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CARDIOVASCULAR SYSTEMS INC

FORM 10-Q
(Quarterly Report)

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Table of Contents

Table of Contents

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-Q

☑ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the quarterly period ended September 30, 2007

OR

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

Commission file number: 000-52082

REPLIDYNE, INC.

(Exact name of registrant as specified in its charter)

Delaware	**84-1568247**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification No.)*
1450 Infinite Drive, Louisville, Colorado	**80027**
(Address of principal executive offices)	*(Zip Code)*

303-996-5500
Registrant's telephone number, including area code:

None
(Former name, former address and former fiscal year, if changed since last report)

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

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

Large accelerated filer ☐ Accelerated filer ☐ Non-accelerated filer ☑

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

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date.

Class	Outstanding at October 31, 2007
Common Stock, $.001 par value per share	27,117,866 shares

TABLE OF CONTENTS

PART I FINANCIAL INFORMATION

Item 1. ***Financial Statements***

REPLIDYNE, INC.

CONDENSED BALANCE SHEETS
(unaudited)
(in thousands, except for share and per share amounts)

	September 30, 2007	December 31, 2006
ASSETS		
Current assets:		
Cash and cash equivalents	$ 39,875	$ 24,091
Short-term investments	61,856	101,476
Receivable from Forest Laboratories	—	4,634
Prepaid expenses and other current assets	2,921	2,079
Total current assets	104,652	132,280
Property and equipment, net	2,131	3,170
Other assets	113	111
Total assets	$ 106,896	$ 135,561
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	$ 8,313	$ 7,957
Deferred revenue	—	56,176
Total current liabilities	8,313	64,133
Long-term liabilities	37	56
Total liabilities	8,350	64,189
Commitments and contingencies		
Stockholders' equity:		
Common stock, $0.001 par value. Authorized 100,000,000 shares; issued 27,117,738 and 27,009,749 shares; outstanding 27,066,027 and 26,979,162 shares at September 30, 2007 and December 31, 2006, respectively	27	27
Treasury stock, $0.001 par value; 51,711 and 30,587 shares at September 30, 2007 and December 31, 2006, respectively, at cost	(9)	(2)
Additional paid-in capital	190,847	188,334
Accumulated other comprehensive income (loss)	26	(7)
Accumulated deficit	(92,345)	(116,980)
Total stockholders' equity	98,546	71,372
Total liabilities and stockholders' equity	$ 106,896	$ 135,561

See accompanying notes to condensed financial statements.

REPLIDYNE, INC.

CONDENSED STATEMENTS OF OPERATIONS
(unaudited)
(in thousands, except per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2007	2006	2007	2006
Revenue	$ —	$ 3,679	$58,571	$ 10,601
Costs and expenses:				
Research and development	10,651	7,177	28,462	25,287
Sales, general and administrative	2,988	3,864	9,803	8,676
Total costs and expenses	13,639	11,041	38,265	33,963
Income (loss) from operations	(13,639)	(7,362)	20,306	(23,362)
Investment income and other, net	1,336	1,640	4,329	3,730
Net (loss) income	(12,303)	(5,722)	24,635	(19,632)
Preferred stock dividends and accretion	—	(85)	—	(5,391)
Net (loss) income attributable to common stockholders	$(12,303)	$ (5,807)	$24,635	$(25,023)
Net (loss) income attributable to common stockholders per share — basic	$ (0.46)	$ (0.23)	$ 0.92	$ (2.59)
Net (loss) income attributable to common stockholders per share — diluted	$ (0.46)	$ (0.23)	$ 0.89	$ (2.59)
Weighted average common shares outstanding — basic	26,780	25,748	26,696	9,659
Weighted average common shares outstanding — diluted	26,780	25,748	27,666	9,659

See accompanying notes to condensed financial statements.

REPLIDYNE, INC.

CONDENSED STATEMENTS OF CASH FLOWS
(unaudited)
(in thousands)

	Nine Months Ended September 30,	
	2007	2006
Cash flows from operating activities:		
Net income (loss)	$ 24,635	$ (19,632)
Adjustments to reconcile net income (loss) to net cash (used in) provided by operating activities:		
Depreciation and amortization	1,190	1,031
Stock-based compensation	2,135	698
Discounts and premiums on short-term investments	614	(617)
Amortization of debt discount and issuance costs	—	9
Other	13	79
Changes in operating assets and liabilities:		
Receivable from Forest Laboratories	4,634	(2,568)
Prepaid expenses and other current assets	(842)	(2,436)
Other assets	(2)	176
Accounts payable and accrued expenses	441	(3,489)
Deferred revenue	(56,176)	57,188
Other long-term liabilities	(19)	(19)
Net cash (used in) provided by operating activities	(23,377)	30,420
Cash flows from investing activities:		
Purchases of short-term investments classified as available-for-sale	(19,172)	(120,323)
Purchases of short-term investments classified as held-to-maturity	(64,840)	(60,854)
Maturities of short-term investments classified as available-for-sale	53,747	117,084
Maturities of short-term investments classified as held-to-maturity	69,304	10,053
Acquisitions of property and equipment	(171)	(783)
Proceeds from sale of property and equipment	7	39
Net cash provided by (used in) investing activities	38,875	(54,784)
Cash flows from financing activities:		
Principal payments on debt	—	(169)
Proceeds from issuance of common stock from the exercise of stock options	61	176
Proceeds from issuance of common stock from the employee stock purchase plan	225	—
Proceeds from sale of common stock from initial public offering, net of underwriters discount	—	46,556
Payments of deferred offering costs on the sale of common stock from initial public offering	—	(1,789)
Proceeds from notes receivable from officers repaid in full prior to initial public offering	—	356
Bank overdraft.	—	(25)
Settlement of fractional shares	—	(1)
Proceeds from issuance of Series C redeemable convertible preferred stock from the exercise of warrants	—	100
Net cash provided by financing activities	286	45,204
Net increase in cash and cash equivalents	15,784	20,840
Cash and cash equivalents:		
Beginning of period	24,091	4,353
End of period	$ 39,875	$ 25,193
Supplemental cash flow information:		
Cash paid for interest	$ —	$ 15
Reclassification of preferred stock warrant liability to stockholders' equity	$ —	$ 630
Unpaid deferred offering costs	$ —	$ 225

See accompanying notes to condensed financial statements.

REPLIDYNE, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS
(unaudited)

(1) Business and Organization

Replidyne, Inc. (Replidyne or the Company) is a biopharmaceutical company focused on discovering, developing, in-licensing and commercializing anti-infective products. The Company's lead product candidate, faropenem medoxomil, is a novel oral community antibiotic for which the Company submitted a New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) in December 2005 for treatment of acute bacterial sinusitis, community-acquired pneumonia, acute exacerbation of chronic bronchitis, and uncomplicated skin and skin structure infections in adults. In October 2006, the FDA issued a non-approvable letter for the NDA. According to the non-approvable letter, the FDA recommends further clinical studies for all indications included in the NDA, additional microbiologic confirmation and consideration of alternate dosing of faropenem medoxomil.

The Company's research and development product pipeline also includes REP8839, a drug candidate being developed for topical use for treatment of skin and wound infections, including methicillin-resistant *Staphylococcus aureus* (MRSA) infections. In addition, the Company is pursuing the development of REP3123, an investigational narrow-spectrum antibacterial agent for the treatment of Gram-positive *Clostridium difficile* (*C. difficile*) bacteria and *C. difficile* -associated disease (CDAD), and its bacterial DNA inhibitor replication technology.

In February 2006, the Company entered into a collaboration and commercialization agreement with Forest Laboratories Holding Limited (Forest Laboratories) for the commercialization, development and distribution of faropenem medoxomil in the U.S. Under this agreement, in 2006 the Company received nonrefundable upfront and milestone payments of $60 million. On May 7, 2007, the collaboration and commercialization agreement with Forest Laboratories terminated. As a result, the Company reacquired all rights to faropenem medoxomil previously granted to Forest Laboratories and recognized unamortized deferred revenue arising from these payments in the amount of $55 million as revenue.

(2) Summary of Significant Accounting Policies

Unaudited Interim Financial Statements. The condensed balance sheet as of September 30, 2007, condensed statements of operations for the three and nine months ended September 30, 2007 and 2006, and the condensed statements of cash flows for the nine months ended September 30, 2007 and 2006 and related disclosures, respectively, have been prepared by the Company, without an audit, in accordance with generally accepted accounting principles for interim information. Accordingly, they do not contain all of the information and footnotes required by generally accepted accounting principles for complete financial statements. All disclosures as of September 30, 2007 and for the three and nine months ended September 30, 2007 and 2006, presented in the notes to the condensed financial statements are unaudited. In the opinion of management, all adjustments, which include only normal recurring adjustments, considered necessary to present fairly the financial condition as of September 30, 2007 and results of operations for the three and nine months ended September 30, 2007 and 2006, and the condensed statements of cash flows for the nine months ended September 30, 2007 and 2006 respectively, have been made. These interim results of operations for the three and nine month periods ended September 30, 2007 and 2006 are not indicative of the results that may be expected for the full year ended December 31, 2007. The December 31, 2006 balance sheet and related disclosures were derived from audited financial statements.

Accounting Estimates in the Preparation of Financial Statements. The preparation of financial statements in conformity with accounting principles generally accepted in the U.S. requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenue and expenses during the reporting period. Actual results could differ from these estimates.

Cash and Cash Equivalents. The Company considers all highly liquid investments purchased with maturities of 90 days or less when acquired to be cash equivalents. All cash equivalents are carried at amortized cost, which approximates fair value.

REPLIDYNE, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS — (Continued)

Short-Term Investments. Short-term investments are investments purchased with maturities of longer than 90 days held at a financial institution. At September 30, 2007, contractual original maturities of the Company's short-term investments are two years or less and current weighted average days to maturity is less than six months.

Management determines the classification of securities at purchase based on its intent. In accordance with SFAS No. 115, *Accounting for Certain Investments in Debt and Equity Securities* , the Company classifies its securities as held-to-maturity or available-for-sale. Held-to-maturity securities are those which the Company has the positive intent and ability to hold to maturity and are reported at amortized cost. Available-for-sale securities are those the Company may decide to sell if needed for liquidity, asset/liability management, or other reasons.

Available-for-sale securities are recorded at estimated fair value. The estimated fair value amounts are determined by the Company using available market information. Unrealized holding gains and losses on available-for-sale securities are excluded from earnings and are reported as a separate component of other comprehensive income or loss until realized. Cost is adjusted for amortization of premiums and accretion of discounts from the date of purchase to maturity. Such amortization is included in investment income and other. Realized gains and losses and declines in value judged to be other than temporary on available-for-sale securities are also included in investment income and other. The cost of securities sold is based on the specific-identification method. A decline in the market value of any available-for-sale security below cost that is deemed to be other than temporary results in a reduction in carrying amount to fair value. The impairment is charged to earnings and a new cost basis for the security is established. To determine whether an impairment is other than temporary, the Company considers whether it has the ability and intent to hold the investment until a market price recovery and considers whether evidence indicating the cost of the investment is recoverable outweighs evidence to the contrary. Evidence considered in this assessment includes the reasons for the impairment, the severity and duration of the impairment, changes in value subsequent to period end, and forecasted performance of the investee. No impairments were recorded as a result of this analysis during the three and nine months ended September 30, 2007 and 2006, respectively. The Company's investments were classified as follows at September 30, 2007 and December 31, 2006 (in thousands):

	September 30, 2007	December 31, 2006
Short-Term Investments:		
Available-for-sale securities — recorded at fair value	$ 14,334	$ 49,525
Held-to-maturity securities — recorded at amortized cost	47,522	51,951
Total short-term investments	$ 61,856	$ 101,476

The following is a summary of the types of short-term investments classified as available-for-sale securities (in thousands):

	September 30, 2007		December 31, 2006	
	Amortized Cost	Estimated Fair Value	Amortized Cost	Estimated Fair Value
U.S. government agencies	$ 4,299	$ 4,306	$ 9,898	$ 9,899
U.S. commercial paper	2,489	2,489	8,933	8,924
U.S. bank and corporate notes	7,519	7,539	—	—
Asset-backed securities	—	—	30,701	30,702
	$ 14,307	$ 14,334	$ 49,532	$ 49,525

Unrealized holding gains and losses on available-for-sale securities as of September 30, 2007 were $32 thousand and $6 thousand, respectively. Unrealized holding gains and losses on available-for-sale securities as of

December 31, 2006 were $5 thousand and $12 thousand, respectively. Net unrealized holding gains or losses are recorded in accumulated other comprehensive income or loss.

The following is a summary of short-term investments classified as held-to-maturity securities (in thousands):

	September 30, 2007		December 31, 2006	
	Amortized Cost	Estimated Fair Value	Amortized Cost	Estimated Fair Value
U.S. bank and corporate notes	$ 47,522	$ 47,480	$ 42,962	$ 42,951
Asset-backed securities	—	—	8,989	8,985
	$ 47,522	$ 47,480	$ 51,951	$ 51,936

Unrealized holding gains and losses on held-to-maturity investments as of September 30, 2007 were $2 thousand and $44 thousand, respectively. Unrealized holding gains and losses on held-to-maturity investments as of December 31, 2006 were $3 thousand and $18 thousand, respectively.

Concentrations of Credit Risk. Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash, cash equivalents and short-term investments. The Company has established guidelines to limit its exposure to credit risk by placing investments with high credit quality financial institutions, diversifying its investment portfolio, and making investments with maturities that maintain safety and liquidity.

Property and Equipment. Property and equipment are recorded at cost, less accumulated depreciation and amortization. Depreciation is computed using the straight-line method over the estimated useful lives of the assets, generally three to seven years. Leasehold improvements are amortized over the shorter of the life of the lease or the estimated useful life of the assets. Repairs and maintenance costs are expensed as incurred.

Long-Lived Assets and Impairments. The Company periodically evaluates the recoverability of its long-lived assets in accordance with SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets* , and, accordingly, reduces the carrying value whenever events or changes in business conditions indicate the carrying amount of the assets may not be fully recoverable. SFAS No. 144 requires recognition of impairment of long-lived assets in the event the net book value of such assets exceeds the fair value less costs to sell such assets. The Company has not yet generated positive cash flows from operations on a sustained basis, and such cash flows may not materialize for a significant period in the future, if ever. Additionally, the Company may make changes to its business plan that will result in changes to the expected cash flows from long-lived assets. As a result, it is reasonably possible that future evaluations of long-lived assets may result in impairment.

Accrued Liabilities. As part of the process of preparing its financial statements, the Company is required to estimate accrued liabilities. This process involves identifying services that third parties have performed on the Company's behalf and estimating the level of service performed and the associated cost incurred on these services as of each balance sheet date in the Company's financial statements. Examples of estimated accrued expenses include contract service fees, such as amounts due to clinical research organizations, professional service fees, such as attorneys and accountants, and investigators in conjunction with preclinical and clinical trials, and fees payable to contract manufacturers in connection with the production of materials related to product candidates. Estimates are most affected by the Company's understanding of the status and timing of services provided relative to the actual level of services incurred by the service providers. The date on which certain services commence, the level of services performed on or before a given date, and the cost of services is often subject to judgment. The Company makes these judgments based upon the facts and circumstances known and accounts for these estimates in accordance with accounting principles involving accrued liabilities generally accepted in the U.S.

Segments. The Company operates in one segment. Management uses one measure of profitability and does not segment its business for internal reporting purposes.

REPLIDYNE, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS — (Continued)

Share-Based Compensation. Effective January 1, 2006, the Company adopted SFAS No. 123(R), *Share-Based Payment* , using the prospective method of transition. Under that transition method, compensation cost recognized after adoption includes: (a) compensation costs for all share-based payments granted prior to January 1, 2006, based on the intrinsic value method prescribed by Accounting Principles Board (APB) Opinion No. 25, *Accounting for Stock Issued to Employees*, and (b) compensation cost for all share-based payments granted or modified subsequent to January 1, 2006, based on the grant date fair value estimated in accordance with the provisions of SFAS No. 123 (R).

The Company selected the Black-Scholes option pricing model as the most appropriate valuation method for option grants with service and/or performance conditions. The Black-Scholes model requires inputs for risk-free interest rate, dividend yield, volatility and expected lives of the options. Since the Company has a limited history of stock activity, expected volatility is based on historical data from several public companies similar in size and nature of operations to the Company. The Company will continue to use historical volatility and other similar public entity volatility information until its historical volatility is relevant to measure expected volatility for future option grants. The Company estimates the forfeiture rate based on historical data. Based on an analysis of historical forfeitures, the Company applied an annual forfeiture rate of 4.36% during the three and nine months ended September 30, 2007 and applied an annual forfeiture rate of 6.97% during 2006. The forfeiture rate is re-evaluated on a quarterly basis. The risk-free rate for periods within the contractual life of the option is based on the U.S. Treasury yield curve in effect at the time of the grant for a period commensurate with the expected term of the grant. The expected term (without regard to forfeitures) for options granted represents the period of time that options granted are expected to be outstanding and is derived from the contractual terms of the options granted and historical option exercise behaviors.

For options granted during the nine months ended September 30, 2007, the Company estimated the fair value of option grants as of the date of grant using the Black-Scholes option pricing model with the following weighted average assumptions. Expected volatility was estimated to be 75%. The weighted average risk-free interest rate was 4.47%, and the dividend yield was 0.00%. The weighted average expected lives for each individual vesting tranche under the graded vesting attribution method discussed below was estimated to be 3.05 years.

The Company had a choice of two attribution methods for allocating compensation costs under SFAS No. 123 (R): the “straight-line” method, which allocates expense on a straight-line basis over the requisite service period of the last separately vesting portion of an award, or the “graded vesting attribution method”, which allocates expense on a straight-line basis over the requisite service period for each separately vesting portion of the award as if the award was, in-substance, multiple awards. The Company chose the graded vesting attribution method and accordingly, amortizes the fair value of each option over each option’s vesting period (requisite service period).

Employee stock options granted by the Company are generally structured to qualify as “incentive stock options” (ISOs). Under current tax regulations, the Company does not receive a tax deduction for the issuance, exercise or disposition of ISOs if the employee meets certain holding requirements. If the employee does not meet the holding requirements, a disqualifying disposition occurs, at which time the Company will receive a tax deduction. The Company does not record tax benefits related to ISOs unless and until a disqualifying disposition occurs. In the event of a disqualifying disposition, the entire tax benefit is recorded as a reduction of income tax expense. The Company has not recognized any income tax benefit or related tax asset for share-based compensation arrangements as the Company does not believe, based on its history of operating losses, that it is more likely than not it will realize any future tax benefit from such compensation cost recognized since inception of the Company.

Under SFAS 123(R), the estimated fair value of share-based compensation, including stock options granted under the Company’s Equity Incentive Plan and discounted purchases of common stock by employees under the Employee Stock Purchase Plan, is recognized as compensation expense. The estimated fair value of stock options is expensed over the requisite service period as discussed above. Compensation expense under the Company’s Employee Stock Purchase Plan is calculated based on participant elected contributions and estimated fair values of

REPLIDYNE, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS — (Continued)

the common stock and the purchase discount at the date of the offering. See Note 7 for further information on share-based compensation under these plans. Share-based compensation included in the Company's condensed statement of operations was as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2007	2006	2007	2006
Research and development	$335	$100	$ 939	$222
Sales, general and administrative	412	224	1,196	476
	$747	$324	$2,135	$698

SFAS No. 123(R) was applied only to awards granted or modified after the required effective date of January 1, 2006. Awards granted prior to the Company's implementation of SFAS No. 123(R) are accounted for under the recognition and measurement provisions of APB Opinion No. 25 and related interpretations.

Clinical Trial Expenses. The Company records clinical trial expenses based on estimates of the services received and efforts expended pursuant to contracts with clinical research organizations (CROs) and other third party vendors associated with its clinical trials. The Company contracts with third parties to perform a range of clinical trial activities in the ongoing development of its product candidates. The terms of these agreements vary and may result in uneven payments. Payments under these contracts depend on factors such as the achievement of certain defined milestones, the successful enrollment of patients and other events. The objective of the Company's clinical trial accrual policy is to match the recording of expenses in its financial statements to the actual services received and efforts expended. In doing so, the Company relies on information from CROs and its clinical operations group regarding the status of its clinical trials to calculate the accrual for clinical expenses at the end of each reporting period.

Net (Loss) Income Per Share. Net (loss) income per share is computed using the weighted average number of shares of common stock outstanding and is presented for basic and diluted net (loss) income per share. Basic net (loss) income per share is computed by dividing net (loss) income attributable to common stockholders by the weighted average number of common shares outstanding during the period, excluding common stock subject to vesting provisions. Diluted net (loss) income per share is computed by dividing net (loss) income attributable to common stockholders by the weighted average number of common shares outstanding during the period increased to include, if dilutive, the number of additional common shares that would have been outstanding if the potential common shares had been issued or restrictions lifted on restricted stock. The dilutive effect of common stock equivalents such as outstanding stock options, warrants and restricted stock is reflected in diluted net loss per share by application of the treasury stock method.

REPLIDYNE, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS — (Continued)

The following table sets forth the computation of basic and diluted net (loss) income per share (amounts in thousands, except per share amounts):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2007	2006	2007	2006
Numerator:				
Net (loss) income	$(12,303)	$ (5,722)	$24,635	$(19,632)
Preferred stock dividends and accretion	—	(85)	—	(5,391)
	$(12,303)	$ (5,807)	$24,635	$(25,023)
Denominator:				
Weighted-average shares outstanding, excluding unvested restricted stock	26,780	25,748	26,696	9,659
Effect of dilutive securities	—	—	968	—
Denominator for diluted earnings per share	26,780	25,748	27,666	9,659
Basic (loss) earnings per share	$ (0.46)	$ (0.23)	$ 0.92	$ (2.59)
Diluted (loss) earnings per share	$ (0.46)	$ (0.23)	$ 0.89	$ (2.59)

Potentially dilutive securities representing approximately 3.4 million and 2.4 million shares of common stock for the quarters ended September 30, 2007 and 2006, respectively, and 1.5 million and 2.4 million shares of common stock for the nine months ended September 30, 2007 and 2006, respectively, were excluded from the computation of diluted earnings per share for these periods because their effect would have been antidilutive. Potentially dilutive securities include stock options, warrants, shares to be purchased under the employee stock purchase plan, restricted stock and shares which would be issued under convertible preferred stock.

Fair Value of Financial Instruments. The carrying amounts of financial instruments, including cash and cash equivalents, receivables from Forest Laboratories, and accounts payable approximate fair value due to their short-term maturities.

Revenue Recognition. The Company's commercial collaboration agreements can contain multiple elements, including nonrefundable upfront fees, payments for reimbursement of research costs, payments for ongoing research, payments associated with achieving specific milestones and royalties based on specified percentages of net product sales, if any. The Company applies the revenue recognition criteria outlined in EITF Issue 00-21, *Revenue Arrangements with Multiple Deliverables* (EITF 00-21), in accounting for upfront and milestone payments under the agreement. In applying the revenue recognition criteria within EITF 00-21, the Company considers a variety of factors in determining the appropriate method of revenue recognition under these arrangements, such as whether the elements are separable, whether there are determinable fair values and whether there is a unique earnings process associated with each element of a contract.

Where the Company does not believe that an upfront fee or milestone payment is specifically tied to a separate earnings process, revenues are recognized ratably over the estimated term of the agreement. When the Company's obligations under such arrangements are completed, any remaining deferred revenue is recognized.

Payments received by the Company for the reimbursement of expenses for research, development and commercial activities under commercial collaboration and commercialization agreements are recorded in accordance with EITF Issue 99-19, *Reporting Revenue Gross as Principal Versus Net as an Agent* (EITF 99-19). Per EITF 99-19, in transactions where the Company acts as principal, with discretion to choose suppliers, bears credit risk and performs a substantive part of the services, revenue is recorded at the gross amount of the reimbursement.

Costs associated with these reimbursements are reflected as a component of operating expenses in the Company's statements of operations.

Research and Development. Research and development costs are expensed as incurred. These costs consist primarily of salaries and benefits, licenses to technology, supplies and contract services relating to the development of new products and technologies, allocated overhead, clinical trial and related clinical manufacturing costs, and other external costs.

The Company is currently producing clinical and commercial grade product in its facilities and through third parties. Prior to filing for regulatory approval of its products for commercial sale, and such approval being assessed as probable, these costs are expensed as incurred to research and development.

Comprehensive (Loss) Income. The Company applies the provisions of SFAS No. 130, *Reporting Comprehensive Income* , which establishes standards for reporting comprehensive income or loss and its components in financial statements. The Company's comprehensive (loss) income is comprised of its net income or loss and unrealized gains and losses on securities available-for-sale. For the three and nine months ended September 30, 2007 comprehensive loss was $12.3 million and comprehensive income was $24.7 million, respectively. For the three and nine months ended September 30, 2006 comprehensive loss was $5.7 million and $20.1 million, respectively.

Income Taxes. The Company accounts for income taxes pursuant to SFAS No. 109, *Accounting for Income Taxes* , which requires the use of the asset and liability method of accounting for deferred income taxes. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. A valuation allowance is recorded to the extent it is more likely than not that a deferred tax asset will not be realized. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in operations in the period that includes the enactment date.

Based on an analysis of historical equity transactions under the provisions of Section 382 of the Internal Revenue Service Code, the Company believes that ownership changes have occurred at two points since its inception. These ownership changes limit the annual utilization of the Company's net operating losses in future periods. The Company does not believe that these ownership changes will result in the loss of any of its net operating loss carryforwards existing on the date of each ownership change. The Company's only significant deferred tax assets are its net operating loss carryforwards. The Company has provided a valuation allowance for its entire net deferred tax asset since its inception as, due to uncertainty as to future utilization of its net operating loss carryforwards, due primarily to its history of operating losses, the Company has concluded that it is more likely than not that a deferred tax asset will not be realized.

FASB Interpretation No. 48 (FIN 48), *Accounting for Uncertainty in Income Taxes — An Interpretation of FASB Statement No. 109*, defines a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. FIN 48 also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. At the adoption date of January 1, 2007, the Company had no unrecognized tax benefits which would affect its effective tax rate if recognized. At September 30, 2007, the Company has no unrecognized tax benefits. The Company classifies interest and penalties arising from the underpayment of income taxes in the statement of income as general and administrative expenses. As of September 30, 2007, the Company has no accrued interest or penalties related to uncertain tax positions. The tax years 2003 to 2006 federal returns remain open to examination and the tax years 2002 to 2006 remain open to examination by other taxing jurisdictions to which we are subject.

Recent Accounting Pronouncements. In June 2007, the FASB ratified Emerging Issues Task Force (EITF) 07-03, *Accounting for Advance Payments for Goods or Services to Be Used in Future Research and Development Activities* (EITF 07-03). The scope of EITF 07-03 is limited to nonrefundable advance payments for goods and

services to be used or rendered in future research and development activities pursuant to an executory contractual arrangement. This issue provides that nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities should be deferred and capitalized. Such amounts should be recognized as an expense as the related goods are delivered or the related services are performed. The Company will be required to adopt EITF 07-03 for new contracts entered into in 2008. The Company does not expect that the adoption of EITF 07-03 will have a material impact on its financial position or results of operations.

The EITF has one issue currently under consideration that may impact the Company. EITF 07-01, *Accounting for Collaboration Arrangements Related to the Development and Commercialization of Intellectual Property* , is focused on how the parties to a collaborative agreement should account for costs incurred and revenue generated on sales to third parties, how sharing payments pursuant to a collaboration agreement should be presented in the income statement and certain related disclosure questions. The Company will continue to monitor the development of this EITF issue and evaluate the impact on its financial statements.

(3) Property and Equipment

Property and equipment at September 30, 2007 and December 31, 2006 consists of the following (in thousands):

	September 30, 2007	December 31, 2006
Equipment	$ 4,837	$ 4,760
Furniture and fixtures	828	820
Leasehold improvements	2,214	2,195
	7,879	7,775
Less: accumulated depreciation and amortization	(5,748)	(4,605)
Property and equipment, net	$ 2,131	$ 3,170

For the three months ended September 30, 2007 and 2006 depreciation and amortization expense was $0.4 million and $0.3 million, respectively, and for the nine months ended September 30, 2007 and 2006 was $1.2 million and $1.0 million, respectively.

(4) Agreement with Forest Laboratories Holdings Limited

In February 2006, the Company entered into a collaboration and commercialization agreement with Forest Laboratories for the commercialization, development and distribution of faropenem medoxomil in the U.S. In October 2006, the Company received a non-approvable letter from the FDA for the NDA it submitted for faropenem medoxomil in December 2005. According to the non-approvable letter, the FDA recommended further clinical studies for all indications included in the NDA, additional microbiologic confirmation and consideration of alternate dosing of faropenem medoxomil. In May 2007, the collaboration and commercialization agreement with Forest Laboratories was terminated. In accordance with the terms of the agreement, following the termination, all of Forest Laboratories' rights and licenses with respect to faropenem medoxomil have ceased.

The Company received $60 million in upfront and milestone payments from Forest Laboratories during the first quarter of 2006, which the Company was recognizing into revenue through 2020, the then estimated term of the agreement. Effective May 7, 2007, the termination date of the agreement with Forest Laboratories, the Company recognized all remaining deferred revenue related to the upfront and milestone payments, which were non-refundable, of approximately $55 million as revenue in the second quarter of 2007.

REPLIDYNE, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS — (Continued)

(5) Commitments and Contingencies

Indemnifications. The Company has agreements whereby it indemnifies directors and officers for certain events or occurrences while the director or officer is, or was, serving in such capacity at the Company's request. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is unlimited.

Asubio Pharma License Agreement. In 2004, the Company entered into a license agreement with Asubio Pharma Co., Ltd. (Asubio Pharma) to develop and commercialize faropenem medoxomil in the U.S. and Canada for adult and pediatric use, which was amended as to certain terms in 2006. The Company has an exclusive option to license rights to faropenem medoxomil for the rest of the world excluding Japan. The Company bears the cost of and manages development, regulatory approvals and commercialization efforts. Asubio Pharma is entitled to upfront fees, milestone payments and royalties.

In consideration for the license, in 2003 and 2004 the Company paid Asubio Pharma an initial license fee of ¥400 million ($3.8 million). In December 2005, the Company submitted its first NDA for adult use of faropenem medoxomil and, at that time, recorded an accrual in the amount of ¥250 million ($2.1 million) for the first milestone due to Asubio Pharma under this agreement. This amount was expensed to research and development in 2005, and paid in 2006. In February 2006, this milestone payment was increased to ¥375 million (approximately $3.0 million). The increased milestone amount of ¥125 million ($1.1 million) was accounted for as research and development expense in the quarter ended March 31, 2006 when the modified terms of the license were finalized. Under the modified license agreement the Company is further obligated to make future payments of up to ¥375 million (approximately $3.3 million at September 30, 2007) upon filing of an NDA at a higher dose and up to ¥1,250 million (approximately $10.9 million at September 30, 2007) in subsequent regulatory and commercial milestone payments for faropenem medoxomil. If the Company terminates its license agreement with Asubio Pharma it will be obligated to pay a termination fee of up to ¥375 million (approximately $3.3 million as of September 30, 2007). Additionally, the Company is responsible for royalty payments to Asubio Pharma based upon net sales of faropenem medoxomil. The license term extends to the later of: (i) the expiration of the last to expire of the licensed patents owned or controlled by Asubio Pharma or (ii) 12 years after the first commercial launch of faropenem medoxomil. The Company has recorded payments made to date as research and development expense, as faropenem medoxomil has not been approved by the FDA.

Asubio Pharma and Nippon Soda Supply Agreement. Under a separate supply agreement entered into in December 2004 among Asubio Pharma, Nippon Soda and the Company, the Company is obligated to purchase, and Nippon Soda is obligated to supply, all of the Company's commercial requirements for faropenem medoxomil for the U.S. and Canadian markets. At the time of full commercial launch, the Company becomes obligated to purchase minimum quantities of drug substance to be determined initially by the Company and Nippon Soda. If the full commercial launch is delayed, beyond specified dates, the Company becomes obligated to pay escalating annual delay compensation of up to ¥280 million (approximately $2.4 million at September 30, 2007) to Nippon Soda which began to accrue on July 1, 2007. In 2006, upon receiving the non-approvable letter from the FDA, the Company accrued delay compensation under this agreement totaling $0.9 million.

If the Company terminates this agreement by material breach, bankruptcy, abandonment of the development or commercialization of faropenem medoxomil or significant delay in launch, as defined in the agreement, and fails to launch faropenem medoxomil, it is obligated to reimburse Nippon Soda for up to ¥65 million (approximately $0.6 million at September 30, 2007) in engineering costs. The Company continues to evaluate amounts which may become payable to Asubio Pharma and Nippon Soda under the terms of the agreement, and adjusts its accrual accordingly.

MEDA Supply Agreement. In 2005, the Company and MEDA Manufacturing GmbH (formerly Tropon GmbH), or MEDA, entered into a supply agreement for production of 300 mg adult tablets of faropenem medoxomil, which was amended as to certain terms in 2006. Beginning in 2006, the Company became obligated

to make annual minimum purchases of 300 mg adult tablets from MEDA of €2.3 million (approximately $3.3 million at September 30, 2007). If in any year the Company did not satisfy its minimum purchase commitments, the Company was required to pay MEDA the shortfall amount. Fifty percent (50%) of the shortfall amount, if applicable, may be credited against future drug product purchases. The Company was required to buy all of its requirements for 300 mg adult oral faropenem medoxomil tablets from MEDA until cumulative purchases exceed €22 million (approximately $31.4 million at September 30, 2007).

This agreement was amended in March 2006 such that the Company's obligations with respect to all purchase commitments and facility decontamination costs were suspended and deemed satisfied by Forest Laboratories pursuant to an agreement between MEDA and Forest Laboratories. Under its agreement with Forest Laboratories, the Company remained liable for any shortfall amount in 2006 that may not have been credited against future drug product purchases. In 2006, the Company incurred $1.5 million relating to its portion of the 2006 shortfall in minimum purchases under these agreements. The amount was accounted for as research and development expense in 2006. In May 2007, concurrent with Forest Laboratories termination of its supply agreements with MEDA, the previously suspended provisions in the Company's agreements with MEDA were no longer suspended and the Company's obligations with respect to purchase commitments and facility decontamination costs were no longer waived. In April 2007, the Company provided notice to MEDA of its intention to terminate the supply agreement in accordance with the termination provisions of the agreement as future clinical development of faropenem medoxomil adult tablets would use 600 mg dosing. As a result of this notice occurring before the termination date of the Company's collaboration agreement with Forest Laboratories, and as Forest Laboratories, under the terms of the collaboration agreement, was responsible for supply chain management of faropenem medoxomil, including obligations under the MEDA agreement, through May 7, 2007 (the term of the collaboration agreement), the Company has not accrued for any minimum purchase or termination fees under this agreement. MEDA has indicated that it disputes the Company's right to terminate the agreement on the basis indicated in its notice of termination. The Company believes that it had the right to terminate the agreement. However, if it is determined that the Company has obligations to MEDA beyond May 7, 2007 under the agreement, then additional costs may be incurred.

The Company has entered into an arrangement with a bank for services related primarily to identifying a licensing partner for its faropenem medoxomil program. Under the terms of the agreement, the Company may incur transaction fees of up to $6 million based on the value of the license transaction as defined.

(6) Common Stock

The Company's Certificate of Incorporation, as amended and restated on July 3, 2006, authorizes the Company to issue 105,000,000 shares of $0.001 par value stock which is comprised of 100,000,000 shares of common stock and 5,000,000 shares of preferred stock. Each share of common stock is entitled to one vote on each matter properly submitted to the stockholders of the Company for their vote. The holders of common stock are entitled to receive dividends when and as declared or paid by the board of directors, subject to prior rights of the Preferred Stockholders, if any.

(7) Share-Based Compensation

Stock Option Plan. The Company's Equity Incentive Plan, as amended (the Option Plan), provides for issuances of up to 7,946,405 shares of common stock for stock option grants. Options granted under the Option Plan may be either incentive or nonqualified stock options. Incentive stock options may only be granted to Company employees, including its officers. Nonqualified stock options may be granted to Company employees, which include its officers, directors, and consultants of the Company. Generally, options granted under the Option Plan expire ten years from the date of grant and vest over four years: 25% on the first anniversary from the grant date and ratably in equal monthly installments over the remaining 36 months. This plan is considered a compensatory plan and subject to the provisions of SFAS No. 123(R).

REPLIDYNE, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS — (Continued)

Stock options outstanding at September 30, 2007, changes during the period, and options exercisable at September 30, 2007 are presented below (share amounts in thousands):

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
			(In millions)	
Options outstanding at January 1, 2007	2,068	$ 4.10		
Granted	1,042	5.35		
Exercised	(19)	1.72		
Forfeited	(22)	7.50		
Options outstanding at March 31, 2007	3,069	4.51	9.10	$ 3.2
Granted	93	5.50		
Exercised	(20)	0.74		
Forfeited	(40)	9.08		
Options outstanding at June 30, 2007	3,102	4.51	8.89	$ 4.0
Granted	10	5.40		
Exercised	(10)	1.50		
Forfeited	(25)	5.04		
Options outstanding at September 30, 2007	3,077	4.52	8.64	$ 6.0
Options exercisable at September 30, 2007	690	$ 3.30	7.94	$ 2.2

REPLIDYNE, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS — (Continued)

Additional information regarding outstanding stock options as of September 30, 2007 is presented below (in thousands, except for exercise price and weighted average data):

	Stock Options Outstanding			Stock Options Exercisable	
Exercise Price	Number of Shares	Weighted Average Remaining Contractual Life (Years)	Exercise Price	Number of Shares	Exercise Price
$0.49	21	5.29	$ 0.49	21	$ 0.49
0.61	420	7.33	0.61	236	0.61
1.32	37	8.02	1.32	20	1.32
3.19	879	8.31	3.19	242	3.19
4.87	6	9.31	4.87	—	—
5.20	189	8.44	5.20	68	5.20
5.35	1,006	9.44	5.35	—	—
5.40	11	9.84	5.40	—	—
5.46	57	9.61	5.46	—	—
5.54	28	9.61	5.54	—	—
5.71	8	9.72	5.71	—	—
6.18	32	9.21	6.18	—	—
8.97	160	8.62	8.97	55	8.97
9.00	26	9.01	9.00	6	9.00
9.38	16	9.03	9.38	—	—
9.51	14	9.04	9.51	—	—
9.64	50	9.04	9.64	—	—
9.82	2	8.94	9.82	—	—
10.00	95	8.76	10.00	36	10.00
10.03	20	8.88	10.03	6	10.03
	3,077		$ 4.52	690	$ 3.30

The weighted average grant date fair value of options granted during the three and nine months ended September 30, 2007 was $2.78 per share and $2.75 per share, respectively, and for the three and nine months ended September 30, 2006 was $3.59 per share and $2.49 per share, respectively. The total intrinsic value of options exercised during the three and nine months ended September 30, 2007 was $45 thousand and $0.2 million, respectively, and during the three and nine months ended September 30, 2006 was $15 thousand and $0.5 million, respectively.

Non-vested Shares. Historically, the Company has granted options for shares of common stock that were eligible to be exercised prior to vesting, provided that the shares issued upon such exercise are subject to restrictions which will be released consistent with the original option vesting period. In the event of termination of the service of an employee, the Company may repurchase all unvested shares from the optionee at the original issue price. Options granted under the Option Plan expire no later than 10 years from the date of grant.

REPLIDYNE, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS — (Continued)

A summary of the changes in restricted shares is presented below (in thousands):

Non-vested shares outstanding at January 1, 2007	400
Restricted stock granted	13
Restricted stock cancelled	(20)
Shares vested upon release of restrictions	(124)
Non-vested shares outstanding at September 30, 2007	269

The purchase price of restricted shares which vested during the nine months ended September 30, 2007 was $0.1 million. As of September 30, 2007, restrictions on 145,288 of these shares will be released at an accelerated rate if a new drug application for faropenem medoxomil is approved by the FDA.

Stock Based Compensation — Stock Options. During the three and nine months ended September 30, 2007, the Company recognized $0.7 million and $2.0 million of stock based compensation for employee awards, respectively. During the three and nine months ended September 30, 2006, the Company recognized $0.3 million and $0.7 million of stock based compensation for employee awards, respectively. As of September 30, 2007, the Company had $3.3 million of total unrecognized compensation costs (net of expected forfeitures) from options granted under the Option Plan to be recognized over a weighted average remaining period of approximately 1.62 years.

Employee Stock Purchase Plan. The Company has reserved 305,872 shares of common stock for issuance under its Employee Stock Purchase Plan (the Purchase Plan). The Purchase Plan allows eligible employees to purchase common stock of the Company at the lesser of 85% of its market value on the offering date or the purchase date as established by the Board of Directors. Employee purchases are funded through after-tax payroll deductions, which participants can elect from one percent to twenty percent of compensation, subject to the federal limit. The Purchase Plan is considered a compensatory plan and subject to the provisions of SFAS No. 123(R). To date, 90,247 shares have been issued pursuant to the Purchase Plan. The Company recognized $41 thousand in share-based compensation expense under SFAS No. 123(R) related to the Purchase Plan during the three months ended September 30, 2007 and $0.2 million during the nine months ended September 30, 2007. The Company recognized $20 thousand during each of the three and nine months ended September 30, 2006.

(8) Income Taxes

SFAS No. 109 requires that a valuation allowance be provided if it is more likely than not that some portion or all deferred tax assets will not be realized. The Company's ability to realize the benefit of its deferred tax assets will depend on the generation of future taxable income through sustained, profitable operations. Due to the uncertainty of future profitable operations, the Company has recorded a full valuation allowance against its net deferred tax assets.

Due to the recognition of previously deferred revenue upon the termination of the collaboration agreement with Forest Laboratories, the Company has reported net income for the nine months ended September 30, 2007. The Company has recorded no provision of income taxes due to the availability of net operating loss carryforwards to fully offset tax obligations on net income reported for the nine months ended September 30, 2007.

The Company has concluded that net income reported for the nine months ended September 30, 2007 does not provide significant evidence that the Company's net deferred tax assets at September 30, 2007, on a more likely than not basis will be realized in future periods. Such assessment is due primarily to the Company's history of operating losses.

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

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, which are subject to the "safe harbor" created by those sections. Forward-looking statements are based on our management's beliefs and assumptions and on information currently available to our management. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "could," "would," "expect," "plans," "anticipates," "believes," "estimates," "projects," "predicts," "potential" and similar expressions intended to identify forward-looking statements. Examples of these statements include, but are not limited to, statements regarding the following: the timing and implications of obtaining regulatory approval of any of our product candidates; the progress of our research programs, including clinical testing; our ability to identify new product candidates; the potential of any product candidates to lead to the development of commercial products; our anticipated timing for initiation or completion of our clinical trials for any of our product candidates and expectations regarding future results of such trials; other statements regarding our future product development activities and plans to develop or acquire and commercialize product candidates, regulatory strategies and clinical strategies, including our intent to develop or seek regulatory approval for our product candidates in specific indications; our future expenditures for research and development and the conduct of clinical trials; the ability of our third-party manufacturing parties to support our requirements for drug supply; the extent to which our intellectual property rights may protect our technology and product candidates; the size and growth of the potential markets for our product candidates and our plans to develop our sales and marketing capabilities to serve those markets; the rate and degree of market acceptance of any future products; the success of competing drugs that are or become available; our plans and ability to enter into collaboration arrangements; any statements regarding our future financial performance, results of operations or sufficiency of capital resources to fund our operating requirements; and any other statements which are other than statements of historical fact. Our actual results could differ materially from those anticipated in these forward-looking statements for many reasons, including the risks faced by us and described in Part II, Item 1A of this Quarterly Report on Form 10-Q and our other filings with the SEC. You should not place undue reliance on these forward-looking statements, which apply only as of the date of this Quarterly Report on Form 10-Q. You should read this Quarterly Report on Form 10-Q completely and with the understanding that 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.

The following discussion and analysis should be read in conjunction with the unaudited financial statements and notes thereto included in Part I, Item 1 of this Quarterly Report on Form 10-Q.

Overview

We are a biopharmaceutical company initially focused on discovering, developing, in-licensing and commercializing innovative anti-infective products. Our lead product candidate, faropenem medoxomil, is a novel oral community antibiotic. Since our inception, we have focused on the in-license and acquisition of technology acquired as in-process research and development, the selection of product candidates for pre-clinical testing, and the manufacture of clinical trial materials. The majority of our activities have been in support of the development of faropenem medoxomil and REP8839.

We submitted a new drug application, or NDA, to the U.S. Food and Drug Administration, or FDA, in December 2005 for faropenem medoxomil based on 11 Phase III studies for the following adult indications: acute bacterial sinusitis; community-acquired pneumonia; acute exacerbation of chronic bronchitis; and uncomplicated skin and skin structure infections. In October 2006, the FDA issued a non-approvable letter with respect to this NDA citing the need for further clinical trials for all indications, including clinical trials using a superiority design versus placebo or an active comparator drug for acute bacterial sinusitis and acute exacerbation of chronic bronchitis, more extensive microbiologic confirmation and consideration of alternate dosing regimens. Since then, we have engaged in ongoing discussions with the FDA directed at determining the specific clinical trial designs required to obtain approval for the community respiratory tract infection indications of acute bacterial sinusitis, acute exacerbation of chronic bronchitis and community-acquired pneumonia. Although a future partner may pursue the indication for

uncomplicated skin and skin structure infections, the focus of our current activities is to clarify the approval process for faropenem medoxomil in the treatment of community respiratory tract infections. Based on the FDA's recommendations in the non-approvable letter, as well as our ongoing discussions, we anticipate that comparator studies demonstrating that faropenem medoxomil is not inferior to currently approved products for the treatment of community acquired pneumonia will be required for approval in this indication. If we seek approval for faropenem medoxomil to treat acute bacterial sinusitis and acute exacerbation of chronic bronchitis in addition to community acquired pneumonia, the faropenem medoxomil adult program may be anchored on at least two clinical trials for the treatment of community acquired pneumonia with single clinical trials using a superiority clinical trial design in acute bacterial sinusitis and acute exacerbation of chronic bronchitis. We anticipate that we will conduct superiority studies comparing treatment with faropenem medoxomil to placebo for acute bacterial sinusitis and continue our ongoing Phase III clinical trial for treatment of acute exacerbation of chronic bronchitis comparing treatment with faropenem medoxomil to placebo utilization study design intended to meet the FDA's new requirements. We further understand that clinical trials for community respiratory indications will include a requirement for minimum levels of microbiologic confirmation of physician assessed clinical outcomes. Future clinical trials of faropenem medoxomil will be conducted using the 600 mg, twice per day, dose. The clinical trials included in the NDA submitted in December 2005 were conducted using a 300 mg, twice per day, dose. We believe that this higher dose may offer the potential for even greater efficacy than the lower dose. Clinical trials at the 600 mg, twice per day dose will need to accumulate a safety database of clinical trial participants using faropenem medoxomil of approximately 1,500 patients.

In February 2006, we entered into a collaboration and commercialization agreement with Forest Laboratories to co-develop and co-market faropenem medoxomil in the U.S. Under this agreement, we received upfront and milestone payments totaling $60 million in 2006. On May 7, 2007, Forest Laboratories exercised its right to terminate this agreement. As a result, we reacquired all rights to faropenem medoxomil previously granted to Forest Laboratories. There were no penalty fees incurred by either us or Forest Laboratories in connection with the termination of the agreement and all amounts received by us under the agreement are non-refundable. Due to the termination of our Forest Laboratories collaboration agreement, our prospects for near term future revenues are substantially uncertain. We are currently seeking a new partner for the development and commercialization of faropenem medoxomil and currently intend to use our cash, cash equivalents, short-term investments and interest earned on these balances toward the funding necessary to support our planned activities. Until we have a partner for the faropenem medoxomil adult program, which cannot be assured, we plan to limit our faropenem medoxomil adult clinical activities to the ongoing Phase III placebo-controlled clinical trial for the treatment of acute exacerbation of chronic bronchitis and planning and initiation for additional clinical trials for the treatment of acute bacterial sinusitis and community-acquired pneumonia.

We have completed a Phase II clinical trial for an oral suspension formulation of faropenem medoxomil among pediatric patients with acute otitis media. The study of over 300 pediatric patients examined four different doses of faropenem medoxomil, administered twice daily as an oral suspension, and demonstrated a dose response in bacteriological eradication. All doses examined were well tolerated. The trial included a double tap design where middle ear fluid is obtained both prior to and during treatment then submitted for culture. These cultures provide microbiologic documentation of faropenem's effectiveness in eradicating bacteria from the middle ear fluid. We believe that these study results will provide us the information to permit dose selection in future Phase III clinical trials. In order to advance the faropenem medoxomil oral suspension program for pediatric patients to Phase III testing we have sought additional discussion on clinical trial design from the FDA. A meeting of the Anti-Infective Drugs Advisory Committee scheduled for the second quarter of 2007 to discuss clinical trial design for treatment of acute otitis media and other topics related to pediatric development of faropenem medoxomil was postponed by the FDA, pending completion of the FDA's Division of Scientific Investigation (DSI) reviews of certain clinical sites included in the 2005 NDA for faropenem medoxomil. Phase III clinical trials of our oral suspension formulation of faropenem medoxomil for treatment of otitis media in pediatric patients are not expected to commence until DSI has completed its ongoing reviews and we have reached an understanding with the FDA on clinical trial design and other matters related to the treatment of acute otitis media in pediatric patients.

Our second product candidate, REP8839, has exhibited promising activity in pre-clinical studies against *S. aureus* , including methicillin resistant *S. aureus* or MRSA, and mupirocin resistant strains of *S. aureus*. We are

developing REP8839 for topical treatment of skin and wound infections. Our initial target indication will be impetigo, one of the most common skin infections among children. We submitted an investigational new drug, or IND, application for the clinical development of REP8839 in May 2006 and announced results from three Phase I clinical trials in September 2007. The results of the Phase I trials show that topically applied REP8839 appears safe, well tolerated and associated with low systemic exposure, or drug absorption into the bloodstream, which is desirable for a topical antibiotic treatment. Based on these results, we plan to initiate Phase II trials of REP8839 in children with impetigo by the end of this year.

We are also developing REP3123, our investigational narrow spectrum antibacterial agent, to treat Gram-positive *Clostridium difficile*, or *C. difficile*, bacteria and *C. difficile* -associated disease, or CDAD. C. *difficile* is a bacterium that causes diarrhea and other intestinal conditions, such as colitis, and is a major cause of morbidity among the elderly and hospitalized patients. People generally contract CDAD through the ingestion of C. *difficile* spores after coming into contact with a contaminated item or surface. These spores then grow and multiply in the digestive tract. In *in vitro* preclinical studies, REP3123 displayed an ability to inhibit growth of the *C. difficile* bacterium and prevent the bacterium from forming the spores that allow it to be spread from person to person, but without inhibiting other key organisms that are essential for normal intestinal functioning. In preclinical studies, REP3123 also exhibited signs it may be able to stop the production of destructive intestinal toxins caused by *C. difficile* bacteria. These results suggest that REP3123 has the potential to reduce CDAD outbreak and relapse rates through reducing the presence of *C. difficile* spores and reduce the severity of, or possibly even prevent, CDAD through inhibiting the growth of or stopping production of toxins caused by *C. difficile* bacteria.

Further, we are pursuing the development of other novel anti-infective products based on our own research efforts. We have developed assays that identify compounds that inhibit bacterial DNA replication. The compounds may be useful to treat bacterial infections.

We have incurred significant operating losses since our inception on December 6, 2000, and, as of September 30, 2007, we had an aggregate net loss of $75.7 million and accumulated net loss attributable to common stockholders of $94.1 million. We have generated no revenue from product sales to date. We have funded our operations to date principally from the sale of our securities and payments received from Forest Laboratories under our former collaboration and commercialization agreement. Although we reported net income for the nine months ended September 30, 2007 as a result of the termination of our agreement with Forest Laboratories, as discussed below, we expect to incur substantial operating losses for the next several years as we pursue our clinical trials and research and development efforts.

Former Collaboration with Forest Laboratories

In February 2006, we entered into a collaboration and commercialization agreement with Forest Laboratories to be our exclusive partner for the development and marketing of faropenem medoxomil in the U.S. On May 7, 2007, Forest Laboratories exercised its right to terminate this agreement. The termination followed issuance in October 2006 of a non-approvable letter by the FDA for our NDA for faropenem medoxomil. As a result, we reacquired all rights to faropenem medoxomil previously granted to Forest Laboratories. There were no penalty fees incurred by either us or Forest Laboratories in connection with the termination of the agreement and no amounts previously received by us under the agreement are refundable. We received $60 million in upfront and milestone payments from Forest Laboratories during the period of our collaboration. For the initial 90 days of the transition period, which ended on May 7, 2007, the terms and conditions of the collaboration agreement remained in effect, including Forest Laboratories' obligations to reimburse us for the majority of ongoing direct development and commercial costs for faropenem medoxomil, as defined. We agreed with Forest Laboratories that such reimbursement would exclude costs incurred to reinitiate our clinical trial among patients with acute exacerbation of chronic bronchitis.

In accordance with our revenue recognition policy for upfront and milestone payments received under collaboration and commercialization agreements, we had recognized revenue in prior periods for the payments received from Forest Laboratories on a straight-line basis over a period of approximately 15 years, which was the estimated period of benefit. These upfront and milestone payments received are non-refundable. As no further obligations exist beyond the termination date of May 7, 2007, we recognized the remaining unamortized deferred

upfront and milestone fees of approximately $55 million as revenue on that date. We also received reimbursements from Forest Laboratories for research and development and sales and marketing activities during 2007. These amounts have been recorded as revenue. This treatment reflected our role as principal in these transactions whereby we were responsible for selecting vendors, performing significant duties and bearing credit risk.

Comparison of Three Months Ended September 30, 2007 and 2006

Revenue. We recognized no revenue during the third quarter of 2007 compared to $3.7 million for the third quarter of 2006. Revenue recognized during the third quarter of 2006 included $1.1 million of license revenue, representing the unamortized portion of $60 million in upfront and milestone payments we received from Forest Laboratories under our former collaboration agreement, and $2.6 million of contract revenue for funded activity under our former collaboration and commercialization agreement with Forest Laboratories.

Research and Development Expense. Research and development expenses were $10.7 million for the third quarter of 2007 as compared to $7.2 million for the third quarter of 2006. Research and development expenditures made to advance our product candidates and other research efforts were as follows (in thousands):

	Three Months Ended September 30,		Change	
	2007	2006	$	%
Faropenem medoxomil	$ 6,863	$3,652	$3,211	88%
REP8839	1,231	1,942	(711)	(37)%
Other research and development	2,557	1,583	974	62%
	$10,651	$7,177	$3,474	48%

Costs to support our faropenem medoxomil program were $3.2 million higher in the third quarter of 2007 as compared to the third quarter of 2006 primarily reflecting increased external clinical trial activity of $3.6 million. Research and development activities in the third quarter of 2007 were focused on the ongoing Phase III clinical trial for the treatment of acute exacerbation of chronic bronchitis (AECB) as well as planning and implementation activities in preparation for potential future Phase III clinical trials for the treatment of acute bacterial sinusitis and community-acquired pneumonia. Research and development activities in the third quarter of 2006 were focused on the AECB clinical trial as well as the Phase II clinical trial in pediatric patients with acute otitis media which results were reported in the first quarter of 2007.

Costs to support our REP8839 program in the third quarter of 2007 decreased by $0.7 million as compared to the third quarter of 2006 primarily reflecting decreased clinical development costs of $0.7 million as we completed three Phase I clinical trials for this compound in the first quarter of 2007.

In the third quarter of 2007, other research and development costs increased by $1.0 million as compared to the third quarter of 2006 as our research and development personnel increased their work in support of our expanded development activities specifically related to our *C. difficile* and DNA replication inhibitors programs.

Clinical development timelines, likelihood of success and associated costs are uncertain and therefore vary widely. Although we are currently focused primarily on faropenem medoxomil for the treatment of community-acquired respiratory tract infections, acute bacterial sinusitis, community-acquired pneumonia and have commenced the clinical trials program for an oral liquid formulation of faropenem medoxomil for treatment of acute otitis media in pediatric patients, we anticipate that we will make determinations as to which research and development projects to pursue and how much funding to direct toward each project on an on-going basis in response to the guidance we receive through meetings with the FDA regarding each intended indication for faropenem medoxomil and the scientific and clinical success of each of our product candidates.

Due to the risks inherent in the clinical trial process, development completion dates and costs will vary significantly for each product candidate and are difficult to estimate. The lengthy regulatory approval process requires substantial additional resources. Any failure by us to obtain, or any delay in obtaining, regulatory approvals for our product candidates could cause the costs of our research and development to increase and have a material

adverse effect on our results of operations. We cannot be certain when any cash flows from our current product candidates will commence.

Selling, General and Administrative Expenses. Selling, general and administrative expenses were $3.0 million for the third quarter of 2007, as compared to $3.9 million for the third quarter of 2006. In the third quarter of 2006 we incurred incremental relocation costs of $0.6 million and market research costs of $0.7 million primarily related to the faropenem medoxomil program. These costs were partially offset by increased share-based compensation of $0.2 million in the third quarter of 2007.

Investment Income and Other, net. Investment income and other was $1.3 million for the third quarter of 2007, as compared to $1.6 million for the third quarter of 2006. The decrease was primarily due to higher overall cash invested in 2006 following receipt of $44.5 million in net proceeds from our initial public offering completed in the third quarter of 2006.

Comparison of Nine Months Ended September 30, 2007 and 2006

Revenue. Revenue was $58.6 million for the first nine months of 2007 as compared to $10.6 million for the first nine months of 2006. Revenue recognized during 2007 includes $56.2 million of license revenue, representing the unamortized portion of $60 million in upfront and milestone payments we received from Forest Laboratories under our former collaboration agreement. This compares to $2.8 million recognized during the first nine months of 2006. Prior to the effective date of termination of our agreement with Forest Laboratories, the upfront and milestone payments were being recognized in our financial statements as revenue over the estimated period of performance of approximately 15 years. Revenue recognized during the first nine months of 2007 also includes $2.4 million of contract revenue for funded activity under our former collaboration and commercialization agreement with Forest Laboratories as compared to $7.8 million recognized during the first nine months of 2006.

Revenue recognized in 2007 due to acceleration of recognition of the Forest Laboratories' payments following termination of our collaboration agreement is not indicative of a change in operating results, but the application of our revenue recognition accounting policy to our collaboration with Forest Laboratories. Due to the termination of this collaboration relationship, our prospects for other near term future revenues are substantially uncertain. Our ability to generate future revenue depends heavily on our ability to obtain a new partner for faropenem medoxomil on acceptable terms.

Research and Development Expense. Research and development expenses were $28.5 million for the first nine months of 2007 as compared to $25.3 million for the first nine months of 2006. Research and development expenditures made to advance our product candidates and other research efforts were as follows (in thousands):

	Nine Months Ended September 30,		Change	
	2007	2006	$	%
Faropenem medoxomil	$17,808	$14,519	$ 3,289	23%
REP8839	3,855	6,275	(2,420)	(39)%
Other research and development	6,799	4,493	2,306	51%
	$28,462	$25,287	$ 3,175	13%

Costs to support our faropenem medoxomil program were $3.3 million higher in the first nine months of 2007 as compared to the first nine months of 2006 primarily reflecting increased external clinical trial activity of $5.2 million. This increase was partially offset by $1.1 million in additional expenses incurred under our license agreement with Daiichi Asubio in 2006 and $0.5 million in additional preclinical research expenses incurred in 2006. Research and development activities in the first nine months of 2007 were focused on the ongoing Phase III clinical trial for the treatment of acute exacerbation of chronic bronchitis (AECB) as well as planning and implementation activities in preparation for potential future Phase III clinical trials for the treatment of acute bacterial sinusitis and community-acquired pneumonia. Research and development activities in the first nine months of 2006 were focused on the AECB clinical trial as well as the Phase II clinical trial in pediatric patients with acute otitis media which results were reported in the first quarter of 2007.

Costs to support our REP8839 program decreased by $2.4 million in the first nine months of 2007 as compared to the first nine months of 2006. In 2006, we incurred $1.5 million under our purchase agreement with GlaxoSmithKline PLC following the filing of our IND related to REP 8839 with the FDA in the second quarter of 2006. Clinical and preclinical research expenses also decreased by $0.9 million during the first nine months of 2007.

In the first nine months of 2007, other research and development costs increased by $2.3 million as compared to the first nine months of 2006 as our research and development personnel increased their work in support of our expanded development activities specifically related to our *C. difficile* and DNA replication inhibitors programs.

Selling, General and Administrative Expenses. Selling, general and administrative expenses were $9.8 million for the first nine months of 2007, as compared to $8.7 million for the first nine months of 2006. The increase was primarily due to increased personnel and related costs of $0.8 million which resulted from additional staff required to support our commercial, business development and finance operations as well as $0.7 million for share-based compensation expense. We also incurred $1.1 million in additional legal, accounting, insurance and other professional costs related to compliance and other obligations associated with being a public company. We completed our initial public offering in July 2006. These increases were partially offset by reduced marketing expenses primarily related to our faropenem medoxomil program of $0.9 million.

Investment Income and Other, net. Investment income and other was $4.3 million for the first nine months of 2007, as compared to $3.7 million for the first nine months of 2006. The increase was primarily due to other expense charges recorded in 2006 to adjust the fair value of preferred stock warrants and foreign currency denominated payables.

Income Taxes. We recorded zero tax provision for the first nine months of 2007 due to net operating loss carryforwards being available to fully offset estimated taxable income in 2007, and our expectations of future losses.

Liquidity and Capital Resources

As of September 30, 2007, we had $101.7 million in cash, cash equivalents and short-term investments. We have experienced significant operating losses since our inception in 2000 and as of September 30, 2007 we had an accumulated deficit of $92.3 million. We have funded our operations to date principally from private placements of equity securities and convertible notes totaling $121.5 million, receipt of payments from Forest Laboratories under our former collaboration and commercialization agreement totaling $74.6 million and net proceeds received from our initial public offering of $44.5 million.

As noted above, our agreement with Forest Laboratories was terminated on May 7, 2007, and as a result, our prospects for other near term future revenues are uncertain. Our ability to generate future revenue depends heavily on our ability to obtain a new collaboration partner for faropenem medoxomil on acceptable terms.

In October 2006, the FDA issued a non-approvable letter for our NDA for faropenem medoxomil that had been filed in December 2005. According to the non-approvable letter, the FDA recommends further clinical studies for all four indications that were the subject of the NDA including studies using superiority design for the indications of acute bacterial sinusitis and acute exacerbations of chronic bronchitis, additional microbiologic testing and consideration of alternate dosing regimens. We are discussing clinical plans with the FDA including the number of clinical trials needed for each indication, and currently expect that at least two to three years will be required for completion of the clinical studies. We are evaluating the impact this FDA action will have on our liquidity and capital resources including costs of additional clinical trials and delays in product launch. As a result of this FDA action, in 2006 we recorded $2.9 million of expenses related to contingent contractual obligations under our supply agreements as noted below.

In 2004, we entered into a license agreement with Asubio Pharma to develop and commercialize faropenem medoxomil in the U.S. and Canada and we have the sole negotiation right to license such rights for the rest of the world except Japan which was modified in December 2005. Under the modified license agreement we are further obligated to future payments of up to ¥375 million (approximately $3.3 million as of September 30, 2007) upon filing of a new NDA at a higher dose of faropenem medoxomil than was studied in the prior NDA and up to ¥1,250 million (approximately $10.9 million as of September 30, 2007) in subsequent regulatory and commercial

milestone payments for faropenem medoxomil. If we terminate our license agreement with Asubio Pharma we will be obligated to pay a termination fee of up to ¥375 million (approximately $3.3 million as of September 30, 2007). Additionally, we are responsible for royalty payments to Asubio Pharma based upon net sales of faropenem medoxomil. The license term extends to the later of: (i) the expiration of the last to expire of the licensed patents owned or controlled by Asubio Pharma or (ii) 12 years after the first commercial launch of faropenem medoxomil. We have recorded payments made to date as research and development expense, as faropenem medoxomil has not been approved by the FDA.

Under a supply agreement entered into in December 2004 between Asubio Pharma, Nippon Soda and us, we are obligated to purchase, and Nippon Soda is obligated to supply, all our commercial requirements of the faropenem medoxomil active pharmaceutical ingredient. During the three years following placement of an initial purchase order by us with Nippon Soda, we are obligated to make certain annual minimum purchase commitments to be determined initially by us and Nippon Soda at the time of a commercial launch. Since full commercial launch of an approved faropenem medoxomil drug has been delayed, we are obligated for escalating delay compensation to Nippon Soda of up to ¥280 million (approximately $2.4 million as of September 30, 2007) per year, which commences on July 1, 2007. If we terminate the faropenem medoxomil program, under certain circumstances, we may be obligated to reimburse Nippon Soda for up to ¥65 million (approximately $0.6 million as of September 30, 2007) in engineering costs. Based on the non-approvable letter we received from the FDA in October 2006, we determined that we would incur delay compensation under this agreement, and recorded such amount, totaling approximately $0.9 million, in 2006. We continue to evaluate amounts which may become payable to Asubio Pharma and Nippon Soda under the terms of the agreement, and adjust our accrual accordingly.

In April 2005, we entered into a supply agreement for production of 300 mg adult tablets of faropenem medoxomil with MEDA, which was amended in March 2006. Beginning in 2006, we became obligated to make annual minimum purchases of MEDA's product of €2.3 million (approximately $3.3 million as of September 30, 2007). If in any year we have not satisfied this minimum purchase commitment, we were required to pay MEDA the shortfall amount. Fifty percent (50%) of the shortfall amount, if applicable, would have been credited against future drug product purchases. We were required to buy all of our requirements for adult oral faropenem medoxomil tablets from MEDA until cumulative purchases exceeded €22 million (approximately $31.4 million at September 30, 2007). Upon termination of the agreement, under certain circumstances, we would have been obligated to pay up to €1.7 million (approximately $2.4 million as of September 30, 2007) in facility decontamination costs incurred by MEDA. In March 2006 when the agreement was amended, our obligations with respect to all purchase commitments and facility decontamination costs were suspended and deemed satisfied by Forest Laboratories pursuant to an agreement between MEDA and Forest Laboratories. Under our agreement with Forest Laboratories, we remained responsible for any shortfall amount in 2006 that may not be credited against future drug product purchases. Based on the non-approvable letter we received from the FDA in October 2006, we incurred expenses of $1.5 million under these agreements in 2006. In May 2007, following termination of our collaboration agreement with Forest Laboratories and the termination by Forest Laboratories of its supply agreement with MEDA, all previously suspended provisions in our direct agreement with MEDA are no longer suspended. In April 2007, we provided MEDA notice of termination of the supply agreement in accordance with the terms of the agreement as future clinical testing of faropenem medoxomil for adults is to be conducted using 600 mg tablets. As a result of this termination occurring before the termination date of our agreement with Forest Laboratories, we have not accrued for any minimum purchase or termination fees under this agreement. Supply chain obligations, including fees that may arise from this agreement with MEDA, incurred through May 7, 2007 are the responsibility of Forest Laboratories under the commercialization and collaboration agreement. MEDA has indicated to us that it disputes our right to terminate the agreement on the basis indicated in our notice of termination. We believe that we had the right to terminate the agreement. However, if it is determined that we have obligations to MEDA beyond May 7, 2007 under the agreement, then we may incur additional costs. Consistent with our position that we had the right to terminate this agreement and that Forest Laboratories is responsible for all supply chain obligations, we have not accrued for any minimum purchase or termination fees under this agreement.

In May 2007, we entered into an arrangement with a bank for services related primarily to identifying a licensing partner for our faropenem medoxomil program. Under the terms of the agreement, we may incur transaction fees of up to $6 million based on the value of the license transaction as defined.

We have not yet commercialized our product candidates or generated any revenue from product sales. We anticipate that we will continue to incur substantial net losses in the next several years as we develop our products, conduct and complete clinical trials, pursue additional product candidates, expand our clinical development team and corporate infrastructure and prepare for the potential commercial launch of our product candidates including faropenem medoxomil. We do not anticipate generating any product related revenue until we obtain FDA approval for faropenem medoxomil and we or a future partner launches the product, which may not occur.

The pace and outcome of our clinical development programs and the progress of our discovery research program are difficult to predict. These projects may require several years and substantial expenditures to complete and may ultimately be unsuccessful. If we enter into additional third party collaborations or acquire new product candidates, the timing and amounts of any related licensing cash flows or expenses are likely to be highly variable. As a result, we anticipate that our quarterly results will fluctuate for the foreseeable future. In view of this variability and of our limited operating history, we believe that period-to-period comparisons of our operating results are not meaningful and you should not rely on them as indicative of our future performance.

Based on the current status of our product development and commercialization plans, we believe that our current cash, cash equivalents, short-term investments and interest earned on these balances will be sufficient to satisfy our anticipated cash needs for working capital and capital expenditures through at least the next 12 months. This forecast of the period in which our financial resources will be adequate to support operations is a forward-looking statement and involves risks, uncertainties and assumptions. Our actual results and the timing of selected events may differ materially from those anticipated as a result of many factors, including but not limited to those discussed under “Risk Factors” in Part II, Item 1A of this quarterly report.

Our future capital uses and requirements depend on a number of factors, including but not limited to the following:

- the rate of progress and cost of our pre-clinical studies, clinical trials and other research and development activities;
- our ability to obtain a new partner for development and commercialization of faropenem medoxomil on acceptable terms;
- the scope and number of clinical development and research programs we pursue;
- the costs, timing and outcomes of regulatory approvals;
- the costs of establishing or contracting for marketing and sales capabilities, including the establishment of our own sales force;
- the extent to which we acquire or in-license new products, technologies or businesses;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights; and
- the terms and timing of any additional collaborative, strategic partnership or licensing agreements that we may establish.

If our available cash, cash equivalents, short-term investments and interest earned on these balances are insufficient to satisfy our liquidity requirements, or if we develop additional products or pursue additional applications for our products or conduct additional clinical trials beyond those currently contemplated, we may seek to sell additional equity or debt securities or acquire a credit facility. The sale of additional equity may result in additional dilution to our stockholders. If we raise additional funds through the issuance of debt securities, those securities could have rights senior to those of our common stock and could contain covenants that would restrict our operations. We may require additional capital beyond our currently forecasted amounts. Any such required additional capital may not be available on reasonable terms, if at all. If we are unable to obtain additional financing, we may be required to modify our planned research, development and commercialization strategy, which could adversely affect our business.

Critical Accounting Policies and Estimates

This discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the U.S. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, contingent assets and liabilities revenues, expenses and related disclosures. Actual results may differ from these estimates. Our significant accounting policies are described in Note 2 of Notes to Condensed Financial Statements included elsewhere in this quarterly report. We believe the following accounting policies affect our more significant judgments and estimates used in the preparation of our financial statements.

Revenue Recognition. We generate revenue through research, license, collaboration and commercialization agreements. These agreements can contain multiple elements, including non-refundable upfront fees, payments for reimbursement of research and commercialization costs, non-refundable payments associated with achieving specific milestones, and royalties based on specified percentages of net product sales.

In determining when to recognize revenue related to upfront and milestone payments under these agreements we apply the revenue recognition criteria as outlined in EITF Issue 00-21, *Revenue Arrangements with Multiple Deliverables* (EITF 00-21). In applying these criteria, we consider a variety of factors to determine the appropriate method of revenue recognition, including whether the elements of the agreement are separable, whether payments received are subject to refund or forfeiture, whether there are determinable fair values and whether there is a unique earnings process associated with each element of an agreement.

When a payment is specifically tied to a separate earnings process and the amount to be received is fixed and determinable, revenue is recognized when the performance obligation associated with the payment is completed. Performance obligations typically consist of significant and substantive milestones. Revenues from milestone payments may be considered separable from funding for research, development or commercial activities because of the uncertainty surrounding the achievement of the milestones. Accordingly, these payments could be recognized as revenue when the performance milestone is achieved as described in EITF 00-21. In circumstances where we cannot identify a separate earnings process related to an upfront or milestone payment, we record deferred revenue and recognize revenue ratably over the period of expected benefit, which is generally the unexpired contract term.

Revenues derived from reimbursement of expenses for research, development and commercial activities under our collaboration and commercialization agreements are recorded in compliance with EITF Issue 99-19, *Reporting Revenue Gross as Principal Versus Net as an Agent* (EITF 99-19). In accordance with the criteria established by EITF 99-19, in transactions where we act as principal, with discretion to choose suppliers, bear credit risk and perform a substantive part of the services, revenue is recorded at the gross amount of the reimbursement. Costs associated with these reimbursements are reflected as a component of operating expenses in our statements of operations.

Under our former agreement with Forest Laboratories entered into in February 2006, we recorded the initial $50 million upfront payment received in February 2006 as deferred revenue and were recognizing this amount into revenue ratably over the expected term of the agreement. In addition, we received a development milestone payment of $10 million in March 2006. Due to this milestone being achieved within one month of entering into the collaboration and commercialization agreement with Forest Laboratories, we could not identify a separate earnings process related to this milestone payment and were recognizing revenue related to this payment over the expected term of the agreement. In February 2007, we and Forest Laboratories announced that our agreement would terminate, and as a result, we reacquired all U.S. adult and pediatric rights previously granted to Forest Laboratories. As no further obligations exist beyond May 7, 2007, the effective date of the termination, we recognized the remaining unamortized deferred revenue balance as revenue in the second quarter of 2007.

We have also received amounts from Forest Laboratories as reimbursement for certain research and development. We believe that, as it relates to these activities, we act as the principal, performing a substantive part of the services directly, having the discretion to choose our suppliers and bearing all credit risk associated with the performance of these activities. We therefore have recorded these amounts as revenue in accordance with our revenue recognition policy. See Note 2 to our condensed financial statements for more information about our revenue recognition policies.

Clinical Trial Expenses. We record clinical trial expenses based on estimates of the services received and efforts expended pursuant to contracts with clinical research organizations (CROs) and other third party vendors associated with our clinical trials. We contract with third parties to perform a range of clinical trial activities in the ongoing development of our product candidates. The terms of these agreements vary and may result in uneven payments. Payments under these contracts depend on factors such as the achievement of certain defined milestones, the successful enrollment of patients and other events. The objective of our clinical trial accrual policy is to match the recording of expenses in our financial statements of the actual services received and efforts expended. In doing so, we rely on information from CROs and our clinical operations group regarding the status of our clinical trials to calculate our accrual for clinical expenses at the end of each reporting period. Our estimates and assumptions could differ significantly from the amounts that we actually may incur.

Share-Based Compensation. Effective January 1, 2006, we adopted Statement of Financial Accounting Standards No. 123(R), *Share-Based Payment* (SFAS 123(R)), which requires compensation costs related to share-based transactions, including employee stock options, to be recognized in the financial statements based on fair value. SFAS 123(R) revises SFAS 123, as amended, *Accounting for Stock-Based Compensation* (SFAS 123), and supersedes Accounting Principles Board (APB) Opinion No. 25, *Accounting for Stock Issued to Employees* (APB 25). We adopted SFAS 123(R) using the prospective method. Under this method, compensation cost is recognized for all share-based awards granted or modified on or after January 1, 2006.

We selected the Black-Scholes option pricing model as the most appropriate valuation method for option grants with service and/or performance conditions. The Black-Scholes model requires inputs for risk-free interest rate, dividend yield, volatility and expected lives of the options. Since the Company has a limited history of stock activity, expected volatility is based on historical data from several public companies similar in size and value to us. We will continue to use a weighted average approach using historical volatility and other similar public entity volatility information until our historical volatility is relevant to measure expected volatility for future option grants. We estimate the forfeiture rate based on historical data. Based on an analysis of historical forfeitures, we applied an annual forfeiture rate of 4.36% during the first nine months of 2007. The forfeiture rate is re-evaluated on a quarterly basis. The risk-free rate for periods within the contractual life of the option is based on the U.S. Treasury yield curve in effect at the time of the grant. The expected lives (net of forfeitures) for options granted represents the period of time that options granted are expected to be outstanding and is derived from historical exercise behavior.

During the first nine months of 2007, we estimated the fair value of option grants as of the date of grant using the Black-Scholes option pricing model with the following weighted-average assumptions. Expected volatility was estimated to be 75%. The weighted average risk free interest rate was 4.47% and the dividend yield was 0.00%. The weighted average expected lives for each individual vesting tranche under the graded vesting attribution method discussed below was estimated to be 3.05 years.

We had a choice of two attribution methods for allocating compensation costs under SFAS No. 123(R): the “straight-line” method, which allocates expense on a straight-line basis over the requisite service period of the last separately vesting portion of an award, or the “graded vesting attribution method”, which allocates expense on a straight-line basis over the requisite service period for each separately vesting portion of the award as if the award was, in substance, multiple awards. We chose the graded vesting attribution method and accordingly, amortize the fair value of each option over each option’s vesting period (requisite service period).

Deferred Tax Asset Valuation Allowance. In establishing an allowance on the valuation of our deferred tax assets we are required to make significant estimates and judgments about our future operating results. Our ability to realize deferred tax assets depends on our future taxable income as well as limitations on utilization primarily of net operating losses and tax credits. We are required to reduce our deferred tax assets by a valuation allowance if it is more likely than not that some portion or all of our deferred tax asset will not be realized. Although we reported net income for the three and nine months ended September 30, 2007 as a result of the termination of our agreement with Forest Laboratories, we expect to incur substantial operating losses for the next several years as we pursue our clinical trials and research and development efforts. Accordingly, we have recorded a full valuation allowance on our net deferred tax assets since inception due to uncertainties related to our ability to realize deferred tax assets in the foreseeable future. See Note 8 to our condensed financial statements.

Recent Accounting Pronouncements

In September 2007, the FASB ratified Emerging Issues Task Force (EITF) 07-03, *"Accounting for Advance Payments for Goods or Services to Be Used in Future Research and Development Activities"* (EITF 07-03). The scope of EITF 07-03 is limited to nonrefundable advance payments for goods and services to be used or rendered in future research and development activities pursuant to an executory contractual arrangement. This issue provides that nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities should be deferred and capitalized. Such amounts should be recognized as an expense as the related goods are delivered or the related services are performed. We are required to adopt EITF 07-03 for new contracts entered into in 2008. We do not expect that the adoption of EITF 07-03 will have a material effect on our financial position or results of operations.

The EITF has one issue currently under consideration that may impact us. EITF 07-01, *Accounting for Collaboration Arrangements Related to the Development and Commercialization of Intellectual Property* , is focused on how the parties to a collaborative agreement should account for costs incurred and revenue generated on sales to third parties, how sharing payments pursuant to a collaboration agreement should be presented in the income statement and certain related disclosure questions. A draft consensus has been issued and released for comment. We will continue to monitor the development of this EITF issue and evaluate the impact on our financial statements.

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

Our exposure to market risk is primarily limited to our cash, cash equivalents, and marketable securities. We have attempted to minimize risk by investing in quality financial instruments primarily money market funds, federal agency notes, asset backed securities, corporate debt securities and U.S. treasury notes, with no security having an effective duration in excess of two years. The primary objective of our investment activities is to preserve our capital for the purpose of funding operations while at the same time maximizing the income we receive from our investments without significantly increasing risk. To achieve these objectives, our investment policy allows us to maintain a portfolio of cash equivalents and investments in a variety of marketable securities, including U.S. government and mortgage backed securities, money market funds and under certain circumstances, derivative financial instruments. Our cash and cash equivalents as of September 30, 2007 included liquid money market accounts. The securities in our investment portfolio are classified as available-for-sale and held-to-maturity and are, due to their short-term nature, subject to minimal interest rate risk.

Most of our transactions are conducted in U.S. dollars, although we do have certain contractual obligations and conduct a number of clinical studies, and manufacture active pharmaceutical product with vendors located outside the United States. Some of these expenses are paid in U.S. dollars, and some are paid in the local foreign currency, including the Japanese Yen and the Euro. We do not currently engage in any activities designed to hedge our exposure to foreign currency fluctuations on forecasted expenses denominated in these foreign currencies.

Item 4. *Controls and Procedures*

Evaluation of Disclosure Controls and Procedures. As of the end of the period covered by this report, our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934 ("Exchange Act"). Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of September 30, 2007, our chief executive officer and chief financial officer concluded that, as of such date, the Company's disclosure controls and procedures are effective at providing reasonable assurance that all material information required to be included in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission's rules and forms and that such information is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate, to allow timely decisions regarding required disclosure.

Changes in Internal Controls over Financial Reporting. No changes in our internal control over financial reporting occurred during the period covered by this Quarterly Report on Form 10-Q that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II OTHER INFORMATION

Item 1. *Legal Proceedings*

We are not currently a party to any legal proceedings.

Item 1A. *Risk Factors*

You should carefully consider the risks described below, which we believe are the material risks of our business. Our business could be harmed by any of these risks. The trading price of our common stock could decline due to any of these risks, and you may lose all or part of your investment. In assessing these risks, you should also refer to the other information contained in our SEC filings, including our financial statements and related notes. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations. We are relying upon the safe harbor for all forward-looking statements in this Report, and any such statements made by or on behalf of the Company are qualified by reference to the following cautionary statements, as well as to those set forth elsewhere in this Report.

Risks Related to our Business

We received a non-approvable letter from the FDA for our NDA for faropenem medoxomil, our lead product candidate, and we are currently evaluating our development program for faropenem medoxomil and do not currently know if faropenem medoxomil will ever receive regulatory approval, which is necessary before it can be commercialized.

If we do not receive regulatory approval for faropenem medoxomil and we are not able to commercialize faropenem medoxomil, we will not generate revenue for several years, if at all, and we may never generate sufficient revenue to achieve and sustain profitability. We need approval from the FDA prior to marketing our product candidates in the U.S. In December 2005, we submitted our first NDA to the FDA for use of faropenem medoxomil in four adult clinical indications. In October 2006, the FDA issued a non- approvable letter for all four indications in our NDA and recommended further clinical studies and microbiologic evaluation for all indications. Additionally, the FDA advised us that the Division of Scientific Inspections had to complete their inspections of certain clinical trials sites that participated in the clinical trials included in the NDA. We are in the planning stages with respect to our faropenem medoxomil clinical trials program. Further clinical development of faropenem medoxomil for any indications will require us to complete additional and more extensive clinical trials, which will be costly and time consuming. The amount and timing of the increased costs related to our clinical trials is difficult to predict due to the uncertainty inherent in the timing of clinical trial initiations, the rate of patient enrollment and the detailed design of future trials. However, we expect that at least two to three years will be required to complete additional clinical trials. If we continue our clinical development program for faropenem medoxomil, we may not obtain necessary approvals from the FDA even if our trials demonstrate the effectiveness of faropenem medoxomil for any indication. The data we collect from any additional clinical trials with larger patient populations may not demonstrate sufficient safety and efficacy to support regulatory approval of faropenem medoxomil, in which case we would experience potentially significant delays in, or be required to abandon, development of that product candidate. If we continue our clinical development program for faropenem medoxomil, we will have fewer resources to devote to the research and development of other potential product candidates and development stage programs. If we decide to terminate any further development of faropenem medoxomil, we will be dependent upon the success of the other product candidates in our pipeline or other compounds we may in-license and the size of the potential markets for such other product candidates may not be as significant as the potential markets for faropenem medoxomil. All of our other existing product candidates and development stage programs are in Phase I clinical development or preclinical development.

Even if we obtain FDA approval for faropenem medoxomil, it may not cover all of the clinical indications for which we seek approval. Also, an approval might contain significant limitations with respect to conditions of use in the form of narrow indications, incomplete activity against key bacterial pathogens, warnings, precautions or contra-indications. We cannot predict if or when we might again seek regulatory review of faropenem medoxomil for any indication or of any of our other product candidates.

The FDA has substantial discretion in the approval process and may either refuse to accept an application for substantive review or may conclude after review of our data that our application is insufficient to allow approval of a product candidate. If the FDA does not accept or approve our application, it may require that we conduct additional clinical, pre-clinical or manufacturing validation studies and submit that data before it will reconsider our application. Depending on the extent of these or any other studies, approval of any application that we submit may be delayed by several years, or may require us to expend more resources than we have available. It is also possible that additional studies, if performed and completed, may not be considered sufficient by the FDA to approve our application for any particular indication for which we are seeking approval. If any of these outcomes occur, we may be forced to abandon our application for approval, which might cause us to cease operations.

Our lead product candidate, faropenem medoxomil, has been in-licensed from another pharmaceutical company, Asubio Pharma Co., Ltd., or Asubio Pharma. A previous licensee, Bayer AG, or Bayer, completed extensive pre-clinical studies and Phase II and Phase III clinical trials for a particular dosage of faropenem medoxomil. We may rely on some of the data from these pre-clinical studies and clinical trials in a future application or submission to the FDA for approval to market faropenem medoxomil. Any problems with these previous pre-clinical studies or clinical trials, including problems with the design or statistical analysis of such pre- clinical studies or clinical trials, could cause our application for regulatory approval to be delayed or rejected, in which case we might need to conduct additional trials.

Because of the termination of our collaboration with Forest Laboratories to develop and commercialize faropenem medoxomil, we are seeking a new partner. If we do not obtain a new partner on acceptable terms, we likely will not be able to develop and commercialize faropenem medoxomil for adult indications and may not be able to develop faropenem medoxomil for pediatric indications or generate any future revenue from faropenem medoxomil.

On May 7, 2007, Forest Laboratories exercised their right to terminate our agreement, under which Forest Laboratories had been granted an exclusive sublicense for the development and sale of faropenem medoxomil for all indications in the U.S. and a right of first refusal to extend the territory to include Canada. As a result of the termination we have reacquired all rights to faropenem medoxomil previously granted to Forest Laboratories.

We are currently seeking another partner or partners to assist us in the development and commercialization of faropenem medoxomil. We face competition in our search for partners with whom we may collaborate. Further, faropenem medoxomil has previously been licensed to other licensees who have opted not to develop and commercialize the product. As a result, we may not be successful in finding another partner on acceptable terms, or at all, and any failure to obtain a new partner on acceptable terms may adversely affect faropenem medoxomil development, commercialization and potential future sales. Identifying a new partner and entering into a collaboration agreement with it or developing the necessary infrastructure to commercialize, market and sell faropenem medoxomil to pediatricians ourselves could cause delays in obtaining regulatory approvals and commercializing faropenem medoxomil, which would negatively impact our business. If we obtain regulatory approval of faropenem medoxomil for pediatric indications and we choose to commercialize, market and sell faropenem medoxomil to pediatricians ourselves, we will be required to substantially increase our internal sales, distribution and marketing capabilities. The development of the infrastructure necessary to commercialize, market and sell faropenem medoxomil to pediatricians will require substantial resources and may divert the attention of our management and key personnel and negatively impact our other product development efforts. Further, our current capital resources may not be sufficient to fund and support this type of infrastructure. Moreover, we may not be able to hire a sales force that is sufficient in size or has adequate expertise. It is unusual for the FDA to approve a drug for pediatric use which has not been approved for adult use. As a result, in the event that we are unable to pursue further development of faropenem medoxomil for adult use, it may be difficult to obtain FDA approval for a pediatric indication.

If we fail to enter into new strategic collaborations, we may have to reduce or delay our rate of product development and commercialization and/or increase our expenditures.

Our business model is based in part upon entering into strategic collaborations for discovery and/or development of some of our product candidates. Our strategy to develop and commercialize our products includes entering into various relationships with pharmaceutical or biotechnology companies to advance our programs. We may not be able to negotiate any of our collaborations on acceptable terms. If we are not able to establish collaborative arrangements, we may have to reduce or delay further development of some of our programs and/or increase our expenditures and undertake the development activities at our own expense. If we are not able to establish and maintain strategic collaborations on acceptable terms:

- the development of our current or future product candidates may be reduced in scope, terminated or delayed;
- our cash expenditures related to development of our current or future product candidates would increase significantly;
- we may be required to hire additional employees or otherwise develop expertise, such as sales and marketing expertise, for which we have not budgeted;
- we will bear all of the risk related to the development of each of our current and future product candidates; and
- we may be unable to meet demand for any future products that we may develop.

In that event, we would likely be required to limit the size or scope of one or more of our programs.

Securing a strategic partner to develop and commercialize our product candidates may require us to relinquish valuable rights and will render us dependent on the efforts of any future partners, over which we would have limited control, and if our collaborations are unsuccessful, our potential to develop and commercialize product candidates and to generate future revenue from our product candidates would be significantly reduced.

In order to secure a strategic partner to develop and commercialize our product candidates, we may be required to relinquish valuable rights to our potential products or proprietary technologies. If we are able to identify and reach agreement with collaborators for our product candidates, those relationships will be subject to a number of risks, including:

- collaborators may not pursue further development and commercialization of compounds resulting from collaborations or may elect not to renew research and development programs;
- collaborators may delay clinical trials, under fund a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials, or require the development of a new formulation of a product candidate for clinical testing;
- a collaborator with marketing and distribution rights to one or more of our product candidates may not commit sufficient resources to the marketing and distribution of any future products, limiting our potential revenues from the commercialization of these products;
- disputes may arise delaying or terminating the research, development or commercialization of our product candidates, or result in significant litigation or arbitration;
- strategic partners could develop drugs which compete with our future products, if any;
- strategic partners could turn their focus away from anti-infective products and community respiratory tract infection indications;
- strategic partners could fail to effectively manage manufacturing relationships with suppliers;
- contracts with strategic partners may not provide significant protection or may be difficult to enforce if a strategic partner fails to perform; and

- if an arrangement with a strategic partner expires or is terminated, we may not be able to replace it or the terms on which we replace it may be unacceptable.

If as a result of our financial condition or other factors we enter into a strategic collaboration while a drug candidate program is in early preclinical development, we may not generate as much near- or longer-term revenue from such program as we could have generated if we had the resources to further independently develop such program. In addition, if we raise additional funds through 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.

The type of trials that the FDA is recommending for faropenem medoxomil will be novel in design without historical formal guidance and may require alternative dosing regimens.

In the non-approval letter we received in October 2006, the FDA indicated that it recommends conducting additional large-scale clinical trials at alternate doses for all indications covered by our NDA, including superiority designed studies, which will be costly, difficult and time consuming to conduct. All efficacy studies upon which our NDA was based were designed as non-inferiority studies. In addition, dosages used in these studies were determined by the prior licensee of faropenem medoxomil, Bayer. Historically, the FDA and foreign regulatory authorities have not required superiority studies, such as placebo-controlled clinical trials, for approval of antibiotics but instead have relied on non-inferiority studies. In a non-inferiority study, a drug candidate is compared with an approved antibiotic and it must be shown that the drug product candidate is not less effective than the approved treatment within a defined non-inferiority margin. In a superiority study, a drug candidate is compared either with an approved antibiotic treatment or placebo and it must be shown that the drug candidate is more effective than the approved treatment or placebo, as the case may be. Although the FDA has indicated that superiority designed trials will be required for some indications, there is no approved formal guidance on the design of these studies and we are uncertain at this time as to exactly what types of trials will be required.

Conducting placebo-controlled trials for antibiotics can be time consuming and expensive and can be difficult to complete. Institutional review boards may not grant approval for placebo-controlled trials because of ethical concerns about denying some participating patients access to any antibiotic therapy during the course of the trial. It may be difficult to enroll patients in placebo-controlled trials even if institutional review board approval is obtained because certain patients would receive no therapy during the course of the trial. Although we are currently conducting a placebo-controlled trial for acute exacerbation of chronic bronchitis, we have not completed any placebo-controlled trials for faropenem medoxomil for any indications. We may not be able to show a statistically significant advantage over placebo or another control treatment in any trials that we are able to complete. These factors could delay for several years or ultimately prevent commercialization of faropenem medoxomil for any indications for which the FDA requires superiority designed trials. Demonstration of superiority of a drug candidate over an approved antibiotic is likely to be difficult and require a large number of patients because clinical success rates for most approved antibiotics that would serve as appropriate comparisons are high, typically 70% to 90%.

If we choose, after discussion with the FDA, to pursue additional clinical trials in an effort to gain approval from the FDA for faropenem medoxomil, then our ongoing development programs for faropenem medoxomil will be lengthy and expensive. The amount of time and cost associated with these trials are difficult to predict due to the uncertainty inherent in the timing of clinical trial initiations, the rate of patient enrollment and details of future trial designs. In addition, the guidance we receive from the FDA in future meetings with them will influence the number, size and duration of planned and unplanned trials. Even if clinical trials show our product candidates to be safe and effective in treating their target conditions, we do not expect to be able to record commercial sales of any of our product candidates until at least 2010. Even if we conduct these trials in accordance with FDA recommendations and achieve protocol defined end points, faropenem medoxomil may not be approved.

Further delays in clinical testing or approval could result in increased costs to us and delay our ability to generate revenue.

We may experience delays in clinical testing of our product candidates. We currently plan to limit our faropenem medoxomil adult clinical trial activities to completion of the ongoing Phase III placebo-controlled

clinical trial for treatment of acute exacerbation of chronic bronchitis until we have a collaboration partner for the faropenem medoxomil adult program. Even in this trial, we temporarily stopped enrollment to exclude Ketek ®. We had included Ketek as a comparator in the clinical trial to generate secondary data points versus a product projected to be a competitor product to faropenem. We based our decision to exclude Ketek on the findings of a joint Advisory Meeting of the FDA's Anti-Infective Drug and Drug Safety and Risk Management committees held on December 14 and 15, 2006 that recommended to the FDA that the risks of using Ketek outweigh the benefits of using the drug for treatment of acute exacerbation of chronic bronchitis. This recommendation was adopted by the FDA on February 12, 2007. Following required communication with investigational review boards overseeing the clinical trial sites, we have re-initiated this trial without the Ketek comparator arm. We do not know whether planned clinical trials will begin on time, will need to be redesigned or will be completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including delays in obtaining regulatory approval to commence a trial, in reaching agreement on acceptable clinical trial terms with prospective sites, in obtaining institutional review board or ministry of health approval at each site or country in which we seek to conduct clinical trials, in recruiting patients to participate in a trial, or in obtaining sufficient supplies of clinical trial materials. Many factors affect patient enrollment, including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, competing clinical trials, clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating, and whether the clinical trial design involves comparison to placebo. Our antibiotics treat bacterial infections which tend to be seasonal in nature. As a result, during certain times of the year, it is difficult to find patients to enroll in our trials. Prescribing physicians would also face ethical issues associated with enrolling patients in clinical trials of our product candidates over existing antibiotics that have established safety and efficacy profiles or in placebo-controlled trials. These ethical issues may be even more pronounced in conducting clinical trials of antibiotics in children. Any delays in completing our clinical trials will increase our costs, slow down our product development and approval process and delay our ability to generate revenue or seek approval of faropenem medoxomil.

The success of our current business strategy will depend in part on our ability to obtain FDA approval of faropenem medoxomil for pediatric use and, if FDA approval is obtained, to successfully market an oral liquid formulation for the pediatric market.

The development of faropenem medoxomil for pediatric use is an important part of our current business strategy. We have developed a prototype oral liquid formulation, completed a Phase II clinical trial in acute otitis media (middle ear infection) and are considering conducting future studies in acute otitis media and tonsillitis/pharyngitis. Our ability to successfully develop and market this product candidate for pediatric use is subject to various risks, including the following:

- It is unusual for the FDA to approve a drug for pediatric use that has not been approved for adult use. As a result, in the event that we abandon further development of faropenem medoxomil for adult use, it may be difficult to obtain FDA approval for a pediatric indication.
- The FDA recently postponed a meeting of the Advisory Committee of the Anti-Infective Drugs Advisory Committee (AIDAC) that had been scheduled to discuss clinical trial design for treatment of acute otitis media in pediatric patients. Delays in understanding the pediatric clinical trials program required for the approval of faropenem medoxomil for treating pediatric patients could result in our inability to complete the trials and, even if completed, could delay initiation of pivotal clinical trials, its potential commercial launch and ability to generate future revenue.
- Pre-clinical testing and clinical trials are protracted, expensive and uncertain processes. It may take us and any future collaboration partner several years to complete the testing and trials, and failure can occur at any stage of the process. Success in pre-clinical testing and early clinical trials does not ensure that later clinical trials will be successful. These risks are potentially more pronounced in clinical tests involving children.
- We have completed only one Phase II clinical trial in children with acute otitis media to date. A clinical trial conducted by Bayer for tonsillitis/pharyngitis in adults did not meet its primary endpoint.

- Any NDA or other marketing authorization applications that we may file might be denied by the FDA and analogous foreign regulators.
- Any regulatory approval we ultimately obtain may be limited or subject to post-approval commitments that render the product not commercially viable.
- This product candidate, even if found to be safe and effective, might be difficult to develop into a commercially viable drug or to manufacture on a large scale. It may also prove to be economically unfeasible to market commercially.
- Competitors may develop and market superior drugs or be more effective in marketing equivalent drugs.
- Even if this product candidate is successfully developed and effectively marketed, the size of the market may be smaller than expected or may decrease over time, such that our sales revenue is less than initially contemplated.

Any failure to obtain regulatory approval of faropenem medoxomil for pediatric use would have a material and adverse impact on our ability to successfully execute our current business strategy and would significantly reduce the revenues that we might generate from faropenem medoxomil.

All of the Phase III clinical trials of faropenem medoxomil included in our NDA submitted in December 2005 were conducted using a 300 mg, twice per day, dose. We expect that future clinical trials will be conducted at the alternate 600 mg, twice per day, dose. If the incidence of adverse events from use of faropenem medoxomil at the 600 mg, twice per day, dose is significantly higher than that observed in completed clinical studies at the 300 mg, twice per day, dose we may not be able to generate future revenue from faropenem medoxomil.

The Phase III clinical trials included in our December 2005 NDA were all conducted using a 300 mg, twice per day, dose. The dose was selected by the previous licensee of faropenem medoxomil. We expect that future clinical trials will be conducted at the alternate 600 mg, twice per day, dose. In January 2006, we initiated a Phase III clinical trial for the acute exacerbation of chronic bronchitis indication using the higher dose. We have previously evaluated the potential for adverse events with the 600 mg, twice per day, dose in a Phase I study and a Phase II study conducted in 2005. In the Phase I study, the 600 mg, twice per day, dose was directly compared to a 300 mg, twice per day, dose, both administered for seven days. In the Phase II study, a 600 mg, twice per day, dose for five day treatment course was compared to a 300 mg, twice per day, dose seven day treatment courses in patients with acute bacterial sinusitis. In both trials, the adverse events were similar in both type and frequency. If there is an increased level of adverse events observed for faropenem medoxomil 600 mg, twice per day as compared to 300 mg, twice per day, it will likely reduce future potential product revenue from faropenem medoxomil.

We have limited experience in acquiring or in-licensing product candidates, and integrating third parties' products, businesses and technologies into our current infrastructure. If we determine that future acquisition or in-licensing opportunities are desirable and do not successfully execute on and integrate such targets, we may incur costs and disruptions to our business and we may be unable to grow our business.

A key element of our strategy is to commercialize a portfolio of new anti-infective products in addition to faropenem medoxomil. These efforts include potential licensing and acquisition transactions. To date, we have in-licensed rights to each of our product candidates. In addition to our internal drug development efforts, we may seek to expand our product pipeline and technologies by acquiring or in-licensing products, businesses or technologies that we believe are a strategic fit with our business and complement our existing product candidates, research programs and technologies.

If we decide not to pursue the development of faropenem medoxomil for any or all indications, then we may devote substantial additional time and energy to the pursuit of strategic opportunities, including potential licensing and acquisition transactions. These transactions may include new anti-infective products or product candidates as well as products or product candidates outside of the anti-infective area. The success of this strategy depends upon our ability to identify, select and acquire the right pharmaceutical product candidates and products on terms that are acceptable to us. Proposing, negotiating and implementing an economically viable product acquisition or license is

a lengthy and complex process. Other companies, including those with substantially greater financial, marketing and sales resources, may compete with us for the acquisition or license of product candidates and approved products. We may not be able to acquire or license the rights to additional product candidates and approved products on terms that we find acceptable, or at all.

Any product candidate we license or acquire may require additional development efforts prior to commercial sale, including extensive clinical testing and approval by the FDA and applicable foreign regulatory authorities. All product candidates are prone to the risks of failure inherent in pharmaceutical product development, including the possibility that the product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities. In addition, we cannot ensure that any such products that are approved will be manufactured or produced economically, successfully commercialized or widely accepted in the marketplace.

In addition, future acquisitions 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 the development of acquired products or technologies;
- incurrence of substantial debt or dilutive issuances of securities to pay for acquisitions;
- higher than expected acquisition and integration costs;
- difficulties in and costs of 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.

Finally, we may devote resources to potential acquisitions or in-licensing opportunities that are never completed or fail to realize the anticipated benefits of such efforts.

Our drug discovery approach and technologies and our product candidates other than faropenem medoxomil are unproven and in very early stages of development, which may not allow us to establish or maintain a clinical development pipeline or successful collaborations, and may never result in the discovery or development of commercially viable products.

Because we do not currently know when or if we will continue clinical development of faropenem medoxomil for certain adult indications or any other indications, we are more dependent on the potential success of our internal discovery research programs and product candidates other than faropenem medoxomil. Our only other existing product candidate, REP8839, has just completed its Phase I clinical development. As a significant part of our growth strategy, we intend to develop and commercialize additional products and product candidates through our discovery research program. A significant portion of the research that we are conducting involves new and unproven technologies, and may not result in the discovery or development of commercially viable products. Research programs to identify new disease targets and product candidates require substantial technical, financial and human resources whether or not we ultimately identify any candidates. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development. The process of successfully discovering product candidates is expensive, time-consuming and unpredictable, and the historical rate of failure for drug candidates is extremely high. 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 compounds suitable for recommendation for clinical development. Moreover, any 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. If we are unable to identify new product candidates or advance our lead compounds into clinical development, we may not be able to establish or maintain a clinical development pipeline or generate product revenue. Our ability to identify new 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. If we continue our clinical development program for faropenem medoxomil for certain adult indications or any other indications we will have fewer resources to devote to the further research and development of other product candidates, such as REP8839, or potential product candidates identified through our discovery research program. There is no guarantee that we will be able to successfully advance any product candidates identified through our discovery research program into clinical trials or successfully develop any product candidate we advance into clinical trials for commercial sale. In addition, the size of the potential markets for such other product candidates may not be as attractive as the potential markets for faropenem medoxomil. If we are unable to develop suitable potential product candidates through internal research programs or are not able to advance the development of our early stage product candidates such as REP8839, our business will suffer and we may be unable to grow our business.

We are at an early stage of development as a company, with no current sources of revenue, and we may never generate future revenue or become profitable.

We are a biopharmaceutical company that emerged from the development stage in February 2006 and have a limited operating history. Currently, we have no products approved for commercial sale and, to date, we have not generated any revenue from product sales. Our ability to generate revenue depends heavily on:

- our ability to obtain a new collaboration partner for faropenem medoxomil on acceptable terms;
- obtaining U.S. and foreign regulatory approvals for our lead product candidate, faropenem medoxomil;
- successfully developing and securing regulatory approval for our product candidate, REP8839; and
- successfully commercializing any product candidates for which we receive FDA approval.

Our existing product candidates will require extensive additional clinical evaluation, regulatory approval, significant marketing efforts and substantial investment before they can provide us with any revenue. If we do not receive regulatory approval for and successfully commercialize faropenem medoxomil, we will be unable to generate any royalty revenue from product sales for many years, if at all. If we are unable to generate revenue, we will not become profitable, and we may be unable to continue our operations.

We have incurred significant operating losses since inception and anticipate that we will incur continued losses for the foreseeable future.

We have experienced significant operating losses since our inception in December 2000. At September 30, 2007, we had an accumulated deficit of approximately $92 million. We have generated no revenue from product sales to date. We have funded our operations to date principally from the sale of our securities and payments by Forest Laboratories under our former collaboration agreement. As a result of the October 2006 FDA non-approval letter for our December 2005 NDA for faropenem medoxomil and the termination of our Forest Laboratories collaboration agreement in May 2007, our prospects for near term future revenues are substantially uncertain. We expect to continue to incur substantial additional operating losses for the next several years as we pursue our clinical trials and research and development efforts. Because of the numerous risks and uncertainties associated with developing and commercializing antibiotics, we are unable to predict the extent of any future losses. We may never have any significant future revenue or become profitable on a sustainable basis.

If we fail to obtain additional financing, we may be unable to complete the development and commercialization of faropenem medoxomil and other product candidates, or continue our research and development programs.

Our operations have consumed substantial amounts of cash since inception. We currently expect to spend substantial amounts to:

- complete the clinical development of faropenem medoxomil and REP8839;
- continue our research and development programs;

- license or acquire additional product candidates; and
- launch and commercialize any product candidates for which we receive regulatory approval, including building our own sales force to address certain markets.

We do not expect that our current capital resources will be sufficient to fund the complete development of our faropenem medoxomil and REP8839 product candidates and any product candidates generated from our discovery research program. To date, our sources of cash have been limited primarily to the proceeds from the sale of our securities and payments by Forest Laboratories under our former collaboration agreement. As a result of the termination of our Forest Laboratories collaboration agreement on May 7, 2007, our prospects for near term future revenues are substantially uncertain. We are currently seeking a new collaboration partner for faropenem medoxomil and using our cash and cash equivalents, short-term investments and interest earned on these balances toward the funding necessary to support our planned activities. If we cannot find a new partner on acceptable terms or if the funds provided from existing resources are insufficient to satisfy our future capital needs, or if we develop, in-license or acquire additional products or product candidates or pursue additional applications for our product candidates, we may seek to sell additional equity or debt securities. We cannot be certain that additional funding will be available on acceptable terms, or at all. To the extent that we raise additional funds by issuing equity securities, our stockholders may experience significant dilution. Any debt financing, if available, may involve restrictive covenants, such as limitations on our ability to incur additional indebtedness, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. If we are unable to raise additional capital when required or on acceptable terms, we may have to significantly delay, scale back or discontinue the development and/or commercialization of one or more of our product candidates. We also may be required to:

- seek collaborators for our product candidates at an earlier stage than otherwise would be desirable and on terms that are less favorable than might otherwise be available; and
- relinquish or license on unfavorable terms our rights to technologies or product candidates that we otherwise would seek to develop or commercialize ourselves.

We have limited manufacturing capabilities and will depend on third parties to manufacture faropenem medoxomil and future products. If we cannot develop adequate manufacturing internally or identify suitable third party manufacturers, or these manufacturers fail to meet our requirements and strict regulatory standards, we may be unable to develop or commercialize our products.

We do not have the capability to manufacture commercial quantities of faropenem medoxomil drug substance. If we decide to pursue additional large scale clinical trials for faropenem medoxomil or if our other product candidates advance into full scale clinical trials, we may not have the capability to manufacture quantities of faropenem medoxomil or such other product candidates for our clinical trials. We originally engaged Nippon Soda and MEDA as our sole suppliers of faropenem medoxomil drug substance and faropenem medoxomil tablets, respectively. Pursuant to the terms of our former collaboration agreement with Forest Laboratories, Forest Laboratories had agreed to assume responsibility for supply chain management for faropenem medoxomil and entered into a direct relationship with both Nippon Soda and MEDA as its sole supplier of faropenem medoxomil drug substance. However, following termination of our agreement with Forest Laboratories, the Nippon Soda and MEDA obligations reverted directly to us. Further, in connection with our determination that future clinical development of faropenem medoxomil would be completed using the 600 mg tablet as compared to the 300 mg tablet used in the clinical trials included in the December 2005 NDA for which the FDA issued a non-approval letter in April 2007, we notified MEDA that we would terminate the agreement to manufacture 300 mg tablets. We are contractually bound to purchase all of our requirements for bulk drug substance from Nippon Soda and expect Nippon Soda will be the sole supplier of faropenem medoxomil drug substance for the foreseeable future. Nippon Soda may terminate this supply agreement for a number of reasons, such as:

- an uncured material breach of the supply agreement by us;
- our liquidation or insolvency;
- in some circumstances, following a change of control; or

- our failure to notify Nippon Soda of a launch go date, as defined, for faropenem medoxomil in the U.S. and Canada by July 1, 2009.

Nippon Soda will be subject to ongoing periodic unannounced inspections by the FDA and corresponding state agencies for compliance with good manufacturing practices regulations, or cGMPs, and similar foreign standards. We do not have control over compliance by Nippon Soda with these regulations and standards.

Nippon Soda has only a single facility located in Nihongi, Japan that can readily manufacture commercial quantities of faropenem medoxomil. If that facility were to be damaged or destroyed, we would have no readily available source of supply. Nippon Soda has not yet manufactured faropenem medoxomil at commercial scale on a consistent basis, nor has Nippon Soda completed the manufacturing process validations that are part of the regulatory requirements prior to obtaining marketing approval for faropenem medoxomil.

We may not be able to identify a suitable third party manufacturer to manufacture 600 mg faropenem medoxomil tablets or, if we do identify a manufacturer for 600 mg faropenem medoxomil tablets, we may not be able to obtain suitable terms.

Reliance on a third party manufacturer entails risk, to which we would not be subject if we manufactured products ourselves, including:

- reliance on the third party for regulatory compliance and quality assurance;
- delays or failure to manufacture sufficient quantities needed for clinical trials in accordance with our specifications or to deliver such quantities on the dates we require;
- the possible breach of the manufacturing agreement by the third party because of factors beyond our control; and
- the possibility of termination or non-renewal of the agreement by the third party because of our breach of the manufacturing agreement or based on its own business priorities, and the non-approvable letter we recently received from the FDA for our NDA for faropenem medoxomil may adversely influence the business priorities of our current suppliers.

Any of these factors could cause delay or suspension of clinical trials, regulatory submissions, required approvals or commercialization of faropenem medoxomil and our other product candidates under development, cause us to incur higher costs and could prevent us from commercializing our product candidates successfully. If we obtain regulatory approval for faropenem medoxomil and our contract manufacturers fail to deliver the required commercial quantities of bulk drug substance or finished product on a timely basis and at commercially reasonable prices and we are unable to find one or more replacement manufacturers capable of production at a substantially equivalent cost, in substantially equivalent volumes and quality, and on a timely basis, we would likely be unable to meet demand for faropenem medoxomil and we would lose potential revenue. It may take several years to establish an alternative source of supply for faropenem medoxomil and to have any such new source approved by the FDA, especially because faropenem medoxomil requires dedicated manufacturing facilities.

If the FDA does not approve Nippon Soda's facility, we may be unable to develop or commercialize faropenem medoxomil.

We rely on Nippon Soda to manufacture faropenem medoxomil drug substance and currently have no plans to develop our own manufacturing facility. The facilities used by our contract manufacturer to manufacture our product candidates must be approved by the FDA. Nippon Soda's facility has undergone its initial inspection by the FDA as part of the faropenem medoxomil NDA review. Although no FDA Form 483 observations were noted by the FDA site inspector, if Nippon Soda cannot successfully manufacture material that conforms to our specifications and strict regulatory requirements, Nippon Soda will not be able to maintain FDA approval for its manufacturing facility. If the FDA does not maintain approval of this facility for the manufacture of faropenem medoxomil, we may need to find alternative manufacturing facilities, which would result in significant delay of up to several years in obtaining approval for and manufacturing faropenem medoxomil. In addition, our contract manufacturer will be subject to ongoing periodic unannounced inspections by the FDA and corresponding state and foreign agencies for compliance with cGMPs and similar regulatory requirements. These regulations cover all aspects of the

manufacturing, testing, quality control and record keeping relating to our product candidates. We do not have control over Nippon Soda's compliance with these regulations and standards. Failure by Nippon Soda to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure to grant approval to market our product candidates, delays, suspension or withdrawals of approvals, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business. In addition, we have no control over Nippon Soda's ability to maintain adequate quality control, quality assurance and qualified personnel. Failure by our contract manufacturer to comply with or maintain any of these standards could adversely affect our ability to develop, obtain regulatory approval for or market our product candidates.

Any of our product candidates that are in clinical trials or that we advance into clinical trials 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 any of our product candidates currently in clinical trials or that we advance into clinical trials are subject to extensive regulation by the FDA in the U.S. and by comparable governmental authorities in foreign markets. Currently, we are developing faropenem medoxomil for adult and pediatric use and we have completed Phase I clinical testing of REP8839. In the U.S. and in many foreign jurisdictions, rigorous pre-clinical testing and clinical trials and an extensive regulatory review process must be successfully completed before a new drug can be sold. Satisfaction of these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. Clinical testing is expensive, can take many years to complete and its outcome is uncertain. Failure can occur at any time during the clinical trial process. The results of pre-clinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through initial clinical testing. The time required to obtain approval by the FDA is unpredictable but typically takes many years following the commencement of clinical trials, depending upon numerous factors. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change. We have not obtained regulatory approval for any product candidate.

Our product candidates may fail to receive regulatory approval for many reasons, including the following:

- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for a particular indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or other regulatory authorities for approval;
- the FDA or other regulatory authorities may disagree with the design of our clinical trials;
- we may be unable to demonstrate that a product candidate's benefits outweigh its risks;
- we may be unable to demonstrate that the product candidate presents an advantage over existing therapies, or over placebo in any indications for which the FDA requires a placebo-controlled trial;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from pre-clinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a new drug application or to obtain regulatory approval in the U.S. or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may change.

The FDA or comparable foreign regulatory authorities might decide that our data is insufficient for approval and require additional clinical trials or other studies. Furthermore, even if we do receive regulatory approval to market a commercial product, any such approval may be subject to limitations on the indicated uses for which we

may market the product. It is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain the appropriate regulatory approvals necessary for us or our collaborators to begin selling them.

Also, recent events have raised questions about the safety of marketed drugs and may result in increased cautiousness by the FDA in reviewing new drugs based on safety, efficacy or other regulatory considerations and may result in significant delays in obtaining regulatory approvals and more stringent product labeling requirements. Further, the FDA has been granted new authority to require additional clinical trials of license holders of pharmaceutical products, including post approval clinical trials, and modify previously approved product labels under the FDA Amendments Act of 2007 that was enacted September 2007. Any delay in obtaining, or inability to obtain, applicable regulatory approvals would prevent us from commercializing our product candidates.

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

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel and on our ability to develop and maintain important relationships with leading academic institutions, clinicians and scientists. We are highly dependent upon our senior management and scientific staff, particularly Kenneth Collins, our President and Chief Executive Officer, Roger Echols, M.D., our Chief Medical Officer, Peter Letendre, Pharm. D., our Chief Commercial Officer, and Nebojsa Janjic, Ph.D., our Chief Scientific Officer. The loss of services of any of Mr. Collins, Dr. Echols, Dr. Letendre or Dr. Janjic or one or more of our other members of senior management could delay or prevent the successful completion of our planned clinical trials or the commercialization of our product candidates. In addition, we only recently formed our clinical and regulatory group, the services of which we highly depend upon to conduct our clinical programs and obtain regulatory approvals.

Competition for qualified personnel in the biotechnology and pharmaceutical fields is intense. We will need to hire additional personnel as we expand our clinical development and commercial activities. In addition, we may be required to grant significant amounts of share-based compensation to certain individuals to attract them, which could increase the related non-cash compensation expense. We may not be able to attract and retain qualified personnel on acceptable terms. We do not carry “key person” insurance covering any members of our senior management. Each of our officers and key employees may terminate his or her employment at any time without notice and without cause or good reason.

We currently have no sales organization. If we are unable to establish a direct sales force in the U.S. to promote our product candidates, the commercial opportunity for our product candidates may be diminished.

We currently have no sales organization. If our lead product candidate, faropenem medoxomil, is approved by the FDA for adult use, we will require a partner to market the product. If faropenem medoxomil is approved by the FDA for pediatric use, we may opt to market and sell faropenem medoxomil to pediatricians in the U.S. We will incur significant additional expenses and commit significant additional management resources to establish a pediatric sales force. We may not be able to establish a pediatric specialty sales force in a cost effective manner or realize a positive return on this investment. We will also have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain sales and marketing personnel. If we elect to rely on third parties to sell our product candidates in the U.S., we may receive less revenue than if we sold our product candidates directly. In addition, we may have little or no control over the sales efforts of those third parties. In the event we are unable to develop our own sales force or collaborate with a third party to sell our product candidates, we may not be able to commercialize our product candidates which would negatively impact our ability to generate revenue.

The commercial success of our product candidates will depend upon attaining significant market acceptance of these products among physicians, patients, health care payors and the medical community.

None of our product candidates has been commercialized for any indication. Even if approved for sale by the appropriate regulatory authorities, physicians may not prescribe our product candidates, in which case we would not generate revenue or become profitable. Market acceptance of our lead product candidate, faropenem medoxomil, and any future product candidates by physicians, healthcare payors and patients will depend on a number of factors, including:

- the clinical indications for which the product candidate is approved;
- acceptance by physicians and patients of each product candidate as a safe and effective treatment;
- perceived advantages over alternative treatments;
- the cost of treatment in relation to alternative treatments, including numerous generic antibiotics;
- the extent to which the product candidate is approved for inclusion on formularies of hospitals and managed care organizations;
- the extent to which bacteria develop resistance to the product candidate, thereby limiting its efficacy in treating or managing infections;
- whether the product candidate is designated under physician treatment guidelines as a first-line therapy or as a second- or third-line therapy for particular infections;
- the availability of adequate reimbursement by third parties;
- relative convenience and ease of administration; and
- prevalence and severity of side effects.

Even if faropenem medoxomil ultimately obtains regulatory approval, many of the above factors may be adversely impacted by the historical difficulty of obtaining any such approval and may create a negative perception among physicians and healthcare payors of the advantages or efficacy of faropenem medoxomil.

If lawsuits or arbitration proceedings arising as a result of termination of collaboration or other commercial contracts are successfully brought against us, we may incur substantial liabilities and may be unable to commercialize our product candidates.

Between February 6, 2007 and May 7, 2007, we operated under the termination provisions of our collaboration agreement with Forest Laboratories. On April 27, 2007, under the termination provisions of our agreement with Forest Laboratories, we terminated our agreement with MEDA for the manufacture of 300 mg tablets of faropenem medoxomil. MEDA has indicated to us that it disputes our right to terminate the agreement on the basis indicated in our notice of termination. We believe we have acted in accordance with the terms of these and other commercial agreements. However, if it is determined that we have obligations to MEDA beyond May 7, 2007 under the agreement, then we may incur additional costs. Consistent with our position that we had the right to terminate this agreement and that Forest Laboratories is responsible for all supply chain obligations through May 7, 2007, we have not accrued for any minimum purchase or termination fees under this agreement.

The interpretation of the terms of our collaboration and commercial agreements may be the subject of disagreement between us and our collaborators and other commercial partners that could result in lawsuits and/or arbitration proceedings. If former partners or other parties to our commercial contracts are successful in lawsuits or arbitration proceedings, we may incur judgments against us that could have a material impact on our financial position and limit our ability to complete development of and launch commercially our product candidates.

If our product candidates are unable to compete effectively with generic and branded antibiotics, our commercial opportunity will be reduced or eliminated.

If approved, our lead product candidate, faropenem medoxomil, will compete against both generic and branded community antibiotic therapies. The market for such products is very competitive and includes generic products, such as amoxicillin/clavulanate, and established branded products, such as Omnicef ®, Zithromax ®, Ketek ® and Levaquin ®, which are marketed by major pharmaceutical companies, all of which have significantly greater financial resources and expertise in research and development, pre-clinical testing, conducting clinical trials, obtaining regulatory approvals, manufacturing 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, established companies.

Over the next several years, our future products, if any, will face more competition in the form of generic versions of branded products of competitors that will lose their patent exclusivity. Many of the currently branded antibiotics will be sold as generics before we expect to be able to commercially launch faropenem medoxomil. Generic antibiotic therapies typically are sold at lower prices than branded antibiotics and are preferred by managed care providers of health services. As a result, managed care may place different constraints on formulary status and reimbursement at the time we expect to be able to commercially launch faropenem medoxomil. If we are unable to demonstrate to physicians that, based on experience, clinical data, side-effect profiles and other factors, our products are preferable to these generic antibiotic therapies, we may have limited revenue potential due to formulary status. Our commercial opportunity will also be reduced or eliminated if our competitors develop and commercialize generic or branded antibiotics that are safer, more effective, have fewer side effects or are less expensive than our product candidates.

Asubio Pharma owns a portfolio of patents related to faropenem compounds, including the faropenem parent compound, medoxomil and other faropenem prodrugs. We have licensed from Asubio Pharma the patents to faropenem medoxomil and other faropenem prodrugs. These patents may not prevent competitors from developing other faropenem drugs that are not covered by the Asubio Pharma patents. Beginning in 2008, when the Asubio Pharma patents related to the faropenem parent compound expire, competitors may submit NDAs seeking approval of antibiotics containing the faropenem parent compound as the active ingredient. These applications would have to contain full reports of safety and efficacy data conducted by or for the applicants and could not in any way rely upon the safety and efficacy data utilized in the approval of faropenem medoxomil. In addition, as early as four years after the approval of a faropenem medoxomil NDA, if any, competitors could also file NDA's seeking approval of faropenem drugs that would likely require the applicant to conduct clinical trials in order to bring the product to market in the U.S., though the FDA may allow the applicant to rely in part on the FDA's prior findings of safety and efficacy of faropenem medoxomil.

If product liability lawsuits are successfully brought against us or any future collaboration partners, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.

We face an inherent risk of product liability lawsuits related to the testing of our product candidates, and will face an even greater risk if product candidates are introduced 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. We have agreed to indemnify Nippon Soda from product liability claims under our commercial arrangement. If we cannot successfully defend ourselves against the product liability claim, we may 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;
- significant litigation costs;
- substantial monetary awards to or costly settlement with patients;

- product recalls;
- loss of revenue; and
- the inability to commercialize our product candidates.

We are highly dependent upon consumer perceptions of us, the faropenem medoxomil brand and the safety and quality of our products. We could be adversely affected if we or the faropenem medoxomil brand is subject to negative publicity. We could also be adversely affected if any of our products or any similar products distributed by other companies prove to be, or are asserted to be, harmful to consumers. Also, because of our dependence upon consumer perceptions, any adverse publicity associated with illness or other adverse effects resulting from consumers' use or misuse of our products or any similar products distributed by other companies could have a material adverse impact on our results of operations.

We have global clinical trial liability insurance that covers our clinical trials up to a $10.0 million annual aggregate limit. Our current or future insurance coverage may prove insufficient to cover any liability claims brought against us. We intend to expand our insurance coverage to include the sale of commercial products if marketing approval is obtained for our product candidates. In addition, because of the increasing costs of insurance coverage, we may not be able to maintain insurance coverage at a reasonable cost or obtain insurance coverage that will be adequate to satisfy any liability that may arise.

We may be required to suspend or discontinue clinical trials due to side effects or other safety risks that could preclude approval of our product candidates.

Our clinical trials may be suspended at any time for a number of reasons. We may voluntarily suspend or terminate our clinical trials if at any time we believe that they present an unacceptable risk to participants. In addition, regulatory agencies may order the temporary or permanent discontinuation of our clinical trials at any time if they believe that the clinical trials are not being conducted in accordance with applicable regulatory requirements or that they present an unacceptable safety risk to participants.

Many antibiotics can produce significant side effects. Side effects associated with many current antibiotics include kidney and liver toxicities, heart rhythm abnormalities, photosensitivity, rash, and excessive flushing of the skin and central nervous system toxicities, such as seizures. In clinical trials, side effects of faropenem medoxomil have included gastrointestinal disorders (such as diarrhea, nausea and vomiting), nervous system disorders (such as dizziness and headaches), as well as infections and infestations (such as pneumonia and vaginal mycosis). Later clinical trials in a larger patient population could reveal other side effects. These or other side effects could interrupt, delay or halt clinical trials of our product candidates and could result in the FDA or other regulatory authorities stopping further development of or denying approval of our product candidates for any or all targeted indications. Even if we believe our product candidates are safe, our data is subject to review by the FDA, which may disagree with our conclusions. Moreover, we could be subject to significant liability if any volunteer or patient suffers, or appears to suffer, adverse health effects as a result of participating in our clinical trials.

We rely on third parties to conduct our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates.

We have agreements with third-party contract research organizations to provide monitors for and to manage data for our on-going clinical programs. We and our contract research organizations are required to comply with current Good Clinical Practices, or GCPs, regulations and guidelines enforced by the FDA for all of our products in clinical development. The FDA enforces GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or our contract research organizations fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA may require us to perform additional clinical trials before approving our marketing applications. We cannot ensure that, upon inspection, the FDA will determine that any of our clinical trials comply with GCPs. In addition, our clinical trials must be conducted with product produced under cGMP regulations, and will require a large number of test subjects. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

Our contract research organizations have the right to terminate their agreements with us in the event of an uncured material breach. In addition, some of our contract research organizations have an ability to terminate their respective agreements with us if it can be reasonably demonstrated that the safety of the subjects participating in our clinical trials warrants such termination, if we make a general assignment for the benefit of our creditors, or if we are liquidated. If any of our relationships with these third-party contract research organizations terminate, we may not be able to enter into arrangements with alternative contract research organizations. If contract research organizations do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements, or for other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

Our ability to pursue the development and commercialization of our product candidates depends upon the continuation of our licenses from third parties.

Our license agreement with Asubio Pharma provides us with an exclusive license to develop and sell any products with the compound faropenem medoxomil as an active ingredient for any indication in the U.S. and Canada. Either we or Asubio Pharma may terminate the license agreement immediately upon the bankruptcy or dissolution of the other party or upon a breach of any material provision of the agreement if the breach is not cured within 60 days following written notice. We are currently in discussions with Asubio Pharma regarding the future development plans for faropenem medoxomil. If there is any dispute between us and Asubio Pharma regarding our rights or obligations under the license agreement, including diligence obligations, the achievement of milestones or interpretation of other material provisions, we risk litigation and our business may be adversely affected. If our license agreement with Asubio Pharma were terminated, we would lose our rights to develop and commercialize faropenem medoxomil.

If we fail to gain and maintain approval for our product candidates in international markets, our market opportunities will be limited.

Sales of our product candidates outside of the U.S. will be subject to foreign regulatory requirements governing clinical trials and marketing approval. Even if the FDA grants marketing approval for a product candidate, comparable regulatory authorities of foreign countries must also approve the manufacturing or marketing of the product candidate in those countries. Approval in the U.S., or in any other jurisdiction, does not ensure approval in other jurisdictions. Obtaining foreign approvals could result in significant delays, difficulties and costs for us and require additional trials and additional expenses. Regulatory requirements can vary widely from country to country and could delay the introduction of our products in those countries. Clinical trials conducted in one country may not be accepted by other countries and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. None of our product candidates is approved for sale in international markets and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with these regulatory requirements or to obtain and maintain required approvals, our target market will be reduced and our ability to generate revenue will be diminished.

We may not be able to enter into acceptable agreements to market and commercialize our product candidates in international markets.

If appropriate regulatory approvals are obtained, we intend to commercialize our product candidates in international markets through collaboration arrangements with third parties. If we decide to sell our product candidates in international markets, we may not be able to enter into any arrangements on favorable terms or at all. In addition, these arrangements could result in lower levels of income to us than if we marketed our product candidates entirely on our own. If we are unable to enter into a marketing arrangement for our product candidates in international markets, we may not be able to develop an effective international sales force to successfully commercialize those products in international markets. If we fail to enter into marketing arrangements for our

products and are unable to develop an effective international sales force, our ability to generate revenue would be limited.

Even if we receive regulatory approval for our product candidates, we will be subject to ongoing significant regulatory obligations and oversight.

If we receive regulatory approval to sell our product candidates, the FDA and foreign regulatory authorities may impose significant restrictions on the indicated uses or marketing of such products, or impose ongoing requirements for post-approval studies. Following any regulatory approval of our product candidates, we will be subject to continuing regulatory obligations, such as safety reporting requirements, and additional post-marketing obligations, including regulatory oversight of the promotion and marketing of our products. If we become aware of previously unknown problems with any of our product candidates here or overseas or at our contract manufacturers' facilities, a regulatory agency may impose restrictions on our products, our contract manufacturers or on us, including requiring us to reformulate our products, conduct additional clinical trials, make changes in the labeling of our products, implement changes to, or obtain re-approvals of, our contract manufacturers' facilities, or withdraw the product from the market. In addition, we may experience a significant drop in the sales of the affected products, our reputation in the marketplace may suffer and we may become the target of lawsuits, including class action suits. Moreover, if we fail to comply with applicable regulatory requirements, we may be subject to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution. Any of these events could harm or prevent sales of the affected products or could substantially increase the costs and expenses of commercializing and marketing these products.

Our corporate compliance program cannot guarantee that we are in compliance with all potentially applicable regulations.

The development, manufacturing, pricing, marketing, sales, and reimbursement of our product candidates, together with our general operations, are subject to extensive regulation by federal, state and other authorities within the U.S. and numerous entities outside of the U.S. If we fail to comply with any of these regulations, we could be subject to a range of regulatory actions, including suspension or termination of clinical trials, the failure to approve a product candidate, restrictions on our product candidates or manufacturing processes, withdrawal of products from the market, significant fines, or other sanctions or litigation, and exclusion of our products from the Medicare/Medicaid payment system. As a publicly traded company we are subject to significant regulations, including the Sarbanes-Oxley Act of 2002, some of which have only recently been adopted, and all of which are subject to change. While we have developed and instituted a corporate compliance program based on what we believe are the current best practices and continue to update the program in response to newly implemented or changing regulatory requirements, we cannot ensure that we are or will be in compliance with all potentially applicable regulations. For example, we cannot assure that in the future our management will not find a material weakness in connection with its annual review of our internal control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act. We also cannot ensure that we could correct any such weakness to allow our management to assess the effectiveness of our internal control over financial reporting as of the end of our fiscal year in time to enable our independent registered public accounting firm to attest that such assessment will have been fairly stated in our annual reports filed with the Securities and Exchange Commission or attest that we have maintained effective internal control over financial reporting as of the end of our fiscal year. If we fail to comply with the Sarbanes-Oxley Act or any other regulations we could be subject to a range of consequences, including restrictions on our ability to sell equity or otherwise raise capital funds, significant fines, enforcement or other civil or criminal actions by the Securities and Exchange Commission or delisting by the NASDAQ Global Market or other sanctions or litigation. In addition, if we disclose any material weakness in our internal control over financial reporting or other consequence of failing to comply with applicable regulations, this may cause our stock price to decline.

Reimbursement may not be available for our product candidates, which could diminish our sales or affect our ability to sell any future products profitably.

Market acceptance and sales of our product candidates will depend on reimbursement policies and may be affected by future health care reform measures. Government authorities and third-party payors, such as private

health insurers and health maintenance organizations, decide which drugs they will pay for and establish reimbursement levels. We cannot be sure that reimbursement will be available for any of our product candidates. Also, we cannot be sure that reimbursement amounts will not reduce the demand for, or the price of, our products. We have not commenced efforts to have our product candidates reimbursed by government or third-party payors. If reimbursement is not available or is available only to limited levels, we may not be able to commercialize our products.

In both the U.S. and certain foreign jurisdictions, there have been a number of legislative and regulatory changes to the health care system that could impact our ability to sell our products profitably. In particular, the Medicare Modernization Act of 2003 added an outpatient prescription drug benefit to Medicare, which became effective on January 1, 2006. Drug benefits under this provision are administered through private plans that negotiate price concessions from pharmaceutical manufacturers. We cannot be certain that faropenem medoxomil will successfully be placed on the list of drugs covered by particular health plans or plan formularies, nor can we predict the negotiated price for faropenem medoxomil, which will be determined by market factors. With respect to Medicaid, the Deficit Reduction Act of 2005 made several changes to the way pharmacies are reimbursed under Medicaid, most of which went into effect on January 1, 2007. These changes could lead to reduced drug prices. Many states have also created preferred drug lists and include drugs on those lists only when the manufacturers agree to pay a supplemental rebate. If faropenem medoxomil or our other product candidates are not included on these preferred drug lists, physicians may not be inclined to prescribe them to their Medicaid patients.

As a result of legislative proposals and the trend towards managed health care in the U.S., third-party payors are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement of new drugs. They may also refuse to provide any coverage of uses of approved products for medical indications other than those for which the FDA has granted market approvals. As a result, significant uncertainty exists as to whether and how much third-party payors will reimburse patients for their use of newly-approved drugs, which in turn will put pressure on the pricing of drugs. The availability of numerous generic antibiotics at lower prices than branded antibiotics, such as faropenem medoxomil, if it were approved for commercial introduction, can also be expected to substantially reduce the likelihood of reimbursement for faropenem medoxomil. We expect to experience pricing pressures in connection with the sale of our products due to the trend toward managed health care, the increasing influence of health maintenance organizations and additional legislative proposals.

We may need to modify the size of our organization, and we may experience difficulties in managing either growth or restructuring.

We are a small company with 82 employees as of September 30, 2007. As our development and commercialization plans and strategies develop, we may need to either expand or reduce the size of our employee base for managerial, operational, sales, financial and other resources. Future growth would impose significant added responsibilities on members of management, including the need to identify, recruit, maintain and integrate additional employees. Future restructuring activities may involve significant changes to our drug development and growth strategies, our commercialization plans and other operational matters, including a significant reduction in our employee base. Any restructuring activity could result in disruption to our business, adversely affect the morale of our employees and make it more difficult to retain qualified personnel. Also, our management may have to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing either growth or restructuring activities. Our future financial performance and our ability to commercialize our product candidates and to compete effectively will depend, in part, on our ability to effectively manage any future growth or restructuring, as the case may be. To that end, we must be able to:

- manage our development efforts effectively;
- manage our clinical trials effectively;
- integrate additional management, administrative, manufacturing and sales and marketing personnel, or reorganize these personnel;
- maintain sufficient administrative, accounting and management information systems and controls; and
- hire and train additional or replacement qualified personnel.

We may not be able to accomplish these tasks, and our failure to accomplish any of them could harm our financial results.

Risks Related to our Intellectual Property

It is difficult and costly to protect our proprietary rights, and we may not be able to ensure their protection.

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection of our product candidates, and the methods used to manufacture them, as well as successfully defending these patents against third-party challenges. Our ability to protect our product candidates from unauthorized making, using, selling, offering to sell or importation by third parties is dependent upon the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities.

As of September 30, 2007, we have exclusively licensed from Asubio Pharma two issued U.S. patents, one issued foreign patent and one pending U.S. patent application covering faropenem medoxomil, a prodrug of faropenem. The two issued U.S. patents covering faropenem medoxomil also cover other potential prodrugs of faropenem but do not cover all potential faropenem-based antibiotic compounds. We do not and have not had any control over the filing or prosecution of these patents or patent applications. We cannot be certain that such prosecution efforts have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents. In addition, our enforcement of these faropenem medoxomil patents or defense of any claims asserting the invalidity of these patents would be subject to the cooperation of Asubio Pharma. Although Asubio Pharma has agreed to cooperate with us in such efforts, if requested, we cannot be assured that Asubio Pharma would devote sufficient efforts to cooperate with us in these circumstances.

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. 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 licensed patents, our patents or in third-party patents.

Asubio Pharma owns a portfolio of patents related to faropenem compounds, including the faropenem parent compound, faropenem medoxomil and other faropenem prodrugs. We have licensed from Asubio Pharma the patents to faropenem medoxomil and other faropenem prodrugs. These patents may not prevent competitors from developing other faropenem drugs that are not covered by the Asubio Pharma patents. Beginning in 2008, when the Asubio Pharma patents expire, competitors may submit NDAs seeking approval of antibiotics containing the faropenem parent compound as the active ingredient. These applications would have to contain full reports of safety and efficacy data conducted by or for the applicants and could not in any way rely upon the safety and efficacy data utilized in the approval of faropenem medoxomil. In addition, as early as four years after the approval of a faropenem medoxomil NDA, if any, generic and branded competitors could also file NDAs seeking approval of faropenem drugs that would likely require the applicant to conduct clinical trials in order to bring the product to market in the U.S., though the FDA may allow the applicant to rely in part on the FDA's prior findings of safety and efficacy of faropenem medoxomil. To the extent that any competitor relies on any of the findings of safety or efficacy with respect to faropenem medoxomil, the competitor will have to certify that its compound either does not infringe our patents or that our patents are invalid.

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:

- others may be able to make compounds that are similar to our product candidates but that are not covered by the claims of our licensed patents, or for which we are not licensed under our license agreements;
- we or our licensors might not have been the first to make the inventions covered by our pending patent application or the pending patent applications and issued patents of our licensors;

- we or our licensors 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 our pending patent applications will not result in issued patents;
- our issued patents and the issued patents of our licensors may not provide us with any competitive advantages, or may be held invalid or unenforceable as a result of legal challenges by third parties;
- we may not develop additional proprietary technologies that are patentable; or
- the patents of others may have an adverse effect on our business.

We also may rely on trade secrets to protect our technology, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, outside scientific collaborators and other advisors may unintentionally or willfully disclose our information to competitors. Enforcing a claim that a third party illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the U.S. are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights and we may be unable to protect our rights to, or use, our technology.

If we choose to go to court to stop someone else from using the inventions claimed in our patents or our licensed patents, that individual or company has the right to ask the court to rule that these patents are invalid and/or should not be enforced against that third party. These lawsuits are expensive and would consume time and other resources even if we were successful in stopping the infringement of these patents. In addition, there is a risk that the court will decide that these patents are not valid and that we do not have the right to stop the other party from using the inventions. There is also the risk that, even if the validity of these patents is upheld, the court will refuse to stop the other party on the ground that such other party's activities do not infringe our rights to these patents.

Furthermore, a third party may claim that we or our manufacturing or commercialization partners are using inventions covered by the third party's patent rights and may go to court to stop us from engaging in our normal operations and activities, including making or selling our product candidates. These lawsuits are costly and could affect our results of operations and divert the attention of managerial and technical personnel. There is a risk that a court would decide that we or our commercialization partners are infringing the third party's patents and would order us or our partners to stop the activities covered by the patents. In addition, there is a risk that a court will order us or our partners to pay the other party damages for having violated the other party's patents. We have indemnified our commercial partners against patent infringement claims. The biotechnology industry has produced a proliferation of patents, and it is not always clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we are sued for patent infringement, we would need to demonstrate that our products or methods of use either do not infringe the patent claims of the relevant patent and/or that the patent claims are invalid, and we may not be able to do this. Proving invalidity, in particular, is difficult since it requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents.

Because some patent applications in the U.S. may be maintained in secrecy until the patents are issued, because patent applications in the U.S. and many foreign jurisdictions are typically not published until eighteen months after filing, and because publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our licensors' issued patents or our pending applications or our licensors' pending applications, or that we or our licensors were the first to invent the technology. Our competitors may have filed, and may in the future file, patent applications covering technology similar to ours. Any such patent application may have priority over our or our licensors' patent applications and could further require us to obtain rights to issued patents covering such technologies. If another party has filed a U.S. patent application on inventions similar to ours, we may have to participate in an interference proceeding declared by the U.S. Patent and Trademark Office to determine priority of invention in the U.S. The

costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful, resulting in a loss of our U.S. patent position with respect to such inventions.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations.

Risks Related to Ownership of our Common Stock

The market price of our common stock is highly volatile.

Prior to June 28, 2006, there was no public market for our common stock. We cannot assure you that an active trading market for our common stock will exist at any time. You may not be able to sell your shares quickly or at the market price if trading in our common stock is not active. The trading price of our common stock has been highly volatile and could be subject to wide fluctuations in price in response to various factors, many of which are beyond our control, including:

- announcement of FDA approval or non-approval of our product candidates, or specific label indications for their use, or delays in the FDA review process;
- actions taken by regulatory agencies with respect to our product candidates, clinical trials, manufacturing process or sales and marketing activities;
- termination of significant agreements;
- changes in laws or regulations applicable to our products, including but not limited to clinical trial requirements for approvals;
- the success of our development efforts and clinical trials;
- the success of our efforts to acquire or in-license additional products or product candidates;
- developments concerning our collaborations, including but not limited to those with our sources of manufacturing supply and our commercialization partners;
- actual or anticipated variations in our quarterly operating results;
- announcements of technological innovations by us, our collaborators or our competitors;
- new products or services introduced or announced by us or our commercialization partners, or our competitors and the timing of these introductions or announcements;
- actual or anticipated changes in earnings estimates or recommendations by securities analysts;
- conditions or trends in the biotechnology and biopharmaceutical industries;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- general economic and market conditions and other factors that may be unrelated to our operating performance or the operating performance of our competitors;
- changes in the market valuations of similar companies;
- sales of common stock or other securities by us or our stockholders in the future;
- additions or departures of key scientific or management personnel;
- developments relating to proprietary rights held by us or our competitors;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;

- trading volume of our common stock; and
- sales of our common stock by us or our stockholders.

In addition, the stock market in general and the market for biotechnology and biopharmaceutical companies in particular have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance. In the past, following periods of volatility in the market, securities class-action litigation has often been instituted against companies. Such litigation, if instituted against us, could result in substantial costs and diversion of management's attention and resources, which could materially adversely affect our business and financial condition.

We are at risk of securities class action litigation or may become subject to stockholder activism efforts that each could cause material disruption to our business.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and biopharmaceutical companies have experienced significant stock price volatility in recent years. Further, certain influential institutional investors and hedge funds have taken steps to involve themselves in the governance and strategic direction of certain companies that were perceived to be operating sub-optimally due to governance or strategic related disagreements with such stockholders. Our stock price decreased significantly following our announcement that the FDA had issued a non-approvable letter for our lead product candidate, faropenem medoxomil. If we face such litigation or stockholder activism efforts due to this development or any future development affecting us, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

Our principal stockholders and management own a significant percentage of our stock and are able to exercise significant influence over matters subject to stockholder approval.

Our executive officers, directors and principal stockholders, together with their respective affiliates, currently own a significant percentage of our voting stock, including shares subject to outstanding options and warrants, and we expect this group will continue to hold a significant percentage of our outstanding voting stock. Accordingly, these stockholders will likely be able to have a significant impact on the composition of our board of directors and continue to have significant influence over our operations. This concentration of ownership could have the effect of delaying or preventing a change in our control or otherwise discouraging a potential acquirer from attempting to obtain control of us, which in turn could have a material and adverse effect on the market value of our common stock.

We will incur significant increased costs as a result of operating as a public company, and our management will be required to devote substantial time to compliance initiatives.

As a public company, we incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act, as well as rules subsequently implemented by the Securities and Exchange Commission and the NASDAQ Global Market, have imposed various new requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these new compliance initiatives. Moreover, these rules and regulations have increased our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to incur substantial costs to maintain the same or similar coverage.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. In particular, we must perform system and process evaluation and testing of our internal controls over financial reporting to allow management and our independent registered public accounting firm to report on the effectiveness of our internal controls over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. Our testing, or the subsequent testing by our independent registered public

accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses. Our compliance with Section 404 may require that we incur substantial accounting expense and expend significant management efforts. We currently do not have an internal audit group, and we will need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge. Moreover, if we are not able to comply with the requirements of Section 404 in a timely manner, or if we or our independent registered public accounting firm identifies deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by NASDAQ, the SEC or other regulatory authorities, which would require additional financial and management resources.

Substantial sales of our common stock in the public market could cause our stock price to fall.

Sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that sales may have on the prevailing market price of our common stock.

Certain holders of shares of our common stock and warrants to purchase shares of our common stock are entitled to rights with respect to the registration of their shares under the Securities Act. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares purchased by affiliates. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

We expect that significant additional capital will be required in the future to continue our planned operations. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. We may sell common stock in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock in more than one transaction, stockholders who purchase stock may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to existing stockholders. Pursuant to our 2006 Equity Incentive Plan, our management is authorized to grant stock options to our employees, directors and consultants, and our employees are eligible to participate in our 2006 Employee Stock Purchase Plan. The number of shares available for future grant under our 2006 Equity Incentive Plan can, subject to approval of our board of directors, increase each April 1 by the lesser of five percent of the number of total outstanding shares of our common stock on December 31 of the preceding year or 1,325,448 shares, subject to the ability of our board of directors to reduce such increase. Additionally, the number of shares reserved for issuance under our 2006 Employee Stock Purchase Plan can, subject to approval of our board of directors, increase each April 1 by the lesser of one percent of the number of total outstanding shares of our common stock on December 31 of the prior year or 101,957 shares, subject to the ability of our board of directors to reduce such increase. In addition, we also have warrants outstanding to purchase shares of our common stock. Our stockholders will incur dilution upon exercise of any outstanding stock options or warrants.

All of the shares of common stock sold in our initial public offering are freely tradable without restrictions or further registration under the Securities Act of 1933, as amended, except for any shares purchased by our affiliates as defined in Rule 144 under the Securities Act. Rule 144 defines an affiliate as a person who directly, or indirectly through one or more intermediaries, controls, or is controlled by, or is under common control with, us and would include persons such as our directors and executive officers.

Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.

Under Section 382 of the Internal Revenue Code, if a corporation undergoes an “ownership change” (generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period), the corporation’s ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-

change income may be limited. We believe that, based on an analysis of historical equity transactions under the provisions of Section 382, ownership changes have occurred at two points since our inception. These ownership changes will limit the annual utilization of our net operating losses in future periods. We do not believe, however, that these ownership changes will result in the loss of any of our net operating loss carryforwards existing on the date of each of the ownership changes. We may also experience ownership changes in the future as a result of subsequent shifts in our stock ownership, and such changes may result in the loss of net operating loss carryforwards on such ownership change date.

Some provisions of our charter documents and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders.

Provisions in our certificate of incorporation and bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us, even if doing so would benefit our stockholders. These provisions include:

- authorizing the issuance of "blank check" preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval;
- limiting the removal of directors by the stockholders;
- prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders;
- eliminating the ability of stockholders to call a special meeting of stockholders; and
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings.

In addition, we are subject to Section 203 of the Delaware General Corporation Law, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with an interested stockholder for a period of three years following the date on which the stockholder became an interested stockholder, unless such transactions are approved by our board of directors. This provision could have the effect of delaying or preventing a change of control, whether or not it is desired by or beneficial to our stockholders.

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

Recent Sales of Unregistered Equity Securities.

None.

Use of Proceeds from the Sale of Registered Securities.

After deducting expenses of the initial public offering of our common stock in 2006 pursuant to our Registration Statement on Form S-1 (Reg. No. 333-133021) declared effective by the Securities and Exchange Commission on June 28, 2006 (the "Offering"), we received net offering proceeds of approximately $44.5 million. As of September 30, 2007, we have fully used the net proceeds of the Offering to fund our operations, including clinical trials related to faropenem medoxomil, clinical trials related to REP8839, activities related to the development of our preclinical product candidates, and general corporate purposes.

No payments were made to directors, officers or persons owning ten percent or more of our common stock or to their associates, or to our affiliates, other than payments in the ordinary course of business to officers for salaries and to non-employee directors as compensation for board or board committee service.

Issuer Purchases Of Equity Securities.

Period	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Maximum Number (or Approximate Dollar Value) of Shares That may Yet be Purchased Under the Plans or Programs
9/18/07	12,904(1)	$1.32	None	Not Applicable
9/27/07	237(2)	$5.93	None	Not Applicable

(1) Repurchase of unvested restricted stock from an employee at cost.

(2) Shares acquired in payment of tax liabilities pursuant to the partial vesting of a restricted stock award issued to an Employee under our 2006 Equity Incentive Plan. The tax liabilities were paid in October 2007.

Item 3. ***Defaults Upon Senior Securities***

Not applicable.

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

None.

Item 5. ***Other Information***

Not applicable.

Item 6. ***Exhibits***

Exhibit Number	Description of Document
31.1	Certification of principal executive officer required by Rule 13a-14(a).
31.2	Certification of principal financial officer required by Rule 13a-14(a).
32.1	Section 1350 Certification.

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.

REPLIDYNE, INC.

By: /s/ Mark L. Smith

Mark L. Smith
Chief Financial Officer, Treasurer
(Principal Financial and Accounting Officer)

Date: November 7, 2007

Table of Contents

Exhibit Index

Exhibit Number	Description of Document
31.1	Certification of principal executive officer required by Rule 13a-14(a).
31.2	Certification of principal financial officer required by Rule 13a-14(a).
32.1	Section 1350 Certification.

EXHIBIT 31.1

CERTIFICATIONS

I, Kenneth J. Collins, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Replidyne, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;

b) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

c) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Kenneth J. Collins

Kenneth J. Collins
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 7, 2007

EXHIBIT 31.2

CERTIFICATIONS

I, Mark L. Smith, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Replidyne, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;

b) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

c) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Mark L. Smith

Mark L. Smith
Chief Financial Officer, Treasurer
(Principal Financial and Accounting Officer)

Date: November 7, 2007

EXHIBIT 32.1

CERTIFICATION

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. § 1350), Kenneth J. Collins, Chief Executive Officer of Replidyne, Inc. (the "Company"), and Mark L. Smith, Chief Financial Officer of the Company, each hereby certifies that, to the best of his knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period ended September 30, 2007, to which this Certification is attached as Exhibit 32.1 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Kenneth J. Collins

Kenneth J. Collins
Chief Executive Officer
(Principal Executive Officer)

/s/ Mark L. Smith

Mark L. Smith
Chief Financial Officer
(Principal Financial and Accounting Officer)

Dated: November 7, 2007

A signed original of this written statement required by Section 906 of the Public Company Accounting Reform and Investor Protection Act of 2002 (18 U.S.C. § 1350, as adopted) has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission ("SEC") or its staff upon request. This certification "accompanies" the Form 10-Q to which it relates, is not deemed filed with the SEC and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.