding at September 30, 2004 (unaudited) and December 31, 2003, respectively.	18	2
Additional paid-in capital	98,435	65,255

Deferred compensation		(5,819)		(5,485)
Accumulated deficit		(45,590)		(36,393)
Accumulated other comprehensive loss		(25)		(6)
Total stockholders equity		47,019		23,437
Total liabilities and stockholders equity	$	52,942	$	29,110

See accompanying notes.

Note: The balance sheet at December 31, 2003 has been derived from the audited financial statements at that date but does not include all of the information and footnotes required by U.S. generally accepted accounting principles for complete financial statements.

Metabasis Therapeutics, Inc.

Condensed Statements of Operations

(In thousands, except per share data)

(Unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2004	2003	2004	2003
Revenues:				
Sponsored research	$ 344	$	$ 1,032	$
Milestones			4,500	1,000
License fees	125	5,768	375	7,590
Other revenue	1	69	504	213
Total revenues	470	5,837	6,411	8,803
Operating expenses:				
Research and development	4,222	3,870	11,978	11,103
General and administrative	977	761	2,570	2,085
Amortization of employee stock- based compensation	439	65	1,195	167
Total operating expenses	5,638	4,696	15,743	13,355
(Loss) income from operations	(5,168)	1,141	(9,332)	(4,552)
Other income (expense):				
Interest income	176	30	306	140
Interest expense	(60)	(58)	(171)	(168)
Other, net		1		3
Total interest and other income (expense)	116	(27)	135	(25)
Net (loss) income	$ (5,052)	$ 1,114	$ (9,197)	$ (4,577)
Net (loss) income per share:				
Basic	$ (0.29)	$ 0.88	$ (1.24)	$ (3.11)
Diluted	$ (0.29)	$ 0.76	$ (1.24)	$ (3.11)
Shares used to compute net (loss) income per share:				
Basic	17,707	1,263	7,435	1,474
Diluted	17,707	1,458	7,435	1,474
The composition of employee stock-based compensation is as follows:				
Research and development	$ 305	$ 48	$ 833	$ 120
General and administrative	134	17	362	47
	$ 439	$ 65	$ 1,195	$ 167

See accompanying notes.

Metabasis Therapeutics, Inc.

Condensed Statements of Cash Flows

(In thousands)

(Unaudited)

	Nine months ended September 30,	
	2004	**2003**
Operating activities		
Net loss	$ (9,197)	$ (4,577)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization of deferred employee stock-based compensation	1,195	167
Amortization of deferred compensation on tendered shares	134	44
Deferred rent	(41)	(8)
Depreciation and amortization	508	404
Amortization of discount on equipment loan	10	11
Change in operating assets and liabilities:		
Accounts receivable	515	(4)
Other current assets	(728)	4
Other assets	149	
Deferred revenue	(31)	(7,633)
Accounts payable	73	(110)
Accrued liabilities and other long-term liabilities	(127)	155
Net cash flows used in operating activities	(7,540)	(11,547)
Investing activities		
Purchases of short-term investments	(17,370)	(4,630)
Sales/maturities of short-term investments	15,371	8,450
Purchases of property and equipment	(1,006)	(657)
Net cash flows (used in) provided by investing activities	(3,005)	3,163
Financing activities		
Issuance of common stock, net	31,973	38
Payments under capital lease obligations	(569)	(313)
Proceeds from capital lease obligations	935	762
Prepaid offering costs		(153)
Net cash flows provided by financing activities	32,339	334
Increase (decrease) in cash and cash equivalents	21,794	(8,050)
Cash and cash equivalents at beginning of year	11,017	12,080
Cash and cash equivalents at end of period	$ 32,811	$ 4,030
Supplemental schedule of noncash investing and financing activities:		
Shares tendered from stockholders for repayment of the principal and accrued interest of stockholder loans	$	$ 514
Conversion of convertible preferred stock to common stock upon initial public offering	$ 64	$

See accompanying notes.

Metabasis Therapeutics, Inc.

Notes to Condensed Financial Statements

(Unaudited)

1. Basis of Presentation

The accompanying unaudited condensed financial statements have been prepared in accordance with U.S. generally accepted accounting principles and with the rules and regulations of the Securities and Exchange Commission related to a quarterly report on Form 10-Q. Accordingly, they do not include all of the information and disclosures required by U.S. generally accepted accounting principles for complete financial statements. The balance sheet at December 31, 2003 has been derived from the audited financial statements at that date but does not include all information and footnotes required by U.S. generally accepted accounting principles for complete financial statements. The interim financial statements reflect all adjustments which, in the opinion of management, are necessary for a fair presentation of the financial condition and results of operations for the periods presented. Except as otherwise disclosed, all such adjustments are of a normal recurring nature.

Operating results for the three and nine months ended September 30, 2004 are not necessarily indicative of the results that may be expected for the year ending December 31, 2004. For further information, see the financial statements and notes thereto for the year ended December 31, 2003 included in the Prospectus filed by the Company pursuant to Rule 424(b) under the Securities Act of 1933, as amended (the Securities Act), with the Securities and Exchange Commission on June 15, 2004.

The preparation of financial statements in conformity with U.S. generally accepted accounting principles 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.

2. Stock-Based Compensation

The Company has elected to follow Accounting Principles Board Opinion No. 25 (APB 25), *Accounting for Stock Issued to Employees*, and related interpretations in accounting for its employee and director stock options. Under APB 25, if the exercise price of the Company s employee and director stock options equals or exceeds the estimated fair value of the underlying stock on the date of grant, no compensation expense is recognized. In conjunction with the Company s initial public offering completed in June 2004, the Company reviewed its historical exercise prices through June 15, 2004 and, as a result, revised the estimate of fair value for the stock underlying all stock options granted subsequent to June 30, 2002. With respect to employee and director options granted, the Company has deferred stock compensation balances of $5,331,000 and $4,862,000 at September 30, 2004 and December 31, 2003, respectively, for the difference between the original exercise price per share determined by the Board of Directors and the revised estimate of fair value per share at the respective grant dates. The weighted average exercise price for the 930,000 options granted to the Company s employees and directors during July 2002 through June 15, 2004 was $1.46. Deferred stock compensation is recognized and amortized on a straight-line basis over the vesting period of the related options, generally four years. Compensation expense related to stock options granted to the Company s employees and directors was $439,000 and $65,000 for the three months ended September 30, 2004 and 2003, respectively and $1.2 million and $167,000 for the nine months ended September 30, 2004 and 2003, respectively.

Options or stock awards issued to nonemployees have been valued in accordance with Statement of Financial Accounting Standards (SFAS) No. 123, *Accounting for Stock-Based Compensation*, and

Emerging Issues Task Force (EITF) Issue 96-18, *Accounting for Equity Instruments that are Issued to Other than Employees for Acquiring, or in Conjunction with Selling Goods or Services*, and expensed over the period the services are provided. Deferred charges for options granted to non-employees are periodically remeasured as the options vest.

As required under SFAS No. 123, the pro forma effects of stock-based compensation on net income or loss were estimated at the date of grant using the minimum-value method for all grants made through June 15, 2004, the effective date of the Company s registration statement for its initial public offering, and the Black-Scholes method thereafter. The Company became a public company on June 16, 2004, and accordingly began using the Black-Scholes valuation model in accordance with SFAS No. 123. The minimum-value method and the Black-Scholes valuation model were developed for use in estimating the fair value of publicly traded options that have no vesting restrictions and are fully transferable. Because the Company s employee and director stock options have characteristics significantly different from those of publicly traded options, and because changes in the subjective input assumptions can materially affect the fair value estimate, in management s opinion, these existing models do not necessarily provide a reliable single measure of the fair value of the Company s employee and director stock options.

For purposes of pro forma disclosures, the estimated fair value of the options is amortized to expense over the vesting period of such stock options. The Company s pro forma information is as follows:

	Three months ended September 30,		Nine months ended September 30,	
	2004	2003	2004	2003
	(in thousands, except per share amounts)			
Net (loss) income as reported	$ (5,052)	$ 1,114	$ (9,197)	$ (4,577)
Add: Stock-based employee compensation expense included in reported net (loss) income	439	65	1,195	167
Deduct: Stock-based employee compensation expense determined under fair value method	(562)	(83)	(1,319)	(237)
Pro forma net (loss) income	$ (5,175)	$ 1,096	$ (9,321)	$ (4,647)
Net (loss) income per share:				
Basic	$ (0.29)	$ 0.88	$ (1.24)	$ (3.11)
Diluted	$ (0.29)	$ 0.76	$ (1.24)	$ (3.11)
Pro forma net (loss) income per share:				
Basic	$ (0.29)	$ 0.87	$ (1.25)	$ (3.15)
Diluted	$ (0.29)	$ 0.75	$ (1.25)	$ (3.15)

3. Comprehensive Income or Loss

SFAS No. 130, *Reporting Comprehensive Income*, requires that all components of comprehensive income or loss, including net income or loss, be reported in the financial statements in the period in which they are recognized. Comprehensive income or loss is defined as the change in equity during a period from transactions and other events and circumstances from nonowner sources. The Company s comprehensive income or loss is as follows:

	Three months ended September 30,		Nine months ended September 30,	
	2004	2003	2004	2003
	(in thousands)			
Net (loss) income	$ (5,052)	$ 1,114	$ (9,197)	$ (4,577)
Unrealized (loss) gain on available for-sale investments	(11)	(4)	(19)	2
Comprehensive (loss) income	$ (5,063)	$ 1,110	$ (9,216)	$ (4,575)

4. Net Income or Loss Per Share

The Company calculated net income or loss per share in accordance with SFAS No. 128, *Earnings Per Share*. Basic earnings per share (EPS) is calculated by dividing the net income or 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 income or 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 earnings per share when their effect is dilutive. Common shares issued for nominal consideration (as defined), if any, would be included in the per share calculations as if they were outstanding for all periods presented. No common shares have been issued for nominal consideration.

The pro forma shares used to calculate pro forma basic and diluted EPS represent basic and diluted EPS, increased by the weighted average number of shares outstanding assuming conversion of all outstanding shares of preferred stock into shares of common stock using the as-of converted method as of the beginning of the period or the date of issuance, if later.

Actual and pro forma basic and diluted net income or loss per share were calculated as follows:

	Three months ended September 30,		Nine months ended September 30,	
	2004	2003	2004	2003
	(in thousands, except per share amounts)			
Actual:				
Numerator:				
Net (loss) income	$ (5,052)	$ 1,114	$ (9,197)	$ (4,577)
Denominator:				
Weighted average common shares	18,140	1,741	7,868	1,715
Weighted average unvested common shares subject to repurchase	(433)	(478)	(433)	(241)
Weighted average common shares - basic	17,707	1,263	7,435	1,474
Net effect of dilutive securities*				
Stock options		195		
Weighted average common shares - diluted	17,707	1,458	7,435	1,474
Net (loss) income per share:				
Basic	$ (0.29)	$ 0.88	$ (1.24)	$ (3.11)
Diluted	$ (0.29)	$ 0.76	$ (1.24)	$ (3.11)

* The net effect of dilutive stock options was not assumed for certain periods as the result would have been anti-dilutive.

	Three months ended September 30,		Nine months ended September 30,	
	2004	2003	2004	2003
	(in thousands, except per share amounts)			
Pro forma:				
Numerator:				
Pro forma net (loss) income	$ (5,052)	$ 1,114	$ (9,197)	$ (4,577)
Denominator:				
Weighted average common shares - basic	17,707	1,263	7,435	1,474
Pro forma adjustments to reflect assumed weighted average effect of conversion of preferred stock		7,088	6,973	7,088
Pro forma shares used to compute basic net (loss) income per share	17,707	8,351	14,408	8,562
Weighted average common shares - diluted	17,707	1,458	7,435	1,474
Pro forma adjustments to reflect assumed weighted average effect of conversion of preferred stock		7,088	6,973	7,088
Pro forma shares used to compute diluted net (loss) income per share	17,707	8,546	14,408	8,562
Pro forma net (loss) income per share:				
Basic	$ (0.29)	$ 0.13	$ (0.64)	$ (0.53)
Diluted	$ (0.29)	$ 0.13	$ (0.64)	$ (0.53)

5. Milestone Revenues

In March 2004, the Company earned $3.5 million for the achievement of the third developmental milestone under its collaboration agreement with Sankyo Company, Ltd, and in April 2004, the Company earned the second of two $1.0 million payments upon achievement of the second developmental milestone under its collaboration with Valeant Pharmaceuticals International.

6. Stockholders Equity

Initial Public Offering

On June 21, 2004, the Company completed an initial closing of its initial public offering in which it sold 5,000,000 shares of common stock for proceeds of $30.7 million, net of underwriting discounts and commissions and offering expenses. In addition, on July 20, 2004, the Company completed an additional closing of its initial public offering in which it sold an additional 75,000 shares of common stock pursuant to the exercise by the underwriters of an over-allotment option which resulted in proceeds of $0.5 million, net of underwriting discounts and commissions.

Authorized Capital Stock

On June 21, 2004, the Company filed an amended and restated certificate of incorporation to provide for authorized capital stock of 100,000,000 shares of common stock and 5,000,000 shares of preferred stock.

Convertible Preferred Stock

Effective immediately prior to the initial closing of the Company s initial public offering, shares of outstanding subordinated and Series A, C, D and E convertible preferred stock then outstanding were automatically converted into 11,043,949 shares of common stock.

Stock Split

On May 10, 2004, the Company effected a 1-for-6.075 reverse stock split of the outstanding common stock. The accompanying financial statements and these notes give retroactive effect to the reverse stock split for all periods presented.

Incentive Plans

On June 21, 2004, the Company completed the following actions:

the amendment and restatement of the Amended and Restated 2001 Equity Incentive Plan with a reserve of 2,213,995 shares of common stock,

the creation of the 2004 Non-Employee Directors Stock Option Plan with a reserve of 300,000 shares of common stock, and

the creation of the 2004 Employee Stock Purchase Plan with a reserve of 500,000 shares of common stock.

7. New Accounting Pronouncements

In March 2004, the Emerging Issues Task Force reached a consensus on Issue No. 03-1, *The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments*. EITF Issue No. 03-1 provides guidance on other-than-temporary impairment models for marketable debt and equity securities accounted for under SFAS No. 115, *Accounting for Certain Investments in Debt and Equity Securities.* The EITF developed a basic three-step model to evaluate whether an investment is other-than-temporarily impaired. The provisions of EITF Issue No. 03-1 were effective for the Company s third quarter of fiscal 2004 and subsequent fiscal periods and will be applied prospectively to all current and future investments. Quantitative and qualitative disclosures for investments accounted for under SFAS No. 115 are effective for the Company s fiscal year ending 2004 and subsequent fiscal periods. The adoption of EITF Issue No. 03-1 did not have a material effect on results of operations and financial condition.

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, 2003 included with our prospectus filed with the Securities and Exchange Commission pursuant to Rule 424(b)(4) of the Securities Act of 1933, as amended, on June 16, 2004. 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 small molecule drugs principally to treat metabolic diseases linked to pathways in the liver and to treat liver diseases. Examples of common metabolic diseases include diabetes, hyperlipidemia, a disease involving elevated levels of lipids such as cholesterol, and obesity. Since we became an independent company in 1999, we have established a broad and growing product pipeline targeting large markets with significant unmet medical needs.

We currently have three product candidates in clinical trials, CS-917, remofovir and MB07133, indicated for the treatment of type 2 diabetes, hepatitis B and primary liver cancer, respectively. In addition to our clinical stage programs, we have research programs focused on metabolic diseases linked to pathways in the liver such as type 2 diabetes, hyperlipidemia and obesity, as well as liver diseases such as hepatitis C and liver fibrosis. We believe our advanced research programs, which are research programs in which we have identified lead drug compounds and shown them to have efficacy in animal models, have the potential to yield additional clinical development candidates within the next two years. One of these advanced research programs recently yielded a compound, MB07803, that we recommended for clinical development. MB07803 is a clinical development candidate for the treatment of type 2 diabetes that works by the same mechanism as CS-917.

We have incurred annual net losses since inception. As of September 30, 2004, our accumulated deficit was approximately $45.6 million. We expect to incur substantial and increasing losses for the next several years as 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, 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 and equity investments from our collaborative partners. We have received

additional funding through equipment financing arrangements and Small Business Innovation Research, or SBIR, grants.

Our agreements with collaborators may include joint marketing or promotion arrangements of our products or products licensed from our collaborators. For example, we have retained co-promotion rights for CS-917 in North America. Alternatively, we may grant exclusive marketing rights to our collaborators in exchange for up-front fees, milestones and royalties on future sales, if any. We have licensed worldwide commercialization rights for remofovir to Valeant Pharmaceuticals International. We have retained worldwide commercialization rights to MB07133, MB07803 and all of the compounds generated from our current research programs, with the exception of hepatitis C product candidates covered by our collaboration with Merck & Co., 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 pre-clinical 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 compensation and other expenses for research and development personnel, costs associated with pre-clinical 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 trial of MB07133, the further advanced pre-clinical development of MB07803, and the research and development of the lead compounds in our other research programs. In September 2003, we initiated a Phase I clinical trial of MB07133 in the U.S. and Asia. We are responsible for all costs incurred in our research programs with the exception of the hepatitis C program partnered with Merck. Under the terms of our collaboration agreement with Merck, we had received approximately $1.4 million in research funding through September 30, 2004. Sankyo Company, Ltd. and Valeant are responsible for the costs of clinical development of CS-917 and remofovir, respectively.

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. 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 increase as we continue the development of our current product candidates, as well as continue and expand our research programs.

Generally, Phase I clinical trials can be expected to last from 6 to 18 months, Phase II clinical trials can be expected to last from 12 to 24 months and Phase III clinical trials can be expected to last from 18 to 36 months. However, clinical development timelines vary widely, as do

the likelihood of success and total costs of clinical trials. Although we are currently focused primarily on advancing MB07133 and MB07803

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, as well as an ongoing assessment of its market potential.

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 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 and other related costs for personnel in executive, finance, accounting, business development and human resource functions. Other costs include facility costs not otherwise included in research and development expenses and professional fees for legal and accounting services.

We anticipate continued increases in general and administrative expenses for investor relations and other activities associated with operating as a publicly-traded company. These increases will also likely include the hiring of additional personnel.

Other Income, Net

Other income, net includes interest earned on our cash, cash equivalents and short-term investments, net of interest expense.

Critical Accounting Policies

Our discussion and analysis of our financial condition and results of operations are based on our unaudited financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles, or GAAP, for interim information, and with the rules and regulations of the Securities and Exchange Commission related to a quarterly report on Form 10-Q. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. 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, 101, *Revenue Recognition in Financial Statements* and Emerging Issues Task Force, or EITF, Issue 00-21, *Revenue Arrangements with Multiple Deliverables*. SAB 101 and EITF Issue 00-21 provide guidance related to revenue recognition based on the

interpretations and practices developed by the Securities and Exchange Commission. Many of our agreements contain multiple elements, including downstream milestones and royalties. Revenue from milestones is recognized when earned, provided that:

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

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

If both of these criteria are not met, the milestone payment is recognized over the remaining minimum period of our performance obligations under the agreement. Upfront, nonrefundable fees under our collaborations are recognized over the period the related services are provided and may be deferred if the period of performance extends beyond an intervening balance sheet measurement date. Nonrefundable upfront fees not associated with our future performance are recognized when received. Amounts received for research funding are recognized as revenues as the services are performed. Amounts received for 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.

Recently Issued Accounting Pronouncements

In March 2004, the Emerging Issues Task Force reached a consensus on Issue No. 03-1, *The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments*. EITF Issue No. 03-1 provides guidance on other-than-temporary impairment models for marketable debt and equity securities accounted for under SFAS No. 115, *Accounting for Certain Investments in Debt and Equity Securities.* The EITF developed a basic three-step model to evaluate whether an investment is other-than-temporarily impaired. The provisions of EITF Issue No. 03-1 were effective for our third quarter of fiscal 2004 and subsequent fiscal periods and will be applied prospectively to all current and future investments. Quantitative and qualitative disclosures for investments accounted for under SFAS No. 115 are effective for our fiscal year ending 2004 and subsequent fiscal periods. The adoption of EITF Issue No. 03-1 did not have a material effect on results of operations and financial condition.

Results of Operations

Comparison of the Three Months Ended September 30, 2004 and 2003

Revenues. Revenues were $0.5 million for the three months ended September 30, 2004, compared with $5.8 million for the three months ended September 30, 2003. The $5.3 million decrease was mainly due to a decline in license fee revenue of approximately $5.6 million attributable to an exclusive option agreement we entered into with Sankyo in October 2002 and completed in the third quarter of 2003. This

decrease was partially offset by a $344,000 increase in sponsored research resulting from the initiation in 2004 of the research portion of our collaboration agreement with Merck.

Research and Development Expenses. Research and development expenses were $4.2 million for the three months ended September 30, 2004, compared with $3.9 million for the three months ended September 30, 2003. The $352,000 increase was mainly due to a $217,000 increase in development expenses related to MB07133.

General and Administrative Expenses. General and administrative expenses were $977,000 for the three months ended September 30, 2004, compared with $761,000 for the three months ended September 30, 2003. The $216,000 increase reflected mainly an increase in professional services expense of $81,000 and higher payroll and related benefits costs of $70,000.

Amortization of Employee Stock-based Compensation. In connection with the grant of stock options to employees and directors, we recorded amortization of deferred stock-based compensation of approximately $439,000 and $65,000 for the three months ended September 30, 2004 and 2003, respectively. We anticipate recording amortization of stock-based deferred compensation expense of approximately $527,000, $1.9 million, $1.9 million, $1.4 million and $128,000 for the three months ended December 31, 2004 and the years ended December 31, 2005, 2006, 2007 and 2008, respectively.

Other Income, Net. Net interest income was $116,000 for the three months ended September 30, 2004, compared to net interest expense of $27,000 for the three months ended September 30, 2003. The $143,000 net increase was mainly due to higher invested cash resulting from the proceeds of our initial public offering in June 2004.

Comparison of the Nine Months Ended September 30, 2004 and 2003

Revenues. Revenues were $6.4 million for the nine months ended September 30, 2004, compared with $8.8 million for the nine months ended September 30, 2003. The $2.4 million decrease was mainly due to a decline in license fee revenue of approximately $7.2 million attributable to an exclusive option agreement we entered into with Sankyo in October 2002 and completed in the third quarter of 2003. This decrease was partially offset by higher milestone revenue in the current year period, which included $3.5 million earned under our collaboration agreement with Sankyo. Additionally, we realized a $1.0 million increase in sponsored research resulting from the initiation in 2004 of the research portion of our collaboration agreement with Merck, and a $291,000 increase in other revenue mainly due to a SBIR grant awarded to us in September 2003.

Research and Development Expenses. Research and development expenses were $12.0 million for the nine months ended September 30, 2004, compared with $11.1 million for the nine months ended September 30, 2003. The $875,000 increase was mainly due to increased spending of $437,000 in payroll and related benefits, a $352,000 increase in clinical studies expense related to MB07133, and a $133,000 increase in lab supplies expense. These increases were partially offset by a $290,000 decrease in external services primarily related to MB07133.

General and Administrative Expenses. General and administrative expenses were $2.6 million for the nine months ended September 30, 2004, compared with $2.1 million for the nine months ended September 30, 2003. The $485,000 increase was primarily due to payroll and related benefits.

Amortization of Employee Stock-based Compensation. In connection with the grant of stock options to employees and directors, we recorded amortization of deferred stock-based compensation of approximately $1.2 million and $167,000 for the nine months ended September

30, 2004 and 2003, respectively.

Other Income, Net. Net interest income was $135,000 for the nine months ended September 30,

2004, compared to net interest expense of $25,000 for the nine months ended September 30, 2003. The $160,000 net increase was mainly due to higher invested cash resulting from the proceeds of our initial public offering in June 2004.

Liquidity and Capital Resources

On June 21, 2004, we completed an initial closing of our initial public offering in which we sold 5,000,000 shares of common stock for proceeds of $30.7 million, net of underwriting discounts and commissions and offering expenses. In addition, on July 20, 2004, we completed an additional closing of our initial public offering in which we sold an additional 75,000 shares of common stock pursuant to the exercise by the underwriters of an over-allotment option which resulted in proceeds of $0.5 million, net of underwriting discounts and commissions. Prior to our initial public offering, we financed our operations and internal growth primarily through private placements of preferred stock as well as direct payments of sponsored research funding, license fees, milestone payments and equity investments from our collaborative partners. Additional funding has come through equipment financing arrangements and via our receipt of SBIR grant funds.

As of September 30, 2004, we had financed through leases and loans the purchase of equipment and leasehold improvements totaling approximately $3.8 million, of which $2.2 million was outstanding at that date. During 2004, we had financed under these loans the purchase of equipment totaling approximately $935,000. The loans are collateralized with the purchased equipment, bear interest at rates ranging from approximately 8.6% to 12.1%, and are due in monthly installments through July 2008. Additionally, we have received cumulative SBIR grant funding of approximately $1.2 million through September 30, 2004.

As of September 30, 2004, we had $49.0 million in cash and cash equivalents and short-term investments available-for-sale as compared to $25.3 million as of December 31, 2003, an increase of $23.7 million. The increase mainly reflected net proceeds of $31.2 million raised following our initial public offering in June 2004, partially offset by net cash used in operations of $7.5 million due largely to our net operating loss of $9.2 million.

We anticipate investing approximately $0.5 million for the three months ending December 31, 2004 for capital equipment and leasehold improvements necessary to support our future growth.

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 our facilities to support our operations, to locate suitable replacement facilities and to relocate the company after our current sublease term expires,

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.

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.

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 offerings of our equity securities, cash payments under our strategic collaborations, debt financing arrangements and government grants. In addition, we may finance future cash needs through the sale of other equity securities, entering into additional strategic collaboration agreements, government grants and debt financing. 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 short-term investments resources 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. If we raise additional funds by issuing equity securities, substantial dilution to existing stockholders would likely result. If we raise additional funds by incurring debt financing, the terms of the debt may involve significant cash payment obligations as well as covenants and specific financial ratios that may restrict our ability to operate our business.

As of September 30, 2004, we did not have any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. In addition, we do not engage in trading activities involving non-exchange traded contracts. As such, we are not materially exposed to any financing, liquidity, market or credit risk that could arise if we had engaged in these relationships.

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, projec would 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 Risk Factors section below and in our other filings with the Securities and Exchange Commission, including our prospectus filed pursuant to Rule 424(b)(4) of the Securities Act of 1933 on June 16, 2004. 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.

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.

Risks Related to our Business

We are dependent on the success of one or more of our three 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 three current product candidates, CS-917, remofovir and MB07133. CS-917 demonstrated it was capable of significantly lowering blood glucose levels in two recently completed Phase II clinical trials in type 2 diabetics. Likewise, results of a study in patients treated with remofovir have provided a preliminary indication of efficacy. However, our product candidates will require additional development, clinical trials and regulatory clearances before they can be commercialized. Positive results from pre-clinical studies and early clinical trials do not necessarily mean later clinical trials will succeed. Before we can market these product candidates or MB07133, we will need to demonstrate that they are safe and effective in humans, and we will also need to obtain necessary marketing approval from the FDA, or similar foreign regulatory agencies. Our product development efforts may not lead to commercial drugs, either because our product candidates fail to be safe and effective in clinical trials or because we have inadequate financial or other resources to pursue our product candidates through the clinical trial process. 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 several years, if at all. Even if we were ultimately to receive regulatory approval for these product candidates, we may be unable to commercialize them successfully for a variety of reasons. These include, for example, the availability of alternative treatments, 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 three 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 clinical trials of our product candidates do not produce successful results, we will be unable to commercialize these products.

To receive regulatory approval for the commercialization of CS-917, remofovir, MB07133 or any other product candidates that we may develop, adequate and well-controlled clinical trials must be conducted to demonstrate safety and efficacy in humans to the satisfaction of the FDA in the U.S. and other regulatory agencies elsewhere in the world. In order to support marketing approval, these agencies typically require successful results in one or more Phase III clinical trials, which our current product candidates have not yet reached and may never reach. Clinical testing is expensive, can take many years

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

our clinical trials may produce negative or inconclusive results,

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

costs of our clinical trials 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 clinical trials of our product candidates may not devote sufficient resources to these trials or conduct them in a timely manner, or

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

Success in pre-clinical testing and early clinical trials does not mean that later clinical trials will be successful because product candidates in later-stage clinical trials may fail to demonstrate sufficient safety and efficacy despite having progressed through initial clinical testing. Companies frequently suffer significant setbacks in advanced clinical trials, even after earlier clinical trials have shown promising results. Our clinical experience with our product candidates is limited with tests in only a small fraction of the number of patients that will likely need to be studied to gain regulatory approval of these product candidates. 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.

The targeted endpoints for clinical trials of CS-917 and remofovir have been, and will continue to be, established by Sankyo and Valeant, respectively, with collaboration from us in the case of remofovir. We are solely responsible for establishing the targeted endpoints for clinical trials of MB07133. These targeted endpoints may be inadequate to demonstrate the safety and efficacy levels required for regulatory approvals. Even if we believe data collected from clinical trials 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, pre-clinical and clinical data 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.

The inhibition of gluconeogenesis, a metabolic pathway in the liver that is responsible for the excessive production of glucose by patients with type 2 diabetes, can cause elevated levels of lactic acid, or lactate, which, if high and sustained, under certain conditions can lead to lactic acidosis, a serious and potentially fatal condition. Certain pre-clinical trials have shown that CS-917 raises lactate levels two- to three-fold in some but not all animal models at glucose lowering doses. In a 14-day Phase II study of CS-917, two patients treated with the highest dose of CS-917, 400 milligrams, exhibited lactate levels above the normal range on each day they received CS-917. Lactate levels in both patients returned to normal levels prior to administration of the next scheduled dose. The other six patients in this dose group as well as patients administered lower doses of CS-917 showed lactate levels within the normal range. In a 28-day Phase II study 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 study. However, one patient who received 200 milligrams of CS-917 twice a day was withdrawn from the study by the investigator on day 15 due to concerns over consistently elevated lactate levels measured the previous day. Notwithstanding these early findings, we believe the pre-clinical and early clinical data suggests that a separation between those doses that effectively lower glucose levels from those doses that may cause significant and persistent lactic acid elevations above the normal range can be defined; however, we have not yet fully proven this separation and may not be able to do so. If we are unable to define this separation, it may prevent regulatory approval or commercialization.

It is also possible that CS-917 may cause other side effects. In certain pre-clinical studies, as expected based on the mechanism of the compound, 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 study that involved multi-day administration of the highest dose tested to date in patients (400 milligrams twice a day). This dose is above what is expected to be used in Phase III 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 and/or decreasing other glucose-producing mechanisms in the body, especially in elderly patients who are already prone to develop this condition. Some rodent models of diabetes studied in pre-clinical 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 clinical trials of CS-917 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. To date, studies of both remofovir and MB07133 have not demonstrated any byproduct-related toxicities. 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.

Undesirable side effects caused by our product candidates could interrupt, delay or halt clinical trials and could result in the denial of regulatory approval by the FDA or other regulatory authorities for any or all targeted indications, and in turn prevent us from commercializing our product candidates and generating revenues from their sale. 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,

we may be required to change the way the product is administered, conduct additional clinical trials, 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 dependent on our collaborations with Sankyo and Valeant for development of CS-917 and remofovir, respectively, and events involving these collaborations, our collaboration with Merck, or any future collaborations could prevent us from developing and commercializing our product candidates and achieving or sustaining profitability.

We have entered into collaborations with Sankyo and Valeant for the development and commercialization of CS-917 and remofovir, respectively. We have also entered into a collaboration with Merck to seek new products for the treatment of hepatitis C infection. Sankyo and Valeant have agreed to finance the clinical trials for these product candidates and, if they are approved, manufacture and market them. Accordingly, we are dependent on Sankyo and Valeant to gain FDA and other foreign regulatory agency approval of, and to commercialize, CS-917 and remofovir. Although our collaboration with Merck has not yet yielded a product candidate, should it be successful, we will be dependent on Merck for further development and commercialization. Also, 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 MB07133, we may need to enter into additional collaborative agreements to assist in the development and commercialization of some of these potential products. However, our discussions with potential collaborators may not lead to the establishment of new collaborations on acceptable terms, if at all.

We have limited control over the amount and timing of resources that Sankyo, Valeant, Merck 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. 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 would 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.

Our agreement with Sankyo contains certain rights and restrictions regarding our access to and use of confidential data and information generated by Sankyo. We are developing a second generation gluconeogenesis inhibitor that Sankyo has no rights to and that may be a direct competitor to CS-917. Because of this and with our consent, the transfer of confidential information and data related to CS-917 from Sankyo has already been reduced and we expect that further reductions in information flow will occur. This situation may limit our ability to provide information regarding clinical results unless they are publicly released by Sankyo, may limit our ability to influence decisions made at Sankyo regarding CS-917, may limit our ability to accurately track Sankyo s diligence on the development program and could lead to disagreements between Sankyo and us.

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,

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. For example, Sankyo is currently developing a second, unrelated product candidate for the treatment of type 2 diabetes known as CS-011. Sankyo may choose to focus its development efforts on this product candidate rather than CS-917. Also, if CS-011 receives marketing approval, it may compete with CS-917.

Because our collaboration with Merck involves Merck s proprietary compounds, if Merck terminates development of product candidates applying our HepDirect technology to those compounds, we may not have the right to pursue development of these product candidates on our own.

The objective of our collaboration with Merck is to develop product candidates for the treatment of hepatitis C by applying our HepDirect technology to certain Merck compounds. Accordingly, if Merck terminates our collaboration before a defined stage of development of a product candidate, which it may do without cause at any time after the end of the collaboration s research term upon 90 days advance written notice to us, we will not have any right to develop or commercialize that product candidate. In addition, if our collaboration with Merck terminates and Merck successfully develops products based on these proprietary compounds without applying our HepDirect technology, we will not be entitled

to milestone payments or royalties with respect to those products.

Further, under our collaboration agreement with Merck, we have agreed to work exclusively with Merck on research and development of compounds using our HepDirect technology for hepatitis C during the initial one-year research term and, at Merck s option, during an extended period thereafter. The only exception to this exclusivity obligation is our right to continue our internal hepatitis C research program, and Merck has an exclusive option during a defined period of time to license compounds resulting from this internal program. Consequently, if Merck terminates our collaboration, we may be at a significant disadvantage to our competitors in the research and development of treatments for hepatitis C as a result of having agreed to these restrictions on our internal efforts.

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 Sankyo, Valeant, Merck 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,

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.

For example, in 2003 we believed we had earned a milestone payment under our collaboration agreement with Sankyo and a milestone payment under our collaboration agreement with Valeant. As a result of discussions with Sankyo and Valeant, we agreed that these payments would be earned only upon completion of additional activities under these collaboration agreements. These activities have now been completed and the related milestone payments earned.

Our agreement with Sankyo contains certain rights and restrictions regarding our access to and use of confidential data and information generated by Sankyo. We are developing a second generation gluconeogenesis inhibitor that Sankyo has no rights to and that may be a direct competitor to CS-917. Because of this and with our consent, the transfer of confidential information and data related to CS-917 from Sankyo has already been reduced and we expect that further reductions in information flow will occur. This situation may limit our ability to provide information regarding clinical results unless they are publicly released by Sankyo, may limit our ability to influence decisions made at Sankyo regarding CS-917, may limit our ability to accurately track Sankyo s diligence on the development program and could lead to disagreements between Sankyo and us.

Our efforts to discover product candidates beyond CS-917, remofovir and MB07133 may not succeed, and any product candidates we recommend for clinical development may not actually begin clinical trials.

We intend to use our proprietary NuMimetic and HepDirect technologies and our knowledge and expertise to discover, develop and commercialize new products for the treatment of metabolic diseases linked to pathways in the liver and the treatment of liver diseases. Our goal is to expand our clinical development pipeline by recommending new drug compounds for clinical development. Once recommended for clinical development, we test a candidate to determine manufacturing methods, to measure its toxicity in animal models and to develop a suitable dosage form. A successful candidate would then be ready for human clinical testing. 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 compound suitable for recommendation for clinical development.

Moreover, any drug compounds we recommend for clinical development may not be effective or safe for their designated use, which would prevent their advancement into clinical trials and impede our ability to maintain or expand our clinical development pipeline. For example, in 1999, one of the drug compounds we previously recommended for clinical development was not advanced into clinical trials due to significant toxicity demonstrated in pre-clinical trials. 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 testing could result in increased costs to us and delay our ability to generate significant revenues.

Delays in the commencement or completion of clinical testing 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 in:

obtaining regulatory approval to commence a clinical trial,

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

manufacturing sufficient quantities of a product candidate,

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

recruiting and enrolling patients to participate in a clinical trial.

For example, clinical studies of product candidates targeting primary liver cancer have generally shown slow enrollment rates, and this may affect our ability to enroll patients in clinical trials of MB07133. 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 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 will increase, we may lose any competitive advantage associated with early market entry and our ability to generate significant revenues will 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 to conduct our clinical trials. 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.

Sankyo and Valeant are responsible for conducting clinical trials of CS-917 and remofovir, respectively. Although our collaboration with Merck has not yet yielded a product candidate, should it be successful, we will be dependent on Merck to conduct clinical trials of any resulting product candidate. We intend to rely on other third parties, such as contract research organizations, medical institutions, clinical investigators and contract laboratories, to conduct our clinical trials of MB07133 and other product candidates that we may develop for which a collaborator is not responsible for clinical development. If Sankyo, Valeant, Merck or these other third parties do not successfully meet their obligations under our agreements, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to clinical protocols or for other reasons, clinical trials 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 our HepDirect technology to discover remofovir and MB07133. We intend to use these and future proprietary technologies to expand our product pipeline in the future. We also plan to leverage our HepDirect technology through strategic alliances and collaborations with other companies, such as our collaboration with Merck in which we are applying our HepDirect technology to certain compounds Merck has studied for the treatment of hepatitis C. 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.

For example, HepDirect prodrugs are activated by an enzyme expressed predominantly in the liver which converts the prodrug to the biologically active form of the target drug. The levels of this enzyme in the liver vary across different patient populations and may also be reduced in patients with certain liver diseases. HepDirect prodrugs may demonstrate decreased efficacy and safety when used in patients exhibiting low levels of this liver enzyme. In addition, liver diseases that significantly decrease levels of this liver enzyme may not be susceptible to treatment using our HepDirect technology.

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 pre-clinical testing and clinical trials 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,

impose civil or criminal penalties,

suspend regulatory approval,

suspend any ongoing clinical trials,

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

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

seize or detain products or require a product recall.

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

If we and our collaborators fail to comply with applicable foreign regulatory requirements, we and our collaborators may be subject to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Our inability to timely secure the use of a facility beyond the expiration of our current sublease could increase our costs and delay or prevent the commercialization of our products.

We perform all of our research, development, management, administrative and other activities in a single facility, which we occupy under a sublease from Sicor. The term of the sublease expires in September 2005, and may expire earlier if the master lease for the facility is terminated. We do not have a contractual option to renew the sublease and we have no control over the early termination of the master lease. Prior to the termination of the sublease, we will need to locate and enter into a lease for an alternate facility. We cannot guarantee that we will be able to enter into a new lease in a timely manner or on acceptable terms, if at all. Any delay in securing the use of a suitable facility beyond the expiration of our current sublease could delay or prevent the commercialization of our products, increase our costs and adversely affect our ability to generate revenues, which could prevent us from achieving or maintaining profitability.

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. CS-917 will face significant competition from various formulations of metformin and products containing metformin. Metformin is a

drug that, like CS-917,

inhibits liver glucose production, albeit through an unknown mechanism. Because it does not cause weight gain, metformin is often prescribed as a first line therapy to obese diabetics, who are reported to comprise more than 90% of newly diagnosed type 2 diabetics. Metformin is currently marketed under the brand name Glucophage® by Bristol-Myers Squibb Company. Bristol-Myers-Squibb also markets Glucovance®, a single pill that contains both metformin and the insulin secretion enhancer glyburide. In addition, a less expensive generic form of metformin recently became available. Accordingly, unless CS-917 demonstrates a significant benefit over metformin, the price required to effectively compete with the generic form of metformin may be so low that it becomes uneconomical for us or Sankyo to market CS-917. Other competitors to CS-917 may include, but are not limited to, the insulin sensitizers Actos® (pioglitazone), co-marketed by Takeda Chemical Industries, Ltd. and Eli Lilly and Company, Avandia® (rosiglitazone), marketed by GlaxoSmithKline PLC, and other products that may be developed from time to time. GlaxoSmithKline has combined metformin and Avandia in a single pill called Avandamet®.

Competitors to remofovir may include, but are not limited to: Intron® A (interferon alfa-2b), marketed by Schering-Plough Corporation, Epivir-HBV® and Zeffix (lamivudine), marketed by GlaxoSmithKline, or Hepsera (adefovir dipivoxil), marketed in the U.S. by Gilead Sciences, Inc. Remofovir and Hepsera are prodrugs of the same active drug, and therefore will directly compete. In order to effectively compete with Hepsera, remofovir will have to be significantly more beneficial or less expensive than Hepsera.

There are no currently approved drugs for primary liver cancer. However, there are potential competitors and treatments which may include, but are not limited to: Amgen Inc., which is developing a product candidate called T67 currently in Phase II/III trials for the treatment of primary liver cancer, Eximias Pharmaceutical Corporation which is developing a product candidate called Thymitaq® currently in Phase III trials for the treatment of primary liver cancer and other products that may be developed from time to time. We will also compete with non-surgical therapies that use microscopic beads injected through a catheter directly into the liver to deliver radiation to primary liver cancer tumors, such as TheraSphere®, a product marketed by MDS Nordion, or SIR-Spheres®, a product marketed by Sirtex Medical Limited.

In addition, many other competitors 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, pre-clinical 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,

30

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 clinical testing and eventual commercialization. Sankyo and Valeant are responsible for all clinical and commercial manufacturing of CS-917 and remofovir, respectively. For example, we have relied on Raylo Chemicals, Inc. to manufacture sufficient quantities of MB07133 for use in our current clinical trial. Although none of our current product candidates has been manufactured on a commercial scale, Raylo has manufactured other companies products on a commercial scale. However, we have not yet determined if Raylo is capable of manufacturing our products on a commercial scale. Similarly, we rely on outside manufacturing for MB07803. 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 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 future clinical trials of MB07133, we will rely on Raylo to manufacture MB07133. 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 MB07133 or these chemicals that we can purchase. While we believe alternative sources to manufacture MB07133 and to produce chemicals needed to manufacture MB07133 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. We cannot estimate these costs with certainty but do not expect them to be material. In addition, any resulting interruption or delay we experience in the supply of MB07133 or the chemicals needed to manufacture MB07133 may impede MB07133 s clinical development.

In addition, we, our collaborators or other third-party manufacturers of our products must comply with current good manufacturing practice, 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 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. Sankyo and Valeant are responsible for worldwide marketing and commercialization for CS-917 and remofovir, respectively, although we have an option to co-promote CS-917 in North America with Sankyo. Although our collaboration with Merck has not yet yielded a product candidate, should it be successful, Merck will be responsible for worldwide marketing and commercialization of any resulting product candidate. In order to co-promote CS-917 in North America, or commercialize 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. Developing a sales force 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, health care 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, health care 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,

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.

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 from the body through the kidney, it may be of limited use in diabetics with kidney dysfunction. Also, CS-917 and HepDirect prodrugs such as remofovir and MB07133 may also exhibit interactions with other marketed drugs that could limit their combination with those drugs. 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 prevent us from achieving 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 payors of health care costs to contain or reduce costs of health care may adversely affect:

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

our ability to generate revenues and achieve or maintain profitability,

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 was recently enacted. This legislation provides a new Medicare prescription drug benefit beginning 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. The new Medicare prescription drug benefit or any similar proposals may particularly harm our ability to commercialize MB07133 because we expect that we will market MB07133, if approved, at a relatively high price in order to generate sufficient revenues to recoup our costs and provide a return on our investment, given the relatively small number of treatable patients in the U.S. with primary liver cancer.

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 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 will need to increase the size of our organization, and we may experience difficulties in managing growth.

Since we became an independent company in 1999, we have increased the number of our full-time employees from 50 to 84 as of September 30, 2004. We will 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 future growth. Our need to effectively manage our operations, 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 any principal member of our management or scientific staff, particularly Paul K. Laikind, Ph.D., our Chairman of the Board, Chief Executive Officer and President, and Mark D. Erion, Ph.D., our Executive Vice President of Research and Development, 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. We maintain a key man insurance policy in the amount of $1 million for each of Drs. Laikind and Erion.

Competition for qualified personnel in the biotechnology field is intense. We will need to hire additional personnel as we continue to expand our manufacturing, research and development activities. 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. We are not currently a party to any agreements or commitments and we have no understandings with respect to any such acquisitions. 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 at all.

We have incurred net losses from our inception. As of September 30, 2004, we had an accumulated deficit of approximately $45.6 million. We expect to increase our operating expenses over the next several years as 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 expect to continue to 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 at all.

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 clinical trials 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 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.

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. 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 facilities to support our operations, to locate suitable replacement facilities and to relocate the company after our current sublease term expires,

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 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.

Raising additional funds by issuing securities or through collaboration and licensing arrangements may 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, debt financings or corporate collaboration and licensing arrangements. To the extent that we raise additional capital by issuing equity securities, our existing stockholders ownership will be diluted. Any debt financing we enter into may involve covenants that restrict our operations. These restrictive covenants may include limitations on additional borrowing, specific restrictions on the use 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,

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, and

our execution of collaborative, licensing or other arrangements, and the timing of payments we may make or receive under these arrangements.

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.

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 trade secret protection of our product candidates, proprietary technologies and their uses, as well as successfully defending these patents against third-party challenges. We will 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 patent positions of 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 remofovir and MB07133, if approved, will be marketed in foreign countries with high incidences of hepatitis B and primary liver cancer, respectively, such as China and other Asian countries. 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. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our patents or in third-party patents.

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

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

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

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

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

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

our issued patents may not be valid or enforceable,

we may not develop additional proprietary technologies that are patentable, or

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

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

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

Our commercial success also 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 remofovir in the future.

Our product candidate remofovir 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. Adefovir is covered by U.S. and foreign patents that are scheduled to expire in April 2006. On their face, these patents are assigned to Gilead. We currently anticipate that, if approved, remofovir will not be commercialized until after April 2006, and therefore should not infringe upon these patents. However, in some cases, the terms of U.S. and foreign patents covering drug products approved for commercialization may be extended if the holder of the patents requests an extension within a specified period following the date of regulatory approval and the request for extension is approved by the appropriate agencies. We are not aware that the term of the U.S. patents covering adefovir was extended following regulatory approval of Hepsera in the U.S., and the period in which extensions may have been requested has ended. The extension of any patent covering adefovir may prevent the commercialization of remofovir in the relevant country until the expiration of the extended patent term, unless we or Valeant obtained a license to this patent. We are not aware of any request for an extension of patents covering adefovir in Europe.

We are aware of third party patents and patent applications in European and other foreign countries with claims to prodrugs of adefovir. These patents are scheduled to expire in September 2011. Although we do not believe that any valid claim covers remofovir, we cannot guarantee this. If it is determined that patent claims are valid and cover remofovir, we may not be able to commercialize remofovir in foreign countries, including those in Europe. Further, we are aware that a patent term extension of one of these prodrug patents has been requested in one or more European countries based on the regulatory approval of Hepsera. If the extension request is granted, the patents would expire in September 2016. If granted, this extension may have an adverse impact on the commercialization of remofovir in any such country if it is determined that the patent claims are valid and cover remofovir. Additional third party patents covering Hepsera or adefovir may exist, and may expire later than April 2006 in the U.S. and later than 2011 in foreign countries.

Risks Related to Other Legal Matters

We may incur significant costs complying with environmental laws and regulations, some of which we have previously violated.

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.

In February 2000, August 2001 and October 2002, we underwent routine inspections in which county authorities identified violations of county and state health and safety codes. In November 2001, we underwent an inspection, and in February 2002 we received a warning letter, in which the federal Environmental Protection Agency identified violations of federal waste management and environmental regulations. To date, no penalties have been imposed against us as a result of these county, state and federal violations, which we believe we have corrected in a satisfactory and timely manner. However, we cannot guarantee that we will not incur fines or damages as a result of these violations, or that we will not be required to take additional corrective actions. We may also incur significant costs complying with environmental laws and regulations adopted in the future.

The radioactive isotopes and compounds we use can cause radiation contamination to our facility. State and federal laws require that before permanently leaving a facility in which radioactive materials have been used, the user of the radioactive materials must make certain that the facility passes a series of tests known as decommissioning. The decommissioning process is highly regulated and may be expensive. When, upon the expiration of our current sublease on or before September 2005, we move to an alternate facility, we may face substantial costs in the decommissioning of our current facility. The decommissioning process may also prevent us from moving to an alternate facility in a timely manner, which could increase our costs and delay or prevent the commercialization of our products.

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

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

decreased demand for our product candidates,

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. However, we do not carry specific biological or hazardous waste insurance coverage and 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. Accordingly, in the event of contamination or injury, we could be held liable for damages or penalized with fines in an amount exceeding our 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 part because our shares have only recently been traded publicly. 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 results of our clinical trials,

events affecting Sankyo, Valeant, Merck 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,

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 acquirors 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 may incur increased costs as a result of recently enacted and proposed changes in laws and regulations relating to corporate governance matters.

Recently enacted and proposed changes in the laws and regulations affecting 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, will result in increased costs to us as we continue to evaluate the implications of these laws and regulations and respond to their requirements. 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.

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 68% of our common stock as of September 30, 2004. 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.

Our current stockholders hold a substantial number of shares of our common stock that they will be

able to sell in the public market in the near future. In addition, we have outstanding warrants to purchase 1,347,176 shares of common stock that, if exercised, will result in these additional shares becoming available for sale. A large portion of these shares and warrants are held by a small number of persons and investment funds. Sales by these stockholders or warrant holders of a substantial number of shares could significantly reduce the market price of our common stock. Moreover, the holders of 11,043,949 shares of unregistered common stock and warrants to purchase 1,347,176 shares of unregistered common stock 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 the warrants, or to include these shares in registration statements that we may file for ourselves or other stockholders.

We have registered all common stock that we may issue under our amended and restated 2001 incentive plan, our 2004 non-employee directors stock option plan, and our 2004 employee stock purchase plan. An aggregate of 2,213,995, 300,000 and 500,000 shares of our common stock have been reserved for issuance under our amended and restated 2001 equity incentive plan, our 2004 non-employee directors stock option plan and our 2004 employee stock purchase plan, respectively, and these share reserves are subject to automatic annual increases in accordance with the terms of the plans. These shares can be freely sold in the public market upon issuance, subject to applicable lock-up agreements. If any of these events cause a large number of our shares to be sold in the public market, the sales could reduce the trading price of our common stock and impede our ability to raise future capital.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because the majority of our investments are in short-term marketable securities. Due to the nature of our short-term investments, we believe that we are not subject to any material market risk exposure. We do not have any foreign currency or other derivative financial instruments.

Item 4. Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission s rules and forms and that such information is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate, to allow for timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As required by 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 2. Unregistered Sales of Equity Securities and Use of Proceeds

Our initial public offering of our common stock, par value $0.001, was effected through a Registration Statement on Form S-1 (File No. 333-112437) that was declared effective by the Securities and Exchange Commission on June 15, 2004. The Registration Statement covered the offer and sale of up to 5,750,000 shares of our common stock for an aggregate offering price of $40.3 million. Our initial public offering commenced on June 15, 2004. On June 21, 2004, 5,000,000 shares of our common stock were sold for an aggregate offering price of $35.0 million. On July 20, 2004, 75,000 shares of our common stock were sold for an aggregate offering price of $525,000 upon the partial exercise of the underwriters over-allotment option. Our initial public offering terminated following the sale of all of the securities registered on the registration statement and the expiration of the underwriters over-allotment option. Our initial public offering resulted in aggregate proceeds to us of approximately $31.2 million, net of underwriting discounts and commissions of approximately $2.5 million and offering expenses of approximately $1.8 million, through a syndicate of underwriters managed by SG Cowen & Co., LLC, Deutsche Bank Securities Inc., Thomas Weisel Partners LLC, and Legg Mason Wood Walker, Incorporated.

No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or person owning ten percent or more of any class of our equity securities or to any other affiliates. All offering expenses were paid directly to others.

As of September 30, 2004, we had used approximately $31.2 million of the initial public offering proceeds for investments in medium-term, interest-bearing obligations, investment-grade instruments, or guaranteed obligations of the U.S. government.

The foregoing payments were direct payments made to third parties who were not our directors or officers (or their associates), persons owning ten percent or more of any class of our equity securities or any other affiliate, except that the proceeds used for working capital included regular compensation for officers and directors. The use of proceeds does not represent a material change from the use of proceeds described in the prospectus we filed pursuant to Rule 424(b)(4) of the Securities Act of 1933, as amended, with the Securities and Exchange Commission on June 16, 2004.

Item 6. Exhibits

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation as currently in effect (filed as Exhibit 3.1 to Registration Statement File No. 333-112437)
3.2	Amended and Restated Bylaws as currently in effect (filed as Exhibit 3.2 to Registration Statement File No. 333-112437)
4.1	Form of Common Stock Certificate (filed as Exhibit 4.1 to Registration Statement File No. 333-112437)

10.1	Amendment No. 1 to Sublease Agreement made as of March 18, 2004, by and between Sicor Inc. And Metabasis Therapeutics, Inc.

10.2	Amendment No. 2 to Sublease Agreement made as of September 14, 2004, by and between Sicor Inc. And Metabasis Therapeutics, Inc.
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

SIGNATURES

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

Date: November 12, 2004

By: /s/ John W. Beck
John W. Beck, C.P.A., *Vice President of Finance, Chief Financial Officer and Treasurer (Principal Financial and Accounting Officer)*