CARDIOVASCULAR SYSTEMS INC

FORM 10-Q
(Quarterly Report)

Filed 11/09/06 for the Period Ending 09/30/06

Address	651 CAMPUS DRIVE
	ST PAUL, MN 55112
Telephone	651-259-1600
CIK	0001180145
Symbol	CSII
SIC Code	3841 - Surgical and Medical Instruments and Apparatus
Industry	Medical Equipment & Supplies
Sector	Healthcare
Fiscal Year	06/30

REPLIDYNE INC

FORM 10-Q
(Quarterly Report)

Filed 11/9/2006 For Period Ending 9/30/2006

Address	1450 INFINITE DRIVE
	LOUISVILLE, Colorado 80027
Telephone	303-665-3450
CIK	0001180145
Industry	Biotechnology & Drugs
Sector	Healthcare

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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, 2006

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, 2006**
Common Stock, $.001 par value per share	26,935,680 shares

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PART I FINANCIAL INFORMATION

Item 1. *Financial Statements*

REPLIDYNE, INC.

CONDENSED BALANCE SHEETS
(In thousands, except for share and per share amounts)
(Unaudited)

	September 30, 2006	December 31, 2005
ASSETS		
Current assets:		
Cash and cash equivalents	$ 25,193	$ 4,353
Short-term investments	109,139	55,067
Receivable from Forest Laboratories	2,568	—
Notes receivable from officers	—	375
Prepaid expenses and other current assets	2,820	275
Total current assets	139,720	60,070
Property and equipment, net	2,900	3,248
Other assets	86	261
Total assets	$ 142,706	$ 63,579
LIABILITIES, PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable and accrued expenses	$ 5,206	$ 9,154
Current portion of deferred revenue	4,444	—
Current portion of long-term debt, net of discount	—	161
Total current liabilities	9,650	9,315
Deferred revenue, net of current portion	52,744	—
Other long-term liabilities	62	81
Total liabilities	62,456	9,396
Commitments and contingencies		
Preferred stock, Authorized 5,000,000 and 88,862,226 shares; issued and outstanding zero and 88,522,222 shares at September 30, 2006 and December 31, 2005, respectively:		
Series A redeemable convertible preferred stock, $0.01 par value. Authorized 13,140,000 shares; issued and outstanding 13,000,000 shares; and liquidation preference of $17,015 at December 31, 2005; at accreted redemption value	—	16,940
Series B convertible preferred stock, $0.01 par value. Authorized 4,000,000 shares; issued and outstanding 4,000,000 shares; and liquidation preference of $6,030 at December 31, 2005	—	6,030
Series C redeemable convertible preferred stock, $0.01 par value. Authorized 37,000,004 shares; issued and outstanding 36,800,000 shares and liquidation preference of $51,764 at December 31, 2005; at accreted redemption value	—	51,635
Series D redeemable convertible preferred stock, $0.001 par value. Authorized, issued and outstanding 34,722,222 shares; liquidation preference of $64,364 at December 31, 2005; at accreted redemption value	—	62,210
Stockholders' equity (deficit):		
Common stock, $0.001 par value. Authorized 100,000,000 and 115,000,000 shares; issued 26,965,642 and 1,897,620 shares; outstanding 26,935,055 and 1,867,033 shares at September 30, 2006 and December 31, 2005, respectively	27	2
Treasury stock, $0.01 par value; 30,587 shares, at cost	(2)	(2)
Deferred stock-based compensation	—	(4)
Additional paid-in capital	187,583	—
Accumulated other comprehensive income	5	479
Accumulated deficit	(107,363)	(83,107)
Total stockholders' equity (deficit)	80,250	(82,632)
Total liabilities, preferred stock and stockholders' equity (deficit)	$ 142,706	$ 63,579

See accompanying notes to condensed financial statements.

REPLIDYNE, INC.

CONDENSED STATEMENTS OF OPERATIONS
(In thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2006	2005	2006	2005
Revenue	$ 3,679	$ 174	$ 10,601	$ 441
Costs and expenses:				
Research and development	7,177	7,107	25,287	18,184
Sales, general and administrative	3,864	1,156	8,676	3,064
Total costs and expenses	11,041	8,263	33,963	21,248
Loss from operations	(7,362)	(8,089)	(23,362)	(20,807)
Interest and other income, net	1,640	27	3,730	217
Net loss	(5,722)	(8,062)	(19,632)	(20,590)
Preferred stock dividends and accretion	(85)	(1,959)	(5,391)	(4,541)
Net loss attributable to common stockholders	$ (5,807)	$ (10,021)	$ (25,023)	$ (25,131)
Net loss attributable to common stockholders per share — basic and diluted	$ (0.23)	$ (9.47)	$ (2.59)	$ (26.19)
Weighted average common shares outstanding — basic and diluted	25,747,889	1,058,038	9,658,949	959,641
Pro forma net loss attributable to common stockholders per share — basic and diluted	$ (0.22)		$ (0.88)	
Pro forma weighted average common shares outstanding — basic and diluted	26,171,068		22,447,230	

See accompanying notes to condensed financial statements.

REPLIDYNE, INC.

CONDENSED STATEMENTS OF CASH FLOWS
(In thousands)
(Unaudited)

	Nine Months Ended September 30,	
	2006	2005
Cash flows from operating activities:		
Net loss	$ (19,632)	$ (20,590)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation	1,031	987
Stock-based compensation	698	—
Amortization of debt discount and issuance costs	9	9
Other	79	(13)
Amortization of discounts and premiums on short-term investments	(617)	—
Changes in operating assets and liabilities:		
Receivable from Forest Laboratories	(2,568)	—
Prepaid expenses and other current assets	(2,436)	(35)
Other assets	176	(78)
Accounts payable and accrued expenses	(3,489)	1,864
Deferred revenue	57,188	(307)
Other long-term liabilities	(19)	—
Net cash provided by (used in) operating activities	30,420	(18,163)
Cash flows from investing activities:		
Purchases of short-term investments classified as available-for-sale	(120,323)	(133,168)
Purchases of short-term investments classified as held-to-maturity	(60,854)	—
Sale and maturities of short-term investments classified as available-for-sale	117,084	113,132
Sale and maturities of short-term investments classified as held-to-maturity	10,053	—
Proceeds from the sale of property and equipment	39	1
Acquisition of property and equipment	(783)	(1,136)
Net cash used in investing activities	(54,784)	(21,171)
Cash flows from financing activities:		
Principal payments on debt	(169)	(967)
Proceeds from issuance of common stock from the exercise of stock options	176	23
Proceeds from sale of common stock from initial public offering, net of underwriters discount	46,556	—
Payments of offering costs on the sale of common stock from initial public offering	(1,789)	—
Proceeds from sale of Series D redeemable convertible preferred stock, net	—	60,312
Bank overdraft	(25)	—
Settlement of fractional shares	(1)	—
Proceeds from notes receivable from officers repaid in full prior to initial public offering	356	—
Proceeds from issuance of Series C redeemable convertible preferred stock from the exercise of warrants	100	—
Net cash provided by financing activities	45,204	59,368
Net increase in cash and cash equivalents	20,840	20,034
Cash and cash equivalents:		
Beginning of period	4,353	4,640
End of period	$ 25,193	$ 24,674
Supplemental cash flow information:		
Cash paid for interest	$ 15	$ 56
Reclassification of preferred stock warrant liability to stockholders' equity	$ 630	$ —
Notes receivable issued to officers for the exercise of stock options	$ —	$ 356
Unpaid offering costs on the sale of common stock from initial public offering	$ 225	$ —

See accompanying notes to condensed financial statements.

REPLIDYNE, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS
(Unaudited)

(1) The Company and Summary of Significant Accounting Policies

(a) The Company

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 exacerbations 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 (see Note 2).

The Company's research and development product pipeline also includes REP8839 being developed for topical use for treatment of skin and wound infections and prevention of staphylococcus aureus *(S. aureus)* infections, including methicillin-resistant *S. aureus* (MRSA) infections in hospital settings. The Company is also pursuing the development of other novel anti-infective products based on an in-house library of proprietary compounds and its bacterial DNA replication technology.

The Company completed an initial public offering of its common stock on July 3, 2006. In connection with this offering, the Company issued 4,500,000 shares of common stock at an offering price of $10 per share. On August 2, 2006, in accordance with the terms of its agreement with the underwriters of the initial public offering, the Company sold an additional 506,000 common shares at $10 per share, representing a partial exercise of their over-allotment option. Including the exercise of the over-allotment option, the Company issued a total of 5,006,000 shares of its common stock in its initial public offering. Total proceeds received from the initial public offering, including exercise of the over-allotment allocation, were $44.5 million, net of underwriters' discount and offering costs.

Prior to and in connection with the initial public offering, on June 26, 2006 all issued and outstanding common shares and options to purchase the Company's common shares were subject to a 1-for-4.904 reverse stock split. Upon completion of the initial public offering on July 3, 2006, and in accordance with the terms of the preferred stock purchase agreements, each outstanding share of the Company's preferred stock automatically converted into 0.204 common shares. Additionally, each outstanding warrant to purchase the Company's preferred stock automatically converted into a warrant to purchase 0.204 shares of common stock.

On July 3, 2006, also in accordance with the terms of the preferred stock purchase agreements, with the conversion of preferred stock into common stock, unpaid accumulated dividends on preferred stock were paid through issuance of 1,781,826 shares of common stock.

(b) Basis of Presentation

Through December 31, 2005, the Company had generated limited revenue and its activities consisted primarily of research and development, clinical trials and regulatory approval, initial sales and marketing development, raising capital, and recruiting personnel. Accordingly, at December 31, 2005, the Company was considered to be in the development stage as defined in Statement of Financial Accounting Standards (SFAS) No. 7, *Accounting and Reporting by Development Stage Enterprises.*

During 2006, the Company began generating revenue from its planned principal operations as a result of its agreement with Forest Laboratories Holding Limited (Forest Laboratories). As such, the Company is no longer considered to be in the development stage effective February 10, 2006.

REPLIDYNE, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS — (Continued)

(c) Reverse Stock Split

In May 2006, the Company authorized a 1-for-4.904 reverse stock split, effective June 26, 2006. All common stock data and shares issuable upon the conversion of preferred stock presented herein have been restated to retroactively reflect the reverse stock split.

(d) Unaudited Interim Financial Statements

The condensed balance sheet as of September 30, 2006, statements of operations for the three and nine months ended September 30, 2006 and 2005 and the statements of cash flows for the nine months ended September 30, 2006 and 2005 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, 2006 and for the three and nine months ended September 30, 2006 and 2005, 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, 2006 and results of operations for the three and nine months ended September 30, 2006 and 2005 and the statements of cash flows for the nine months ended September 30, 2006 and 2005, have been made. These interim results of operations for the three and nine month periods ended September 30, 2006 and 2005 are not necessarily indicative of the results that may be expected for the full year ended December 31, 2006. The December 31, 2005 balance sheet was derived from audited financial statements.

(e) 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.

(f) 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.

(g) Short-Term Investments

Short-term investments are investments purchased with maturities of longer than 90 days, but less than one year, held at a financial institution.

Management determines the classification of securities at purchase. In accordance with Statement of Financial Accounting Standards (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 fair value. Unrealized holding gains and losses, net of the related tax effect, 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 interest and other income. Realized gains and losses and declines in value judged to be other than temporary on available-for-sale securities are also included in interest and other income. 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.

The Company's securities consisted of the following at September 30, 2006 and December 31, 2005 in thousands:

	September 30, 2006		December 31, 2005	
	Amortized Cost	Estimated Fair Value	Amortized Cost	Estimated Fair Value
Available-for-sale securities				
U.S. government agencies	$ 15,835	$ 15,837	$ 1,470	$ 1,473
U.S. commercial paper	9,873	9,870	—	—
Asset-backed securities	32,511	32,517	53,158	53,594
	$ 58,219	$ 58,224	$ 54,628	$ 55,067
Held-to-maturity securities				
U.S. bank and corporate notes	$ 40,944	$ 40,934	$ —	$ —
Asset-backed securities	9,971	9,965	—	—
	$ 50,915	$ 50,899	$ —	$ —

The estimated fair value amounts are determined by the Company using available market information. Unrealized net holding gains of $5 thousand and $0.5 million are included in accumulated other comprehensive income at September 30, 2006 and December 31, 2005, respectively.

(h) Concentrations of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash, cash equivalents, short-term investments, and derivative instruments. 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 placing investments with maturities that maintain safety and liquidity.

(i) Derivative Instruments

The Company recognizes derivative instruments as either assets or liabilities in its balance sheet and measures those instruments at fair value. The accounting for changes in the fair value of a derivative depends on the intended use of the derivative and the resulting designation.

For a derivative instrument designated as a fair value hedge, the gain or loss is recognized in earnings in the period of change together with the offsetting loss or gain on the hedged item attributed to the risk being hedged. For a derivative instrument designated as a cash flow hedge, the effective portion of the derivative's gain or loss is initially reported as a component of other comprehensive income and subsequently reclassified into earnings when the hedged exposure affects earnings. The ineffective portion of the gain or loss is reported in earnings immediately. For derivative instruments that are not designated as accounting hedges, changes in fair value are recognized in earnings in the period of change.

The fair values of the Company's derivative instruments as of September 30, 2006 and December 31, 2005 was $30 thousand and $0.2 million, respectively. These derivative instruments have not been designated as hedges for

accounting purposes. Changes in fair value are included in the Company's earnings and have been immaterial to date.

(j) 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.

(k) 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* , (SFAS No. 144) 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, 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 possible that future evaluations of long-lived assets may result in an impairment.

(l) Segments

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

(m) Stock-Based Compensation

(i) Stock-Based Compensation under APB No. 25

Prior to January 1, 2006, the Company applied the intrinsic-value-based method of accounting prescribed by Accounting Principles Board (APB) Opinion No. 25, *Accounting for Stock Issued to Employees* , and related interpretations, including Financial Accounting Standards Board (FASB) Interpretation No. 44, *Accounting for Certain Transactions involving Stock Compensation, an interpretation of APB Opinion No. 25* , in accounting for its employee stock options. Under this method, compensation expense is generally recorded on the date of grant only if the estimated fair value of the underlying stock exceeds the exercise price.

The Company accounts for stock options issued to non-employees in accordance with the provisions of SFAS No. 123, *Accounting for Stock-Based Compensation* , and Emerging Issues Task Force (EITF) No. 96-18, *Accounting for Equity Instruments that are Issued to Other than Employees, or in Conjunction with Selling Goods or Services* , which requires valuing the stock options using a Black- Scholes option pricing model and re-measuring such stock options to the current fair value until the performance date has been reached. Effective January 1, 2006, the Company applied the provisions of SFAS No. 123 as amended by SFAS No. 123(R).

(ii) Stock Based Compensation under SFAS No. 123(R):

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 in the three and nine month periods ended September 30, 2006 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 Opinion No. 25, *Accounting for Stock Issued to Employees ("APB Opinion No. 25")* , and (b) compensation cost for

all share-based payments granted beginning January 1, 2006, based on the grant date fair value estimated in accordance with the provisions of SFAS No. 123(R).

Prior to the adoption of SFAS No. 123(R), the Company presented its unamortized portion of deferred compensation cost for non-vested stock options in the statement of stockholders' equity (deficit) with a corresponding credit to additional paid-in capital. Under SFAS No. 123(R), an equity instrument is not considered to be issued until the instrument vests. As a result, compensation costs are recognized over the requisite service period with an offsetting credit to additional paid-in capital, and the deferred compensation balance of $4 thousand at January 1, 2006 was netted against additional paid-in capital.

The Company selected the Black-Scholes-Merton (Black-Scholes) option pricing model as the most appropriate valuation method for option grants with service and/or performance conditions. The fair value of these option grants is estimated as of the date of grant using the Black-Scholes option pricing model with the following weighted-average assumptions for options granted during the nine month period ended September 30, 2006. The Company has separated optionees into two groups: grants with early exercise provisions and grants without early exercise provisions. The Company has determined that the exercise behavior of the two option groups is distinct and, therefore, the assumptions are different for purposes of valuing the options. The expected lives (net of expected forfeitures) for options with and without early exercise provisions are estimated to be 4.00 years and 4.40 years, respectively. Expected volatility for the two groups is estimated to be 75%. The risk free interest rate is 4.68% for both groups, and the dividend yield is 0%.

In January 2006, the Company also issued options that vest over the earlier to be achieved service or market condition. In determining the estimated fair value of these option awards on the date of grant, the Company elected to use a binomial lattice option pricing model together with Monte Carlo simulation techniques using the following weighted average assumptions at the date of grant: risk-free interest rate of 5.08%, expected dividend yield of 0%, expected volatility of 75%, forfeiture rate of 6.97%, suboptimal exercise factor of 2, and post-vesting exit rate of 6.97%.

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 nature, size and value to the Company. The Company will continue to use a weighted average approach using historical volatility and other similar public entity volatility information until historical volatility of the Company 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 has applied an annual forfeiture rate of 6.97% to all options granted in the three and nine month periods ended September 30, 2006. This analysis will be re-evaluated quarterly and the forfeiture rate will be adjusted as necessary. 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 expected 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.

The lattice model requires inputs for risk-free interest rate, dividend yield, volatility, contract term, average vesting period, post-vest exit rate and sub-optional exercise factor. Both the fair value and expected life are outputs from the model. The risk-free interest rate was determined based on the yield available on U.S. Treasury securities over the life of the option. The dividend yield and volatility factor were determined in the same manner as described above for the Black-Scholes model. The lattice model assumes that employees' exercise behavior is a function of the option's remaining vested life and the extent to which the option is in-the-money. The lattice model estimates the probability of exercise as a function of the sub-optional exercise factor and the post-vesting exit rate. The sub-optional exercise factor and post-vesting exit rate were based on actual historical exercise behavior.

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

REPLIDYNE, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS — (Continued)

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 latter method (i.e. graded vesting). The Company amortizes the fair value of each option over each option's vesting period (requisite service period).

Employee stock options granted by the Company are 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 for the share-based compensation arrangement due to the fact that the Company does not believe it is more likely than not it will recognize any deferred tax assets from such compensation cost recognized in the current period.

The Company's net loss for the three and nine month periods ended September 30, 2006 includes $0.3 million and $0.7 million, respectively, of compensation costs and no income tax benefit related to the Company's stock-based compensation arrangements. Stock based compensation included in the Company's statements of operations for the three and nine month periods ended September 30, 2006 was:

	Three Months Ended September 30, 2006	Nine Months Ended September 30, 2006
	($000's)	
Research and development	$ 100	$ 222
Sales, general and administrative	224	476
	$ 324	$ 698

Stock options outstanding at September 30, 2006, changes during the nine months then ended, and options exercisable are presented below:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (In millions)
Options outstanding at January 1, 2006	733,339	$ 0.690		
Granted	1,432,218	4.824		
Exercised	(212,874)	0.828		
Forfeited or expired	(33,260)	4.878		
Options outstanding at September 30, 2006	1,919,423	3.719	9.079	$ 10.9
Options exercisable at September 30, 2006	179,196	$ 0.926	8.051	$ 1.5

SFAS No. 123(R) was applied only to awards granted 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.

REPLIDYNE, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS — (Continued)

Under the prospective transition method, prior periods have not been revised for comparative purposes. The valuation provisions of SFAS No. 123(R) apply to new grants and to grants that are subsequently modified. The following table illustrates the effect on net loss for the three and nine months ended September 30, 2005 under the pro forma disclosure requirements of SFAS No. 123 (in thousands, except per share data):

	Three Months Ended September 30, 2005	Nine Months Ended September 30, 2005
Net loss attributable to common stockholders, as reported	$ (10,021)	$ (25,131)
Add: stock-based employee compensation expense included in reported net loss attributable to common stockholders	—	—
Deduct: total stock-based employee compensation expensed determined under the fair value based method for all awards	(25)	(74)
Pro forma net loss attributable to common stockholders	$ (10,046)	$ (25,205)
Net loss attributable to common stockholders per share — basic and diluted, as reported	$ (9.47)	$ (26.19)
Pro forma net loss attributable to common stockholders per share — basic and diluted	$ (9.50)	$ (26.27)

The determination of the fair value of stock option awards is affected by our stock price and a number of complex and subjective variables as noted above. Fair value is estimated using the Black-Scholes option pricing model, which includes a number of assumptions including our estimates of stock price volatility, employee stock option exercise behaviors, future forfeitures, future dividend payments, and risk-free interest rates.

The fair value of each employee stock option award for the three and nine months ended September 30, 2005 was estimated on the date of grant based on the minimum value method using the Black-Scholes option pricing valuation model with the following weighted average assumptions:

	Three and Nine Months Ended September 30, 2005
Expected dividend yield	—%
Risk-free interest rate	4.19%
Volatility	.001%
Expected lives	5 years

(n) Net Loss Per Share

Net loss per share is computed using the weighted average number of shares of common stock outstanding and is presented for basic and diluted net loss per share. Basic net loss per share is computed by dividing net loss 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 per share is computed by dividing net loss 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 potential common shares had been issued. The dilutive effect of outstanding stock options and warrants is reflected in diluted net loss per share by application of the treasury stock method. The Company has excluded all outstanding stock options, restricted common stock, warrants, and shares which would be issued under convertible preferred stock from the calculation of diluted net loss per share because such securities are antidilutive for these periods. Potentially dilutive securities, using the preferred stock conversion ratio of 0.204-for-1

REPLIDYNE, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS — (Continued)

established on July 3, 2006 upon the closing of the Company's initial public offering, total approximately 2,432,000 and 17,934,000 at September 30, 2006 and 2005, respectively.

The pro forma basic and diluted net loss per share calculations assume the conversion of the Series A, B, C and D preferred stock and related dividends into shares of common stock at the beginning of the respective period.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2006	2005	2006	2005
	($000's, except share and per share data)			
Historical				
Numerator:				
Net loss attributable to common stockholders	$ (5,807)	$(10,021)	$(25,023)	$(25,131)
Denominator:				
Weighted average common shares outstanding	25,748	1,058	9,659	960
Net loss attributable to common stockholders per share — basic and diluted	$ (0.23)	$ (9.47)	$ (2.59)	$ (26.19)
Unaudited Pro Forma				
Numerator:				
Net loss attributable to common stockholders used above	$ (5,807)		$(25,023)	
Pro forma adjustment to eliminate dividends and accretion on preferred stock	85		5,391	
Pro forma net loss attributable to common stockholders	$ (5,722)		$(19,632)	
Denominator:				
Shares used above	25,748		9,659	
Pro forma adjustment to reflect weighted average effect of assumed conversion of Series A, B, C and D preferred stock and accrued dividends payable in common stock	423		12,788	
Shares used to compute pro forma basic and diluted net loss attributable to common stockholders	26,171		22,447	
Pro forma net loss attributable to common stockholders per share — basic and diluted	$ (0.22)		$ (0.88)	

(o) Fair Value of Financial Instruments

The carrying amounts of financial instruments, including cash and cash equivalents, notes receivable from officers, and accounts payable and accrued expenses approximate fair value due to their short-term maturities. Based on borrowing rates currently available to the Company, the carrying value of the Company's debt obligations approximate fair value.

In conjunction with entering into debt agreements, as disclosed in Note 4, the Company issued warrants to purchase shares of its Series A and C redeemable convertible preferred stock that were considered liabilities pursuant to SFAS No. 150, *Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity* (SFAS No. 150), and related FASB Staff Position 150-5, *Issuer's Accounting under FASB Statement No. 150 for Freestanding Warrants and Other Similar Investments on Shares That Are Redeemable (FSP 150-5).* The warrants were reported as liabilities at their estimated fair value, and any changes in fair value were reflected in

the statements of operations during the period of the change in value. On July 3, 2006, the warrants were automatically converted into warrants exercisable for common shares and have been reclassified to equity as they are no longer considered liabilities pursuant to SFAS No. 150, FSP 150-5 and EITF 00-19 *"Accounting for Derivative Financial Instruments Indexed to and Potentially Settled in a Company's own Stock."*

(p) Revenue Recognition

The Company's commercial collaboration agreements 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 up-front 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.

(q) Research and Development

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

The Company is currently producing clinical and commercial grade product in its facilities and at third parties facilities. Prior to the receipt of approval of its products for commercial sale, these costs are expensed as incurred to research and development.

As discussed in Note 7, in June 2003, the Company acquired program intellectual property, in exchange for Series B convertible preferred stock, which was recorded as research and development expense. In June 2006, in accordance with the terms of this agreement, the Company paid $1.5 million which was recorded as research and development expense. The Company has no further financial obligations due GSK under this agreement.

(r) Comprehensive Loss

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 is comprised of its net loss and unrealized gains and losses on securities available for sale. For the three month periods ended September 30, 2006 and 2005, comprehensive loss was $5.7 million and $8.0 million, respectively. For the nine month periods ended September 30, 2006 and 2005, comprehensive loss was $20.1 million and $20.5 million, respectively.

REPLIDYNE, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS — (Continued)

(s) Recent Accounting Pronouncements

In July 2006, the FASB issued FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes* (FIN 48). FIN 48 clarifies the accounting and reporting for income taxes recognized in accordance with SFAS No. 109, *Accounting for Income Taxes*. This Interpretation prescribes a comprehensive model for the financial statement recognition, measurement, presentation and disclosure of uncertain tax positions taken or expected to be taken in income tax returns. The provisions of FIN 48 are effective for the Company as of January 1, 2007. The Company is currently evaluating the impact of FIN 48.

In September 2006, the SEC issued Staff Accounting Bulletin No. 108, *Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements* , (SAB 108) to address diversity in practice in quantifying financial statement misstatements. SAB 108 requires that companies quantify misstatements based on their impact on each of our financial statements and related disclosures. SAB 108 is effective as of the end of 2006, allowing a one-time transitional cumulative effect adjustment to retained earnings as of January 1, 2006 for errors that were not previously deemed material, but are material under the guidance in SAB 108. The Company is currently evaluating the impact of adopting SAB 108 but does not believe that it will result in a material impact to its financial statements.

In September 2006, the FASB issued SFAS 157, *Fair Value Measurements* , which defines fair value, establishes a framework for measuring fair value, and expands disclosures about fair value measurements. The provisions of SFAS 157 are effective for the Company as of January 1, 2008. The Company is currently evaluating the impact of adopting SFAS 157.

(2) Subsequent Event

In October 2006, the FDA issued a non-approvable letter for the Company's NDA for faropenem medoxomil. The Company submitted the NDA in December 2005 for four adult indications: acute bacterial sinusitis, community-acquired pneumonia, acute exacerbation of chronic bronchitis and uncomplicated skin and skin structure infections. The non-approvable letter recommends further clinical studies for all indications, including studies with a superority design in the case of acute bacterial sinusitus and acute exacerbations of chronic bronchitis, examination of additional microbiological data in these studies and consideration of alternate dosing regimens.

As a result of the non-approvable letter received from the FDA, the Company may become obligated to fulfill certain contingent commitment obligations under its license and supply agreements. In accordance with the Company's supply agreement with Daiichi Asubio Pharma Co. Ltd (Daiichi Asubio) and Nippon Soda Company, Ltd (Nippon Soda) and other related agreements with Forest Laboratories (see Note 6 (c)), the Company may incur obligations related to contingent fees for delay compensation of up to ¥105 million (approximately $0.9 million at September 30, 2006), and cancellation fees of up to ¥75 million (approximately $0.6 million at September 30, 2006).

In accordance with the Company's supply agreement with Tropon GmbH (Tropon) for production of adult tablets of faropenem medoxomil and other related agreements with Forest Laboratories (see Note 6 (d)), and as a result of the non-approvable letter received from the FDA, the Company will incur obligations related to minimum purchases of Tropon's product of up to €1.15 million (approximately $1.45 million at September 30, 2006) in the fourth quarter of 2006.

(3) 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. Forest Laboratories has the first right of refusal to extend the territory to include Canada.

Under the terms of the agreement, in February 2006 Forest Laboratories made a $50 million initial payment to the Company and an additional $10 million payment milestone payment in March 2006, which are being recognized as revenue ratably over the expected term of the agreement or 13.5 years. The agreement calls for potential additional future development and commercial milestone payments that could total $190 million, which will be reduced by $25.0 million if the Company exercises its option to directly market and promote faropenem medoxomil products to pediatricians. These milestone payments are largely dependent on NDA filings, FDA approvals and achieving certain sales levels of faropenem medoxomil. In addition, the Company is entitled to receive royalty payments based on sales of faropenem medoxomil. Forest Laboratories and Replidyne will jointly oversee the development and regulatory approvals of faropenem medoxomil. Forest Laboratories will be primarily responsible for sales and marketing of faropenem medoxomil and Replidyne will perform marketing and promotion activities directed toward targeted specialists, such as otolaryngologists (ear, nose and throat specialists). Forest Laboratories will reimburse the Company for sales force expenses incurred during the one year prior to commencement of these marketing and promotion activities, up to a maximum amount as provided in the agreement. For the five year period after commencement of such marketing and promotion activities, Forest Laboratories will reimburse the Company for certain marketing and sample expenses (subject to an approved annual budget) and for certain sales force expenses. As to sales force expenses during this period, Forest Laboratories will reimburse the Company for all of the expenses incurred during the first two years after commencement of the marketing and promotion activities up to a maximum amount as provided in the agreement, and for the remaining three years Forest Laboratories will reimburse the Company for such sales force expenses up to a certain percentage of the maximum amount as provided in the agreement. Replidyne also has an option to market and promote faropenem medoxomil products to pediatricians on an exclusive basis in the U.S. for the life of the products, upon FDA approval of an oral liquid formulation. If the Company exercises this option, Forest Laboratories will extend to the Company a $60.0 million line of credit to support its promotional efforts for the pediatric indication.

The agreement with Forest extends until the later of (i) the expiration of the last to expire valid claim of the defined patents claiming the manufacture, use or sale of faropenem medoxomil in the U.S. including any period of extended commercial exclusivity for the product granted, (ii) the commercial introduction by a third party of a generic equivalent to faropenem medoxomil in the United States and (iii) twelve years after the date of first commercial sale of faropenem medoxomil in the U.S. Each party has the right to terminate the agreement upon prior written notice of the bankruptcy or dissolution of the other party, or a material breach of the agreement if such breach has not been cured within the required time period following such written notice. Forest Laboratories may also terminate the agreement upon an agreed notice period in the event Forest Laboratories reasonably determines that the development program indicates issues of safety or efficacy that are likely to prevent or significantly delay the filing or approval of a new drug application or to result in labeling or indications that would have a substantially negative impact on the marketing of any product developed under the agreement.

(4) Long-Term Debt

(a) Equipment Loan and Security Agreement

On July 31, 2002, the Company entered into an Equipment Loan and Security Agreement (the Agreement) providing the Company with an available line of credit of up to $3.5 million. Pursuant to the terms of the Agreement, amounts borrowed are restricted solely for the purchase of eligible equipment (computer equipment, networking equipment, laboratory equipment, test and measurement equipment, office equipment and furnishings) and other equipment (certain accepted tenant improvements and build-out costs, software, software licenses, tooling, and equipment specially manufactured for the Company). The Company borrowed $3.4 million under this arrangement. At December 31, 2005, $0.2 million was due to the lenders and no additional borrowings may be made. Borrowings under this agreement were paid in full in April 2006, and no balance is outstanding at September 30, 2006.

In conjunction with the Agreement, the Company issued warrants to the lenders to purchase 140,000 shares of the Company's Series A redeemable convertible preferred stock, with an exercise price of $1.00 per share. The Company accounted for the warrants in accordance with APB No. 14, *Accounting for Convertible Debt and Debt Issued with Stock Purchase Warrants* (APB No. 14). Accordingly, the warrants were valued at $0.91 per share, based upon the Black-Scholes option pricing valuation model with the following assumptions: fair value of Series A preferred stock of $1.00; risk-free interest rate of 4.65%; 100% volatility; term equal to the maximum contractual life of the warrants of 10 years; and no dividend yield. The relative fair value of the warrants of $0.1 million was recorded as a debt discount and has been amortized to interest expense over the life of the debt. As noted above, in conjunction with the initial public offering in July 2006, all outstanding warrants for preferred stock were automatically converted into warrants to acquire common stock, at a ratio of 0.204 shares of common stock for each share of preferred stock.

(b) Convertible Promissory Notes

In December 2003, the Company entered into an agreement to borrow an aggregate principal amount of $2.0 million, which amount was subsequently amended to $7.0 million. The Company borrowed a total of $7.0 million under this agreement through April 28, 2004. The borrowings were from existing stockholders in the form of convertible notes payable (the Convertible Notes). The Convertible Notes matured on June 19, 2004, or earlier if a financing that met specified criteria (a Qualified Financing) was closed, and bore interest at a stated rate of 6% per annum.

Total borrowings of $7.0 million were converted to 5,600,000 shares of Series C preferred stock.

In connection with these borrowings, the Company issued detachable warrants that were exercisable for 700,000 shares of Series C with an exercise price of $1.25 per share. The Company estimated the value of such warrants using the Black-Scholes option pricing model, and the following assumptions: risk-free interest rate of 4.11%; 100% volatility; maximum contractual life of 10 years; and no dividend yield. In connection with the Series C financing, warrants for 500,000 shares of Series C were contributed back to the Company and cancelled. In conjunction with the initial public offering in July 2006, all outstanding warrants for preferred stock were automatically converted into warrants to acquire common stock, at a ratio of 0.204 shares of common stock for each share of preferred stock (See Note 1(a)).

(5) Related-Party Transactions

(a) Clinical Trials Service Agreement with Quintiles, Inc.

During 2004 and 2005, the Company entered into a consulting agreement and a five year master service agreement with one of its investors, Quintiles, Inc. (Quintiles), for regulatory and documentation consulting services associated with the Company's faropenem medoxomil program. Under these agreements with Quintiles, the Company is required to pay service fees, expenses and pass-through costs in accordance with established clinical trial budgets. During the three months ended September 30, 2006 and 2005, the Company incurred fees of $0.6 million and $1 thousand under these agreements, respectively. During the nine month periods ended September 30, 2006 and 2005, the Company incurred fees of $2.8 million and $38 thousand, respectively, under these agreements, and, as of September 30, 2006 and December 31, 2005, $22 thousand and $0.5 million, respectively, was due to Quintiles for services performed. These amounts are included in accounts payable and accrued expenses in the accompanying condensed financial statements. Additionally, the Company has made certain payments to Quintiles for future clinical trial related expenses under its agreements. At September 30, 2006, $0.4 million was included in prepaid expenses and other current assets in the accompanying condensed financial statements. No prepaid amounts related to these agreements existed as of December 31, 2005.

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NOTES TO CONDENSED FINANCIAL STATEMENTS — (Continued)

(b) Notes Receivable from Officers

In 2005, the Company entered into interest-bearing note receivable agreements with two of its officers for the purpose of early exercising stock options in accordance with the Company's Long-Term Incentive Plan and their option agreements. The loans, totaling $0.4 million, were secured by the underlying restricted common stock received upon exercise, and the Company had full recourse to all assets of the officers to satisfy the notes. The notes receivable bore interest at a rate that was determined to be a market rate. On February 28, 2006, the principal amount of the notes, together with accrued interest, was paid in full in cash.

(6) Commitments and Contingencies

(a) 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.

(b) Daiichi Asubio License Agreement

In 2003, the Company made payments, totaling $0.6 million, under a letter of intent to secure certain in-process research and development. In March 2004, the Company entered into a license agreement with Daiichi Asubio to develop and commercialize faropenem medoxomil in the U.S. and Canada for adult and pediatric use. 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. Daiichi Asubio is entitled to up-front fees, milestone payments and royalties. Under certain circumstances, the Company may be required to make certain payments to Daiichi Asubio upon termination of the agreement or abandonment of certain products. In February 2006, the Company and Daiichi Asubio amended certain terms of this agreement. These amended terms have been reflected below.

In consideration for the license, in 2004 the Company paid Daiichi Asubio an initial license fee of ¥400 million ($3.8 million) less amounts previously paid in 2003. 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 (approximately $2.1 million) for the first milestone due to Daiichi Asubio under this agreement. This amount was expensed to research and development in 2005. In February 2006, this milestone payment was increased to ¥375 million. The increased milestone amount 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 (i) up to ¥375 million upon initial FDA approval of at least two respiratory indications (approximately $3.2 million at September 30, 2006), (ii) ¥500 million upon a product launch (approximately $4.2 million at September 30, 2006) and (iii) up to ¥750 million (approximately $6.4 million at September 30, 2006) in subsequent milestone payments for faropenem medoxomil. Additionally, the Company is responsible for royalty payments to Daiichi Asubio 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 Daiichi Asubio or (ii) 12 years after the first commercial launch of faropenem medoxomil. The Company has recorded payments made to date as a research and development expense, as faropenem medoxomil has not been approved by the FDA. The Company has entered into foreign currency purchase agreements to manage the foreign currency exposure related to certain of these payments.

(c) Daiichi Asubio and Nippon Soda Supply Agreement

Under a separate supply agreement entered into in December 2004 among Daiichi Asubio, 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 at the time of commercial launch. If the full commercial launch is delayed beyond January 1, 2007, the Company will be obligated to pay delay compensation of up to ¥280 million (approximately $2.4 million at September 30, 2006) per year to Nippon Soda beginning on July 1, 2007. In September 2006 the supply agreement was amended concurrent with the execution of a new supply agreement between Forest Laboratories, Daiichi Asubio and Nippon Soda relating to the U.S. market for faropenem medoxomil. Under the amended supply agreement, certain of the Company's obligations with respect to purchase commitments, delay compensation and other matters are waived and deemed satisfied by Forest Laboratories pursuant to its agreement. The Company's supply agreement continues to apply for potential supply of faropenem medoxomil for the Canadian market.

Under an agreement with Forest Laboratories Holdings Limited (Forest Laboratories) entered into in February 2006, the Company remains responsible for only the delay compensation that may accrue for any period ending on or prior to December 31, 2007. Thereafter, Forest Laboratories is primarily responsible for any delay compensation. After consideration of the agreement with Forest Laboratories, the Company's maximum potential delay compensation obligation is ¥105 million (approximately $0.9 million at September 30, 2006). 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, 2006) in engineering costs. Additionally, in accordance with an agreement between Forest Laboratories and the Company signed in August 2006, the Company agreed to share equally in a cancellation fee applicable to Forest Laboratories in its agreement with Daiichi Asubio and Nippon Soda. In the event that Forest Laboratories cancels its initial purchase order of a specified amount, the Company's share of the cancellation fee, if invoked, would be ¥75 million (approximately $0.6 million at September 30, 2006).

Based on the non-approvable letter the Company received from the FDA in October 2006 (see Note 2), the Company may incur obligations related to the contingent fees noted above for delay compensation and cancellation fees in the fourth quarter of 2006.

(d) Tropon Supply Agreement

In April 2005, the Company and Tropon entered into a supply agreement for production of adult tablets of faropenem medoxomil, which was amended as to certain terms in March 2006. Beginning in 2006, the Company becomes obligated to make minimum purchases of Tropon's product of €2.3 million (approximately $2.9 million at September 30, 2006) annually. If in any year the Company has not satisfied its minimum purchase commitments, the Company is required to pay Tropon the shortfall amount. Fifty percent (50%) of the shortfall amount, if applicable, is creditable against future drug product purchases. The Company is required to buy all of its requirements for adult oral faropenem medoxomil tablets from Tropon until cumulative purchases exceed €22 million (approximately $27.9 million at September 30, 2006). If the agreement is terminated, under certain circumstances the Company may be obligated to pay up to €1.7 million (approximately $2.2 million at September 30, 2006) in decontamination costs.

In March 2006 when the agreement was amended, 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 Tropon and Forest Laboratories. Under its agreement with Forest Laboratories, the Company remains liable for any shortfall amount in 2006 that may not be credited against future drug product purchases.

Based on the non-approvable letter the Company received from the FDA in October 2006 (see Note 2), the Company will incur an expense approximately equal to its minimum purchase obligations noted above of up to €1.15 million (approximately $1.45 million at September 30, 2006) in the fourth quarter of 2006.

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NOTES TO CONDENSED FINANCIAL STATEMENTS — (Continued)

(e) Derivative Instruments

The Company uses derivative instruments to minimize the impact of foreign currency fluctuations on current and forecasted payables, denominated in Japanese Yen. As discussed at Notes 6 (b) and 6 (c) the Company is obligated to pay amounts in accordance with its license agreement with Daiichi Asubio and its supply agreement with Nippon Soda in Japanese Yen. These forecasted payments expose the Company's earnings and cash flows to adverse movements in foreign currency exchange rates. To reduce the effects of foreign currency fluctuations the Company has entered into foreign exchange option contracts with maturities of less than 18 months.

The Company does not enter into foreign exchange option contracts for trading purposes. Gains and losses on the contracts are included in earnings. The Company does not expect gains or losses on these derivative instruments to have a material impact on its financial results. The fair value of the Company's foreign exchange option contracts as of September 30, 2006, with a notional amount of $7.1 million, was $30 thousand. During the three months ended September 30, 2006, the Company did not purchase or sell any foreign exchange contracts.

(7) Equity

In May 2006, the Company authorized a 1-for-4.904 reverse stock split effective June 26, 2006. The stock split applied to all common stock and options to purchase the Company's common stock outstanding as of June 26, 2006. All common shares and amounts included in these condensed financial statements have been adjusted to reflect this reverse stock split.

In conjunction with the reverse stock split, on June 26, 2006 the preferred stock conversion to common stock ratio was adjusted from 1-for-1 to 0.204-for-1. On July 3, 2006 when the Company's initial public offering closed, all of the Company's preferred stock and warrants to purchase the Company's preferred stock automatically converted into common stock and warrants to purchase common stock, respectively. Common shares issued upon the conversion of outstanding preferred stock on July 3, 2006 are presented below:

	July 3, 2006 Shares Issued and Outstanding	Common Shares Issued Upon Conversion of Preferred Stock on July 3, 2006
Series A	13,000,000	2,650,895
Series B	4,000,000	815,660
Series C	36,880,001	7,520,387
Series D	34,722,222	7,080,380
	88,602,223	18,067,322

(a) Series A Redeemable Convertible Preferred Stock

In February 2002, the Company issued 13,000,000 shares of $0.01 par value Series A redeemable convertible preferred stock (Series A) at $1.00 per share. Total proceeds from Series A were $12.8 million, net of $0.2 million in issuance costs.

(b) Series B Convertible Preferred Stock

In June 2003, the Company issued 4,000,000 shares of $0.01 par value Series B convertible preferred stock (Series B) for $1.25 per share to GlaxoSmithKline (GSK) in exchange for certain program intellectual property, supporting material and license rights, which was recorded as research and development expense in the year ended December 31, 2003. The fair value of Series B was $5 million. In accordance with the terms of the asset purchase agreement, the Company paid GSK an additional $1.5 million in June 2006 following filing of the Company's

Investigational New Drug Application (IND) for REP8839, the related drug. The amount was recorded as research and development expense in the second quarter of 2006.

(c) Series C Redeemable Convertible Preferred Stock

In April 2004, August 2004, September 2004, and November 2004, the Company issued an aggregate of 36,800,000 shares of $0.01 par value Series C redeemable convertible preferred stock (Series C) at $1.25 per share. Total proceeds from Series C were $38.8 million, net of $0.2 million in issuance costs, and the conversion of $7.0 million of bridge notes payable.

(d) Series D Redeemable Convertible Preferred Stock

In August 2005, the Company issued 34,722,222 shares of $0.001 par value Series D redeemable convertible preferred stock (Series D) at $1.80 per share. Total proceeds from Series D were $60.2 million, net of $2.3 million in issuance costs.

(e) Redeemable Convertible Preferred Stock Warrants

In connection with the issuance of debt and convertible notes, the Company issued warrants to certain lenders and investors to purchase shares of the Company's Series A and Series C redeemable convertible preferred stock. The holders of these warrants can acquire a number of shares of Series A and Series C redeemable convertible preferred stock at exercise prices in effect through July 3, 2006 of $1.00 and $1.25 per share, respectively. On July 3, 2006, upon completion of the Company's initial public offering, the Series A and Series C redeemable convertible preferred stock warrants were automatically converted into warrants to purchase 24,465 and 28,547 shares, respectively, of the Company's common stock at exercise prices of $4.90 and $6.13 per share, respectively.

Prior to the conversion to common stock, the warrants were classified as liabilities on the balance sheet pursuant to SFAS No. 150 and FSP 150-5 and subject to re-measurement at each balance sheet date with changes in fair value recognized as a component of other income (expense). Management determined that the fair value of warrants outstanding at December 31, 2005 was $0.6 million. The fair value of the warrants was estimated by management using the Black-Scholes option pricing model with the following assumptions: risk-free rate of 4.36%; remaining contractual term of 6.5 to 8.3 years; volatility of 75%; and an estimated fair value of the underlying preferred stock of $2.03 to $2.12 per share. In February 2006, warrants for 80,001 shares of Series C redeemable convertible preferred stock were exercised for proceeds of $0.1 million. Changes in the fair value of these warrants through the date of exercise were recorded as other expense, and the exercise-date fair value of $0.2 million was reclassified to equity.

On July 3, 2006, the outstanding warrants became exercisable into 53,012 common shares upon closing of the Company's initial public offering and have been reclassified to equity as they are no longer considered liabilities pursuant to SFAS No. 150, FSP 150-5 and EITF 00-19 *Accounting for Derivative Financial Instruments Indexed to and Potentially Settled in a Company's own Stock.* Management determined that the fair value of warrants outstanding at July 3, 2006 was $0.4 million. The fair value of the warrants was estimated by management using the Black-Scholes option pricing model with the following assumptions: risk-free rate of 5.10%; remaining contractual term of 6.1 to 7.5 years; volatility of 75%; and an estimated fair value of the underlying preferred stock of $2.12 per share.

(f) Preferred Stockholder Rights and Preferences

The holders of the Series A, Series B, Series C, and Series D (Preferred Stockholders) had the following rights and preferences at December 31, 2005. On July 3, 2006, all issued and outstanding preferred shares plus accumulated dividends were converted into 19,849,148 shares of common stock.

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NOTES TO CONDENSED FINANCIAL STATEMENTS — (Continued)

(i) Dividend Provisions

Preferred Stockholders are entitled to receive, when and as declared or paid by the board of directors, dividends at the rate of 8% per annum of the applicable original purchase price, accrued on a daily basis. Dividends shall be payable, as accrued, and whether or not declared, on any liquidation, sale, redemption or conversion of Series A, Series B, Series C, or Series D, respectively, to common stock. No dividend shall be declared or paid on common stock unless, concurrently, a similar dividend or distribution is declared or paid on each outstanding share of Series A, Series B, Series C, and Series D.

If the funds of the Company are insufficient to pay the holders of Preferred Stock the full amount of accrued dividends to which each of them are entitled, then such funds will be distributed first among the holders of Series D at the time outstanding; thereafter, any remaining funds will be distributed among the holders of the remaining series of preferred stock at the time outstanding.

(ii) Liquidation Rights

With respect to rights on liquidation, including a sale of substantially all of the Company's assets, the shares of Series D shall rank senior and prior to the shares of Series A, Series B, and Series C stock. In the event of any liquidation, dissolution or winding-up of the Company, Series D stockholders shall be entitled to receive an amount per share equal to the original purchase price, plus an amount equal to accrued dividends and declared but unpaid dividends (without compounding) before any payment shall be made to the Series A, Series B, and Series C stockholders. In the event of any liquidation, dissolution or winding-up of the Company, and after the payment of the full liquidation preference shall have been made to the Series D stockholders, Series C stockholders shall be entitled to receive an amount per share equal to the original purchase price, plus an amount equal to accrued and declared but unpaid dividends (without compounding) before any payment is made to the Series A and Series B stockholders (the Junior Preferred) or common stockholders. In the event of any liquidation, and after the payment of the full liquidation preference made to the Series D stockholders and Series C stockholders, the holders of shares of the Junior Preferred then outstanding shall be entitled to receive an amount per share equal to the original purchase price, plus an amount equal to accrued dividends and declared but unpaid dividends (without compounding) before any payment is made to the common stockholders. After all liquidation payments have been made in full to the Preferred Stockholders, the Preferred Stockholders participate with the common stockholders in the remaining proceeds on an as-if-converted to common stock basis.

(iii) Redemption

At the request of the holders of a majority of the shares of Series D then outstanding (a Series D Requesting Holder), the Company shall redeem at any time after July 31, 2010 (the Series D Redemption Date) all of the shares of Series D then outstanding at a redemption price per share equal to the original purchase price, plus an amount equal to accrued dividends and declared but unpaid dividends (without compounding).

At the request of the holders of a majority of the shares of Series C (a Series C Requesting Holder), and subject to the approval of the holders of a majority of the shares of Series D then outstanding (the Required Holders), the Company shall redeem at any time after July 31, 2011 (the Series C Redemption Date) up to 25% of the Series C preferred stock owned of record by the requesting stockholder and in each subsequent year thereafter up to 25% of the Series C preferred stock that was owned of record by the requesting stockholder on the redemption date, plus the number of shares of Series C that could have been redeemed in the year or years following the redemption date which the requesting stockholder elected not to redeem, at a redemption price per share equal to the original purchase price, plus an amount equal to accrued dividends and declared but unpaid dividends (without compounding).

At the request of the holders of a majority of the shares of Series A (a Series A Requesting Holder and, together with a Series D Requesting Holder and a Series C Requesting Holder, a Requesting Holder), the Company, subject

to the approval of the Required Holders, shall redeem at any time after July 31, 2011 (the Series A Redemption Date) up to 25% of the Series A preferred stock owned of record by the requesting stockholder and in each subsequent year thereafter up to 25% of the Series A preferred stock that was owned of record by the requesting stockholder on the redemption date, plus the number of shares of Series A preferred stock that could have been redeemed in the year or years following the redemption date which the requesting stockholder elected not to redeem, at a redemption price per share equal to the original purchase price, plus an amount equal to accrued dividends and declared but unpaid dividends (without compounding).

Unless otherwise waived by the Required Holders, in no event shall any shares of Series A or Series C be redeemed prior to the redemption of all shares of Series D, whether or not a redemption request has been made by Requesting Holders.

Pursuant to the Series A, Series C, and Series D redemption rights, and Series B liquidation and conversion rights, the Company accumulated accrued dividends through December 31, 2005 as follows (in thousands):

	December 31, 2005
Series A redeemable convertible preferred stock	$ 4,015
Series B convertible preferred stock	$ 1,030
Series C redeemable convertible preferred stock	$ 5,764
Series D redeemable convertible preferred stock	$ 1,864
	$ 12,673

On July 3, 2006, pursuant to closing the initial public offering of the Company's common stock, all accumulated accrued dividends converted into 1,781,826 shares of common stock. No further dividends were accrued after July 3, 2006.

(iv) Voting

Preferred Stockholders are entitled to vote together with common stockholders as one class based on the number of common stock into which each share of Series A, Series B, Series C, and Series D preferred stock, respectively, is then convertible. Series D stockholders, voting as a separate class, shall have the exclusive right to elect one member of the board of directors. Series C stockholders, voting as a separate class, shall have the exclusive right to elect three members of the board of directors. Series A stockholders, voting as a separate class, shall have the exclusive right to elect two members of the board of directors.

(v) Conversion

Preferred stockholders have the right, at any time, to convert any or all of their preferred stock into fully paid and nonassessable shares of common stock equal to the quotient of the respective original purchase price divided by the respective conversion price. On July 3, 2006 pursuant to the Company's initial public offering, all of the Company's preferred stock and warrants to purchase the Company's preferred stock automatically converted into common stock and warrants to purchase common stock, respectively.

(8) Common Stock

The Company's Certificate of Incorporation, as amended and restated on July 3, 2006, authorizes the Company to issue 100,000,000 shares of $0.001 par value common stock. Each share of common stock is entitled to one 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.

REPLIDYNE, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS — (Continued)

(9) Stock Options and Employee Benefits

The Company maintains a Long-Term Incentive Plan (the Plan). The Plan provides for up to 7,137,030 shares of common stock for stock option grants to employees, officers, directors, and consultants of the Company. Options granted under the Plan may be either incentive or nonqualified stock options. Incentive stock options may only be granted to Company employees; nonqualified stock options may be granted to Company employees, officers, directors, and consultants. Generally, options granted under the 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.

During the nine months ended September 30, 2006 and the year ended December 31, 2005 the Company granted options for 1,432,218 and 1,044,759 shares of common stock, respectively, that are eligible to be exercised prior to vesting, provided that the shares issued are subject to restrictions which will be released consistent with the original option vesting period. Of these shares, restrictions on 145,289 shares will be released at an accelerated rate if our NDA for faropenem medoxomil is approved by the FDA, which has not yet occurred, and the Company has entered into a collaboration and commercialization agreement for faropenem medoxomil, which occurred in February 2006 when we entered into our agreement with Forest Laboratories. 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 Plan expire no more than 10 years from the date of grant. At September 30, 2006 and December 31, 2005, the Company had 461,489 and 564,752 restricted shares outstanding from such early exercises, respectively.

A summary of the changes in restricted shares outstanding during the nine months ended September 30, 2006 is presented below:

Non-vested shares outstanding at December 31, 2005	564,752
Restricted stock granted upon exercise of stock options	78,301
Shares vested upon release of restrictions	(181,564)
Non-vested shares outstanding at September 30, 2006	461,489

Stock option activity for the nine months ended September 30, 2006 is as follows:

	Number of Shares	Weighted Average Exercise Price
Balance — December 31, 2005	733,339	$ 0.687
Granted	1,090,605	3.545
Exercised	(197,086)	0.785
Cancelled	(573)	0.613
Balance — March 31, 2006	1,626,285	2.593
Granted	288,734	8.709
Exercised	(14,234)	1.446
Cancelled	(2,100)	1.378
Balance — June 30, 2006	1,898,685	3.533
Granted	52,879	10.005
Exercised	(1,554)	0.613
Cancelled	(30,587)	5.198
Balance — September 30, 2006	1,919,423	3.719

REPLIDYNE, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS — (Continued)

The following table summarizes information about stock options outstanding as of September 30, 2006:

	Stock Options Outstanding			Stock Options Exercisable	
Exercise Price	Number of Shares	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Number of Shares	Weighted Average Exercise Price
$ 0.490	48,762	6.32	$ 0.490	37,961	$ 0.490
0.613	435,115	8.32	0.613	113,207	0.613
1.324	38,869	9.01	1.324	6,108	1.324
3.188	891,933	9.31	3.188	21,920	3.188
5.198	193,718	9.44	5.198	—	—
8.974	160,269	9.62	8.974	—	—
9.940	2,000	9.94	9.940	—	—
10.000	127,444	9.76	10.000	—	—
10.030	21,313	9.88	10.030	—	—
	1,919,423	9.08	3.719	179,196	0.926

The weighted average grant date fair value of options granted during the nine months ended September 30, 2006 was $2.49. The intrinsic value of options exercised during the nine months ended September 30, 2006 was $0.5 million.

The Company also maintains a 2006 Employee Stock Purchase Plan (ESPP) which currently provides for the purchase of up to 305,872 shares of common stock. The ESPP 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. The employee purchases are funded through after-tax payroll deductions, which ESPP participants can elect from one percent to twenty percent of compensation, subject to the federal limit. During the initial six month offering period, which commenced on June 28, 2006, employees are permitted to make retroactive elections to increase contributions through cash infusions until ten days before the end of the initial offering period. The initial offering is considered to be compensatory under SFAS No. 123(R). In accordance with SFAS No. 123(R) the Company has recorded $20 thousand of stock based compensation during both the three and nine months ended September 30, 2006. The final measure of stock based compensation is equal to the intrinsic value of the stock purchased at the end of the initial offering period and may increase based on changes in participant elections and the fair value of the underlying common stock.

Stock Based Compensation

Awards granted to employees prior to the adoption of SFAS No. 123(R) were valued using the intrinsic value method. The Company recognized no stock-based compensation in the three and nine months ended September 30, 2005 for employee awards, respectively. The intrinsic value of options exercised during the nine months ended September 30, 2005 was approximately $5 thousand. As discussed in Note 1, the Company has applied SFAS No. 123(R) to awards granted after January 1, 2006. 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, 2006, there was $2.2 million of total unrecognized compensation costs (net of expected forfeitures) from options granted under the Plan to be recognized over a weighted average remaining period of 3.53 years.

Awards granted to non-employees were valued using the Black-Scholes option pricing valuation model using the following weighted average assumptions for awards granted during the three and nine months ended

REPLIDYNE, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS — (Continued)

September 30, 2006: risk free interest rate of 4.31%, contractual life of 10 years, expected volatility of 100% and expected dividend yield of 0.00%. During the nine months ended September 30, 2006 and 2005, the Company recognized $1 thousand and no stock based compensation related to option grants to non-employees, respectively.

(10) 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 primarily depends on the generation of future taxable income through profitable operations. The Company believes that there currently is not enough positive evidence to support a conclusion that it is more likely than not that it will utilize some or all of its deferred tax assets. Due to the uncertainty of profitable operations, the Company has recorded a full valuation allowance against its deferred tax assets.

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; the extent to which our intellectual property rights may protect our products and technology; our ability to identify new product candidates; the potential of any product candidates to lead to the development of commercial products and the anticipated timing for any commercial launch; 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, 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; expected trends or projections relating to revenue from our collaboration arrangements; expectations regarding future actions to be taken by us in coordination with our collaboration partners under existing collaboration agreements, including with respect to development plans and clinical plans; 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.

In October 2006, the FDA issued a non-approvable letter for our NDA for faropenem medoxomil. We submitted the NDA in December 2005 for four adult indications: acute bacterial sinusitis, community-acquired pneumonia, acute exacerbation of chronic bronchitis and uncomplicated skin and skin structure infections. According to the non-approvable letter, the FDA recommends further clinical studies for all indications including studies using a superiority design for the indications of acute bacterial sinusitis and acute exacerbations of chronic bronchitis, additional microbrologic testing and consideration of alternate dosing regimens. We intend to discuss the clinical plans with the FDA including the number of clinical trials needed for each indication, and expect that a minimum of two years will be required for completion of any additional clinical studies.

We have entered into a collaboration and commercialization agreement with Forest Laboratories Holdings Limited (Forest Laboratories) to co-develop and co-market faropenem medoxomil in the U.S. We and Forest Laboratories are currently conducting a Phase III placebo-controlled clinical trial for acute exacerbation of chronic bronchitis for adult use. We are also developing, together with Forest Laboratories, an oral liquid formulation of faropenem medoxomil for the pediatric market and are currently conducting a Phase II clinical trial using a

prototype oral liquid formulation among pediatric patients with acute otitis media. We intend to conduct Phase III clinical trials using the oral liquid formulation of faropenem modoxomil following completion of Phase II testing seeking clinical indications for the two largest pediatric indications: acute otitis media and tonsillitis/pharyngitis.

Our second product candidate is REP8839, which we are developing for topical use for skin and wound infections and prevention of staphylococcus aureus *(S. aureus)* infections, including methicillin-resistant *S. aureus* (MRSA), in hospital settings. REP8839 is an inhibitor of methionyl tRNA synthetase and, in pre-clinical studies, has shown promising activity. We submitted to the FDA our Investigational New Drug application, or IND, for the development of a REP8839/mupirocin combination product in May 2006 and commenced Phase I clinical studies in July 2006. Mupirocin is a successful topical anti-infective product and we believe the combination of REP8839 and mupirocin may inhibit the development of bacterial resistance to the product although we may initially develop REP8839 as a standalone compound.

We are also 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 also selected from a proprietary library several potential compounds for development to treat infections in hospital settings caused by clostridium difficile *(C. difficile)* and are in advanced pre-clinical testing.

We completed an initial public offering on July 3, 2006. In connection with our initial public offering, we issued 4,500,000 shares of common stock at an offering price of $10 per common share. On August 2, 2006, in accordance with the terms of our agreement with the underwriters of the initial public offering, we sold an additional 506,000 common shares at $10 per share, representing a partial exercise of their over-allotment option. Including the exercise of the over-allotment option, we issued a total of 5,006,000 shares of common stock in our initial public offering. Total proceeds received from the initial public offering, including exercise of the over-allotment allocation, were $44.5 million, net of underwriters' discount and offering costs.

We were incorporated on December 6, 2000 in Delaware. Prior to inception, we had not commenced any significant activity to develop our technology. On December 6, 2000, an affiliated entity contributed certain assets and liabilities to us, which we recorded at their historical cost at that time, and we commenced development activity. 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. On February 10, 2006, upon entering into our collaboration and commercialization agreement with Forest Laboratories, we were no longer considered a development stage company.

We have incurred significant operating losses since our inception on December 6, 2000, and, as of September 30, 2006, we had an aggregate net loss of $90.7 million and accumulated net loss attributable to common stockholders of $109.0 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 from payments by Forest Laboratories under our collaboration and commercialization agreement. We expect to continue to incur substantial operating losses for the next several years as we pursue our clinical trials and research and development efforts.

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. We granted Forest Laboratories a right of first refusal to extend the territory to include Canada. We received an up-front payment of $50.0 million in February 2006 and $10.0 million in milestone payments in March 2006 from Forest Laboratories. We may receive up to an additional $90.0 million in development milestones and $100.0 million in commercial milestones for both adult and pediatric indications, which will be reduced by $25.0 million if we exercise our option to directly market and promote faropenem medoxomil to pediatricians on an exclusive basis. These milestone payments are largely dependent on the acceptance of additional NDA filings, FDA approvals and achieving certain sales levels of adult and pediatric formulations of faropenem medoxomil. Forest Laboratories will book all faropenem medoxomil sales and pay us a co-promotion fee, reimburse our marketing expenses and pay us

royalties on all sales, milestones on approval and development of the adult tablet and liquid oral formulations and, provided we exercise our option to market faropenem medoxomil directly to pediatricians, a portion of the commercialization milestones. Product development activities under the agreement are a joint responsibility between us and Forest Laboratories, although Forest Laboratories is responsible for a substantial portion of development expenses. We maintain access to all data generated in our joint development efforts for use in territories outside the U.S. Forest Laboratories have agreed to assume responsibility for supply chain management in the territory for faropenem medoxomil. In 2006, Forest Laboratories entered into a direct relationship with Nippon Soda as its sole supplier of faropenem medoxomil drug substance. Forest Laboratories is responsible for sales and marketing activities and associated costs, subject to the exercise of our co-promotion option.

Following regulatory approval of faropenem medoxomil, we would perform marketing and promotion activities directed toward targeted specialists, such as otolaryngologists (ear, nose and throat specialists). With respect to these activities, Forest Laboratories will reimburse us for our sales force expenses incurred during the one year period prior to commencement of these marketing and promotion activities, up to a maximum amount as provided in our agreement. For the five year period after commencement of such marketing and promotion activities following FDA approval, Forest Laboratories will reimburse us for certain marketing and sample expenses (subject to an approved annual budget) and for certain sales force expenses. As to sales force expenses during this period, Forest Laboratories will reimburse us for all of such expenses incurred during the first two years after commencement of our marketing and promotion activities up to a maximum amount as provided in our agreement, and for the remaining three years Forest Laboratories will reimburse us for such sales force expenses up to a certain percentage of the maximum amount as provided in our agreement. We have the right to retain the majority of the marketing margin, defined as net sales less cost of goods and marketing expenses, from faropenem medoxomil prescribed by pediatricians, provided we exercise this option at least six months before this formulation is submitted for regulatory approval. If the sales margin is negative, we will bear the majority of the losses in the period they are generated. If we exercise this option, we and Forest Laboratories will jointly determine the product launch and marketing and selling strategies for the oral liquid formulation of faropenem medoxomil. Further, if we exercise this option, Forest Laboratories will extend us a $60.0 million line of credit to support our promotional efforts to pediatricians.

In accordance with our revenue recognition policy for up-front and milestone payments received under collaboration and commercialization agreements, we have recognized revenue for the payments received to date on a straight-line basis over a period of 13.5 years, which is the period of estimated benefit to us. The up-front payment and milestone payment received are non-refundable. We have accounted for amounts received as reimbursements from Forest Laboratories for research and development and sales and marketing activities as revenue. This treatment reflects our role as principal in these transactions whereby we are responsible for selecting vendors, performing significant duties and bearing credit risk.

Financial Operations Overview

Revenue. Our revenue consists of amounts earned under our collaboration and commercialization agreement relating to faropenem medoxomil with Forest Laboratories.

Research and Development Expense. Research and development expense consists primarily of expenses incurred to acquire in-process research and development and to develop and test our product candidates. Such expenses include:

- external research and development expenses, including the costs of materials relating to our pre-clinical studies and clinical trials;
- third party supplier, consultant and employee related expenses, including compensation and benefits;
- license fees associated with acquiring in-process research and development; and
- facilities, depreciation and other allocated expenses, which include direct and allocated expenses for rent, maintenance of facilities, information technology, laboratory and office supplies and depreciation of capital assets used to research and develop our product candidates.

In March 2004, we licensed all rights to faropenem medoxomil from Daiichi Asubio Pharma. Co. Ltd,, or Daiichi Asubio, in the U.S. and Canada. In addition, we have the sole negotiation right to license such rights for the rest of the world, except Japan. Faropenem medoxomil was in development at the time we entered into the license and we accounted for the license of the technology as acquired in-process research and development. We are in the process of conducting a Phase III placebo-controlled clinical trial using faropenem medoxomil to treat acute exacerbation of chronic bronchitis. We are also conducting a Phase II clinical trial of faropenem medoxomil among pediatric patients for treatment of acute otitis media using an oral liquid formulation. To be accepted in the pediatric market, in addition to an excellent safety and efficacy profile, an oral liquid formulation must have a taste that is acceptable to children. We are continuing development work to optimize the taste of our oral liquid formulation of faropenem medoxomil.

We acquired the worldwide rights to the methionyl tRNA synthetase inhibitor program from GlaxoSmithKline PLC, or GSK, in June 2003 in exchange for equity at an aggregate deemed fair value of $5,000,000. Because this program was in pre-clinical development at the time we acquired the worldwide rights, we accounted for the acquisition as acquired in-process research and development in 2003. Using this acquired technology, we have continued the development of our product candidate REP8839 for the treatment of skin and wound infections and eradication of *S. aureus* in the hospital setting. We filed an IND for REP8839 in combination with mupirocin in the second quarter of 2006, and commenced Phase I clinical testing of a REP8839/mupirocin combination in July 2006. Under the terms of our purchase agreement we paid GSK $1.5 million in June 2006, which was recorded as research and development expense in June 2006. Following this payment, we have no further financial obligations to GSK under this agreement related to REP8839.

Our current year research and development activities are significantly focused on the clinical development of faropenem medoxomil. We expect our research and development expense to increase as we advance faropenem medoxomil, REP8839 and new product candidates into further clinical and pre-clinical development. We are unable to estimate with any certainty the costs we will incur in the continued development of faropenem medoxomil, REP8839 and our other product candidates. We expect to continue to expand our research and development activities relating to the clinical development of our product candidates and pre-clinical research of treatments in the anti-infective area. If we acquire or in-license additional technologies or product candidates in the clinical or pre-clinical development stage, we also expect to expand our research and development activities to develop these technologies or product candidates.

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 and skin infections 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.

Sales, General and Administrative Expense. Sales, general and administrative expense consist principally of compensation and related costs for personnel in executive, sales, marketing, corporate development, legal, finance, accounting and human resource functions. Other sales, general and administrative costs include professional fees, costs of insurance and market research.

Interest and Other Income, net. Interest income consists of interest earned on our cash and cash equivalents and short-term investments. Other income consists primarily of amortization of premiums and discounts and realized gains on short-term investments. Other income and expense also includes income or expenses associated

with adjusting the value of our foreign currency denominated payables and our stock purchase warrants to fair value.

Preferred Stock Dividends and Accretion. Preferred stock dividends and accretion consists of cumulative but undeclared dividends payable and accretion of issuance costs on preferred stock. The issuance costs on the shares of Series A, C and D redeemable convertible preferred stock were recorded as a reduction to the carrying amount of the stock when issued, and accreted to preferred stock ratably through July 31, 2014 by a charge to additional paid-in capital and loss attributable to common stockholders. Upon the closing of our initial public offering on July 3, 2006, and the conversion of the preferred stock into common stock, the cumulative but unpaid dividends on Series A, B, C and D preferred stock totaling $17.8 million were settled through issuance of 1,781,826 shares of common stock to the holders of the preferred shares at the initial public offering price, and no further dividends and accretion will be recorded on this preferred stock.

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, revenues, expenses and related disclosures. Actual results may differ from these estimates. See Note 1 to our financial statements included in our Form S-1 filed with the SEC for a complete discussion of our significant accounting policies.

Revenue Recognition. We generate revenue through research, license, collaboration and commercialization agreements. These agreements can contain multiple elements, including non-refundable up-front fees, payments for reimbursement of research and commercialization costs, non-refundable payments associated with achieving specific milestones, promotion fees based on marketing margins defined in our agreement with Forest Laboratories and royalties based on specified percentages of net product sales.

In determining when to recognize revenue related to up-front 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 agreement with Forest Laboratories entered into in February 2006, we have recorded the initial $50 million upfront payment received in February 2006 as deferred revenue and recognize this amount into revenue ratably over a 13.5 year period. In addition, we have and may continue to receive payments upon the achievement of certain development and commercial milestones. The first milestone was achieved and a payment of $10 million

was received 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 are recognizing revenue related to this payment over 13.5 years, the expected term of the agreement. In assessing the remaining milestone payments contemplated in our agreement with Forest Laboratories we have reviewed the criteria for achievement of future milestones. Based on this review, we believe that achievement is uncertain and dependent upon a number of factors which will involve substantive effort. We further believe that a unique earnings process has been identified for each of the remaining development and commercial milestones, the amounts received will be fixed and determinable and, therefore, we intend to recognize revenue related to these milestones upon achievement.

We have received amounts from Forest Laboratories as reimbursement for certain research and development and expect to receive additional amounts as reimbursement for certain future research and development and sales and marketing activities under our agreement. 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 1 to our condensed financial statements for more information about our revenue recognition policies.

Stock-Based Compensation. Through December 31, 2005, we accounted for employee stock options using the intrinsic-value method in accordance with Accounting Principles Board (APB), Opinion No. 25, *Accounting for Stock Issued to Employees* , Financial Accounting Standards Board (FASB), Interpretation No. 44, *Accounting for Certain Transactions Involving Stock Compensation, an interpretation of APB No. 25* , and related interpretations. For periods prior to December 31, 2005, we have adopted the disclosure-only provisions of Statement of Financial Accounting Standards (SFAS) No. 123, *Accounting for Stock-Based Compensation* , as amended.

Under APB No. 25, we recognized stock-based compensation expense, which is a non-cash charge, when we issued employee stock option grants at exercise prices that, for financial reporting purposes, are deemed to be below the estimated fair value of the underlying common stock on the date of grant.

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 payments granted subsequent to December 31, 2005.

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. As we have historically incurred significant operating losses, it is difficult to conclude with certainty that any of our deferred tax assets will be realized. 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 10 to our condensed financial statements.

Results of Operations

Three Months Ended September 30, 2006 and 2005

Revenue. Total revenue was $3.7 million for the third quarter of 2006, as compared to $0.2 million for the third quarter of 2005. The increase was due to revenue generated from our collaboration and commercialization agreement with Forest Laboratories, which we entered into on February 10, 2006. Revenue recognized during the third quarter of 2006 includes $1.1 million of license revenue, representing a portion of the upfront and milestone payments totaling $60 million that is being recognized as revenue over the estimated period of performance of

13.5 years, and $2.6 million of contract revenue for funded activities under our collaboration and commercialization agreement with Forest Laboratories.

Research and Development Expense. Research and development expenses were $7.2 million for the third quarter of 2006, as compared to $7.1 million for the third quarter of 2005. Research and development expenditures made to advance our product candidates and other research efforts during the quarters ended September 30, 2006 and 2005 were as follows:

	Three Months Ended September 30,		Change	
	2006	2005	$	%
	(in thousands)			
Faropenem medoxomil	$3,652	$5,876	$(2,224)	(38)%
REP8839	1,942	1,054	888	84%
Other research and development	1,583	177	1,406	794%
	$7,177	$7,107	$ 70	1%

Overall, research and development expenses for the third quarter of 2006 were consistent with the third quarter of 2005.

Costs incurred for the development of faropenem medoxomil were lower in the third quarter of 2006 compared to the third quarter of 2005 primarily reflecting decreased external clinical trial activity, which resulted in lower external clinical trial costs of $1.9 million. During the third quarter of 2006 we continued to support our ongoing placebo controlled Phase III trial among patients with acute exacerbations of chronic bronchitis and our Phase II dose ranging clinical trial among pediatric patients with acute otitis media. During the third quarter of 2005, in addition to the thorough QT study we incurred significant external clinical research organization expenses supporting preparation of the NDA for faropenem medoxomil that was filed with the FDA in December 2005.

In the third quarter of 2006 costs to support our REP8839 program increased by $0.9 million compared to the third quarter of 2005 following initiation of our Phase I clinical trials program for this compound in July 2006.

General research and development costs increased by $1.4 million for the third quarter of 2006 compared to the third quarter of 2005. In this category, the cost of internal research and development personnel and related costs increased by $0.6 million as we increased our research and development personnel in support of expanded development activities specifically related to our C. *difficile* and DNA replication inhibition programs. Other significant costs in support of these activities included external pre-clinical research, consulting and laboratory and facility costs that increased by $0.5 million.

Research and development expenses are expected to increase during 2006 and in future periods as we:

- complete additional clinical trials in an effort to gain approval from the FDA of faropenem medoxomil for two to four adult indications;
- advance our Phase III placebo controlled clinical trial for faropenem medoxomil in the treatment of acute exacerbation of chronic bronchitis as well as additional clinical trials for faropenem medoxomil in adults;
- complete our Phase II clinical trials for an oral liquid formulation of faropenem medoxomil among pediatric patients;
- advance our Phase I and Phase II clinical trials for REP8839; and
- advance our development activities related to our C. *difficile* and DNA replication inhibitors programs.

The amount and timing of the increased costs related to our clinical trials is difficult to predict due to the detailed design of future trials, uncertainty inherent in the timing of clinical trial initiations and the rate of patient enrollment.

Selling, General and Administrative Expenses. Selling, general and administrative expenses were $3.9 million for the third quarter of 2006, as compared to $1.2 million for the third quarter of 2005. The increase

was primarily due to increased personnel and related costs of $1.5 million representing additional staff required to support our growing commercial organization and administrative and finance personnel, costs associated with initial adoption of SFAS 123(R), *Share Based Payment* , of $0.2 million, recruiting and relocation costs, as well as $0.5 million in incremental legal, accounting, insurance and other professional costs relating to the compliance obligations associated with being a public company. Market research expenses also increased by $0.4 million, principally related to market research associated with faropenem medoxomil and REP8839.

Sales, general and administrative costs are expected to increase as a result of increased compensation costs, as well as higher legal, accounting, insurance and other professional costs relating to the compliance obligations associated with being a public company.

Interest and Other Income, net. Interest and other income, net was $1.6 million for the third quarter of 2006, as compared to $27 thousand for the third quarter of 2005. The increase was primarily due to higher overall cash and short term investment balances available for investing following the receipt of $60.0 million under our collaboration and commercialization agreement with Forest Laboratories in the first quarter of 2006 and $44.5 million in net proceeds from our initial public offering in the third quarter of 2006.

Comparison of Nine Months Ended September 30, 2006 and 2005

Revenue. Revenue was $10.6 million for the first nine months of 2006 compared to $0.4 for the first nine months of 2005. The increase was due to revenue generated from our collaboration and commercialization agreement with Forest Laboratories which began in 2006. Revenue recognized during the first nine months of 2006 includes $2.8 million of license revenue, representing a portion of the upfront and milestone payments totaling $60 million, which is being recognized as revenue over the estimated period of performance of 13.5 years, and $7.8 million of contract revenue for funded activity under our collaboration and commercialization agreement with Forest Laboratories. Revenue recognized in the first nine months of 2005 consists solely of license revenue generated from a research and development project that was completed in 2005.

Research and Development Expense. Research and development expenses were $25.3 million for the first nine months of 2006, as compared to $18.2 million for the first nine months of 2005. Research and development expenditures made to advance our product candidates and other research efforts during the first nine months of 2006 and 2005 were as follows:

	Nine Months Ended September 30,		Change	
	2006	2005	$	%
	(in thousands)			
Faropenem medoxomil	$14,519	$15,619	$(1,100)	(7)%
REP8839	6,275	2,128	4,147	195%
Other research and development	4,493	437	4,056	928%
	$25,287	$18,184	$ 7,103	39%

Costs incurred for the development of faropenem medoxomil were lower in the first nine months of 2006 compared to the first nine months of 2005 primarily reflecting decreased internal and external clinical trial activity of $1.9 million offset by $1.1 million in additional expense incurred under our February 2006 amended license agreement with Daiichi Asubio upon acceptance by the FDA of the NDA for faropenem medoxomil filed in December 2005. During the first nine months of 2006 we continued to support our ongoing placebo controlled Phase III trial among patients with acute exacerbations of chronic bronchitis and our Phase II dose ranging clinical trial among pediatric patients with acute otitis media. During the first nine months of 2005, in addition to the thorough QT study we incurred significant external clinical research organization expenses supporting preparation of the NDA for faropenem medoxomil that was filed with the FDA in December 2005.

In the first nine months of 2006, costs to support our REP8839 program increased by $4.2 million compared to the first nine months of 2005 following initiation of our Phase I clinical trials program for this compound in July 2006, which resulted in increased external clinical trial costs of $0.9 million, external research and consulting of $0.4 million and internal personnel costs of $0.7 million. In 2006 we also incurred $1.5 million under our purchase

agreement with GSK due upon filing of our IND relating to REP8839 with the FDA. We have no further financial obligations due GSK under this agreement.

In the first nine months of 2006, general research and development costs increased by $4.1 million compared to the first nine months of 2005. In this category, costs of internal research and development personnel and related costs increased by $1.6 million as we increased our research and development personnel in support of our expanded development activities specifically related to our C. *difficile* and DNA replication inhibitors programs. Other costs in support of these activities, included external pre-clinical research, consulting and laboratory and facility costs that increased by $1.6 million.

Selling, General and Administrative Expenses. Selling, general and administrative expenses were $8.7 million for the first nine months of 2006, as compared to $3.1 million for the first nine months of 2005. The increase was primarily due to increased personnel and related costs of $3.7 million representing additional staff required to support our growing commercial organization and administrative and finance personnel, costs of recruiting and relocating personnel, costs associated with the initial adoption of SFAS 123(R), *Share-based Payment* , of $0.5 million, as well as $0.7 million in additional legal, accounting, insurance and other professional costs relating to the compliance obligations associated with being a public company. Market research expenses also increased by $0.7 million, principally related to market research associated with faropenem medoxomil and REP8839.

Interest and Other Income, net. Interest and other income, net was $3.7 million for the first nine months of 2006, as compared to $0.2 million for the first nine months of 2005. The increase was primarily due to higher overall cash available for investing following receipt of $60.0 million under our collaboration and commercialization agreement with Forest Laboratories in the first quarter of 2006 and receipt of $44.5 million in net proceeds from our initial public offering completed in the third quarter of 2006.

Liquidity and Capital Resources

As of September 30, 2006, we had a total of $134.3 million in cash, cash equivalents and short-term investments. We have incurred losses since our inception. As of September 30, 2006, we had an accumulated deficit of $107.4 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 collaboration and commercialization agreement totaling $65.2 million and from net proceeds received from our initial public offering of $44.5 million.

We completed an initial public offering of our common stock on July 3, 2006. In connection with this offering, we issued 4,500,000 shares of common stock at an offering price of $10 per share. On August 2, 2006, in accordance with the terms of our agreement with the underwriters of the initial public offering, we sold an additional 506,000 common shares at $10 per share, representing a partial exercise of their over-allotment option. Including the exercise of the over-allotment option, we issued a total of 5,006,000 shares of common stock in the initial public offering. Total proceeds received from the initial public offering, including exercise of the over-allotment allocation, were $44.5 million, net of underwriters' discount and offering costs.

In October 2006, the FDA issued a non-approvable letter for our NDA for faropenem medoxomil. 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 and Forest Laboratories intend to discuss the clinical plans with the FDA including the number of clinical trials needed for each indication, and expect that a minimum of two years will be required for completion of the clinical studies. We are currently evaluating the impact this FDA action will have on our liquidity and capital resources including costs of additional clinical trials, delays in product launch, postponements of milestone and royalty payments, and the possible acceleration of certain contingency obligations under our license and supply agreements as noted below.

In February 2006, we entered into a collaboration and commercialization agreement with Forest Laboratories for the right to be our development and marketing partner of faropenem medoxomil in the U.S. We also granted Forest Laboratories a right of first refusal to extend the territory to include Canada. Under our agreement, in

February 2006 we have received an up-front payment of $50.0 million and in March 2006 we received a $10.0 million development milestone payment from Forest Laboratories. We may receive up to an additional $190.0 million in development and commercial milestones for both adult and pediatric indications, which will be reduced by $25.0 million if we exercise our option to directly market and promote faropenem medoxomil products to pediatricians. These milestone payments are largely dependent on the acceptance of additional NDA filings, FDA approvals and achieving certain sales levels of adult and pediatric formulations of faropenem medoxomil. Product development activities under the agreement are a joint responsibility between us and Forest Laboratories although Forest Laboratories is responsible for the substantial portion of development expenses. Following regulatory approval of faropenem medoxomil, we would perform marketing and promotion activities directed toward targeted specialists, such as otolaryngologists, for which we will be reimbursed by Forest Laboratories up to established limits for the one year period preceding the first promotion activities to occur following FDA approval. For the following five years, we will be reimbursed up to established limits in accordance with our direct marketing and selling activities. We have the right to retain the majority of the sales margin, defined as net sales less cost of goods and marketing expense, from the oral liquid formulation of faropenem medoxomil prescribed by pediatricians, provided we exercise this option at least six months before this formulation is submitted for regulatory approval. If we exercise this option, we and Forest Laboratories will jointly determine the product launch and marketing and selling strategies for any approved pediatric formulation of faropenem medoxomil. Further, if we exercise this option, Forest Laboratories will extend us a $60.0 million line of credit to support our promotional efforts to pediatricians.

In 2004, we entered into a license agreement with Daiichi Asubio 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. In consideration for the license, we paid an initial license fee of $3.8 million comprising $0.6 million paid in 2003 and $3.2 million paid in 2004. In December 2005, we recorded research and development expense for a milestone payable of $2.1 million in accordance with the terms of the license agreement following submission of an NDA for faropenem medoxomil to the FDA in December 2005. In February 2006, in conjunction with our entering into the license agreement with Forest Laboratories, this milestone payment was increased to ¥375 million (approximately $3.2 million as of September 30, 2006). The increased milestone amount was accounted for as research and development expense in 2006 when the modified terms of the license were finalized. Under the modified license agreement we are further obligated to future payments of (i) up to ¥375 million (approximately $3.2 million as of September 30, 2006) upon initial FDA approval of at least two respiratory indications, (ii) ¥500 million (approximately $4.2 million as of September 30, 2006) upon a product launch and (iii) up to ¥750 million (approximately $6.4 million as of September 30, 2006) in subsequent milestone payments for faropenem medoxomil. Additionally, we are responsible for royalty payments to Daiichi Asubio 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 Daiichi Asubio 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 Daiichi Asubio, 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 we are obligated to make certain annual minimum purchase commitments. If the full commercial launch is delayed, we may be obligated for certain delay compensation to Nippon Soda up to ¥280 million (approximately $2.4 million as of September 30, 2006) per year. In September 2006 the supply agreement was amended concurrent with the execution of a new supply agreement between Forest Laboratories, Daiichi Asubio and Nippon Soda relating to the U.S. market for faropenem medoxomil. Under the amended supply agreement, certain of the Company's obligations with respect to purchase commitments, delay compensation and other matters are waived and deemed satisfied by Forest Laboratories pursuant to its agreement. The Company's supply agreement continues to apply for potential supply of Faropenem medoxomil for the Canadian market. Under the agreement with Forest Laboratories entered into in February 2006, we are responsible for only the delay compensation that may accrue for any period ending on or prior to December 31, 2007. Thereafter, Forest Laboratories will be responsible for any delay compensation. After consideration of the agreement with Forest Laboratories, our maximum potential delay compensation obligation is ¥105 million ($0.9 million at September 30,

2006). 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, 2006) in engineering costs. Additionally, in accordance with an agreement between Forest Laboratories and us signed in August 2006, we agreed to share equally in a cancellation fee applicable to Forest Laboratories in its agreement with Daiichi Asubio and Nippon Soda Company such that in the event that Forest Laboratories cancels its initial purchase order of a specified amount, we may incur a cancellation fee totaling ¥75 million (approximately $0.6 million at September 30, 2006).

In April 2005, we entered into a supply agreement for production of adult tablets of faropenem medoxomil with Tropon, which was amended as to certain terms in March 2006. Beginning in 2006, we are obligated to make minimum purchases of Tropon's product of €2.3 million (approximately $2.9 million as of September 30, 2006) annually. If in any year we have not satisfied the minimum purchase commitments, we are required to pay Tropon the shortfall amount. Fifty percent (50%) of the shortfall amount, if applicable, may be credited against future drug product purchases. We are required to buy all of our requirements for adult oral faropenem medoxomil tablets from Tropon until cumulative purchases exceed €22 million (approximately $27.9 million at September 30, 2006). If the agreement is terminated, under certain circumstances we may be obligated to pay up to €1.7 million (approximately $2.2 million as of September 30, 2006) in facility decontamination costs. 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 Tropon and Forest Laboratories. Under our agreement with Forest Laboratories, we remain responsible for only any shortfall amount in 2006 that may not be credited against future drug product purchases.

In June 2003, we acquired certain intellectual property and supporting material from GSK in exchange for the issuance of 4,000,000 shares of our Series B convertible preferred stock at a fair value of $5.0 million. The acquisition was accounted for as a research and development expense. In June 2006, we paid GSK $1.5 million due upon filing of the IND for REP8839 under this agreement. We have no further financial obligations to GSK under this acquisition agreement.

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 Forest Laboratories 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 the 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 and cash equivalents, short-term investments, funding received or made available under our collaboration agreement with Forest Laboratories 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 15 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" below.

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;
- 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 and cash equivalents, short-term investments, funding received or made available under our collaboration agreement with Forest Laboratories 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 an additional credit facility. The sale of additional equity and debt securities may result in additional dilution to our stockholders. If we raise additional funds through the issuance of debt securities, these 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.

Redeemable Convertible Preferred Stock

Our redeemable convertible preferred stock was classified on the balance sheet between liabilities and stockholders' equity (deficit) as the holders of the redeemable convertible preferred stock had the right to request redemption in the future if certain classes of stockholders voted in favor of such redemption. Our Series B convertible preferred stock was also classified on the balance sheet between liabilities and stockholders' equity (deficit) deficit as the holders of Series B convertible preferred stock had certain rights in liquidation. On July 3, 2006, all of our outstanding shares of preferred stock were converted into shares of common stock concurrent with the completion of an initial public offering and the redemption right and rights in liquidation terminated.

Recent Accounting Pronouncements

In July 2006, the FASB issued FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes* (FIN 48). FIN 48 clarifies the accounting and reporting for income taxes recognized in accordance with SFAS No. 109, " *Accounting for Income Taxes* " (SFAS 109). This Interpretation prescribes a comprehensive model for the financial statement recognition, measurement, presentation and disclosure of uncertain tax positions taken or expected to be taken in income tax returns. The provisions of FIN 48 are effective as of the beginning of our 2007 fiscal year. We are currently evaluating the impact of FIN 48.

In September 2006, the SEC issued Staff Accounting Bulletin No. 108, *Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements* , (SAB 108) to address diversity in practice in quantifying financial statement misstatements. SAB 108 requires that we quantify misstatements based on their impact on each of our financial statements and related disclosures. SAB 108 is effective as of the end of our 2006 fiscal year, allowing a one-time transitional cumulative effect adjustment to retained earnings as of January 1, 2006 for errors that were not previously deemed material, but are material under

the guidance in SAB 108. We are currently evaluating the impact of adopting SAB 108 on our financial statements but do not believe it will have a material impact on our financial statements.

In September 2006, the FASB issued SFAS 157, *Fair Value Measurements*, (SFAS 157) which defines fair value, establishes a framework for measuring fair value, and expands disclosures about fair value measurements. The provisions of SFAS 157 are effective as of the beginning of our 2008 fiscal year. We are currently evaluating the impact of adopting SFAS 157 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 one year. 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, 2006 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. We currently hedge exposure to foreign currency fluctuations on current and forecasted expenses denominated in Japanese Yen. The risk that counterparties to our derivative contracts will default and not settle according to the terms of the agreements is a credit risk. Although these instruments are considered derivatives, their economic risks have historically been insignificant and managed on the same basis as risks of other securities we hold.

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, 2006, 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 recently 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 are not able to commercialize faropenem medoxomil, we will not generate product related royalty revenues 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. We are in the early stages of determining our next steps with respect to our faropenem medoxomil development program. We do not expect to make any decisions until we have met with the FDA in a post-action conference and consulted with our collaboration partner, Forest Laboratories. 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 a minimum of two years will be required to complete additional clinical trials. Forest Laboratories may not agree with our decision regarding further development of faropenem medoxomil which may lead to a dispute under our collaboration agreement. 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 or 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, Daiichi Asubio Pharma Co., Ltd., or Daiichi Asubio. 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.

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

The FDA indicated in its non-approvable letter 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. 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 existing 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. 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 and Forest Laboratories agree, after discussion with the FDA, to pursue additional clinical trials in an effort to gain approval from the FDA of 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 for at least two or three years. 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, including with respect to any clinical trials that may be conducted by Forest Laboratories. 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 faropenem medoxomil depends heavily on our collaboration with Forest Laboratories, which was established only in February 2006 and involves a complex sharing of decisions, responsibilities, costs and benefits. Any loss of Forest Laboratories as a partner, or any adverse developments in the collaboration, would materially harm our business.

In February 2006, we entered into a collaboration agreement with Forest Laboratories to develop and commercialize faropenem medoxomil. We have granted Forest Laboratories an exclusive sublicense for the development and sale of faropenem medoxomil for all indications in the U.S. We have also granted Forest Laboratories a right of first refusal to extend the territory to include Canada. In connection with this agreement, Forest Laboratories paid us a non-refundable, non-creditable license fee of $50 million and in March 2006 we received a $10.0 million development milestone payment. The agreement contemplates up to an additional $190.0 million in development and commercial milestones for both adult and pediatric indications, which will be reduced by $25.0 million if we exercise our option to directly market and promote faropenem medoxomil products to pediatricians. These milestone payments are largely dependent on the acceptance of additional NDA filings, FDA approvals and achieving certain sales levels of adult and pediatric formulations of faropenem medoxomil.

In October 2006, the FDA issued a non-approvable letter for our NDA for faropenem medoxomil, recommending further clinical studies for all four indications that were the subject of the NDA. We and Forest Laboratories intend to discuss the clinical plans with the FDA. Product development activities under our agreement are a joint responsibility between us and Forest Laboratories with Forest Laboratories being responsible for the substantial portion of development expenses. Although we share decision-making authority with respect to the development of faropenem medoxomil through a joint development committee on which we and Forest Laboratories have equal representation, decisions require unanimous approval of the committee or mutual agreement between our respective Chief Executive Officers, which means we need the approval of Forest Laboratories before

any final decisions can be made. Forest Laboratories may not agree with our decision regarding further development of faropenem medoxomil which may lead to a dispute under our collaboration agreement and cause significant delays in the development of faropenem medoxomil. We have limited control over the amount and timing of resources that Forest Laboratories will dedicate to the development, approval and marketing of faropenem medoxomil. We do not have a significant history of working together with Forest Laboratories and we cannot guarantee that Forest Laboratories will not reduce or curtail its efforts to develop faropenem medoxomil, because of changes in its research and development budget, its internal development priorities, the success or failure of its other product candidates or other factors affecting its business priorities or operations. If Forest Laboratories is unwilling to further develop or commercialize faropenem medoxomil, or experiences significant delays in doing so, our business will be materially harmed.

All of our recent revenue consists of amounts earned under our collaboration and commercialization agreement relating to faropenem medoxomil with Forest Laboratories. Due to the recent FDA non-approval letter for our NDA for faropenem medoxomil, our prospects for near term future milestone revenues are substantially uncertain given the postponement of our ability to achieve various development and commercial milestones under the Forest Laboratories collaboration agreement.

Forest Laboratories may also terminate our agreement upon 90 days' notice in the event that Forest Laboratories reasonably determines the development program indicates issues of safety or efficacy that are likely to prevent or significantly delay the filing or approval of an NDA for faropenem medoxomil or to result in labeling or indications that would significantly adversely affect the marketing of any product developed under the agreement. Furthermore, Forest Laboratories may terminate our collaboration agreement upon our material breach of the collaboration agreement or our bankruptcy. If the collaboration agreement is terminated in whole or in part and we are unable to enter into similar arrangements with other collaborators, our business would be materially and adversely affected.

Forest Laboratories may also attempt to renegotiate or revisit terms or arrangements currently provided for in our agreement. Under our existing collaboration agreement, Forest Laboratories is responsible for funding a substantial portion of the continued development of faropenem medoxomil, including clinical trials and regulatory approval. Also, the agreement contemplates up to an additional $190.0 million in development and commercial milestones. These and other material terms involving a complex sharing of decisions, responsibilities, costs and benefits, as well as royalties and co-promotion payments, may be the subject of renegotiation, which may result in modifications adverse to our interests and make the collaboration arrangement less advantageous to us.

We are subject to a number of additional risks associated with our dependence on our collaboration with Forest Laboratories, including:

- We and Forest Laboratories could disagree as to development plans, including clinical trials or regulatory approval strategy, or as to which additional indications for faropenem medoxomil should be pursued. Disputes regarding the collaboration agreement that delay or terminate the development, commercialization or receipt of regulatory approvals of faropenem medoxomil would harm our business and could result in significant litigation or arbitration.
- Forest Laboratories could fail to devote sufficient resources to the development, approval, commercialization, or marketing and distribution of faropenem medoxomil. After the time periods stated in the collaboration agreement, Forest Laboratories could shift its research, development and commercialization resources to other product opportunities including those that might be competitive with faropenem medoxomil.
- Forest Laboratories could fail to effectively manage its manufacturing relationships with its supplier of faropenem medoxomil tablets, Tropon GmbH, or Tropon, or with its supplier of faropenem medoxomil drug substance, Nippon Soda Co., Ltd., or Nippon Soda. Forest Laboratories is contractually bound to purchase all of its tablet requirements and drug substance requirements from Tropon and Nippon Soda, respectively, subject to certain exceptions. However, if our agreement with Forest Laboratories terminates for any reason, then the Tropon and Nippon Soda obligations will revert directly to us.

We do not currently have the resources necessary to develop and market faropenem medoxomil on our own. If either we or Forest Laboratories do not perform our respective obligations under, or devote sufficient resources to, our collaboration, or if we and Forest Laboratories do not work effectively together, faropenem medoxomil may not be successfully commercialized. If our collaboration were to be terminated, we would need to establish an alternative collaboration and may not be able to do so on acceptable terms or at all.

We have broad discretion over the use and allocation of our resources and we may allocate our resources in ways that our stockholders may not approve.

Our board of directors and management has broad discretion as to how to use and allocate our resources and we may focus or allocate our resources in ways with which our stockholders may not agree. Accordingly, you will need to rely on our judgment with respect to the use of our resources and you will not have the opportunity as part of your investment decision to assess whether they are being used or allocated appropriately. Based on the recent FDA non-approvable letter for our NDA for faropenem medoxomil, we are in the early stages of determining our next steps with respect to our faropenem medoxomil development program and we do not expect to make any decisions until we have met with the FDA in a post-action conference and consulted with our collaboration partner, Forest Laboratories. We may use resources to acquire or in-license additional pre-clinical, clinical or approved products. The result of these activities may represent new and uncertain drug development and business strategies, which may result in the expenditure of substantial resources in ways that are not certain to improve and may harm our operating results.

We are at an early stage of development as a company, with limited sources of revenue, and we may never 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:

- 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 2000. At September 30, 2006, we had an accumulated deficit of approximately $107.4 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 from payments by Forest Laboratories under our collaboration agreement. Due to the recent FDA non-approval letter for our NDA for faropenem medoxomil, our prospects for near term future revenues are substantially uncertain given the postponement of our ability to achieve various development and commercial milestones under the Forest Laboratories collaboration agreement. 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.

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

We do not expect that our current capital resources will be sufficient to fund the completion of 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 collaboration agreement. Due to the recent FDA non-approval letter for our NDA for faropenem medoxomil, our prospects for near term additional proceeds from that collaboration are substantially uncertain given the postponement of our ability to achieve various development and commercial milestones under the Forest Laboratories collaboration agreement. We currently intend to use our cash and cash equivalents, short-term investments, funding received or made available under our collaboration agreement with Forest Laboratories and interest earned on these balances toward the funding necessary to support our planned activities. If the funds provided by these sources 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 may experience significant delays in the launch of faropenem medoxomil for commercialization, which in turn could delay or prevent us from generating significant royalty revenues from the sale of faropenem medoxomil products.

We could experience potentially significant delays in the commercial launch of faropenem medoxomil due to many factors, such as:

- if any FDA approval of faropenem medoxomil does not include approvals for at least two commercially viable respiratory indications, which must include both (i) acute sinusitis and (ii) either community-acquired pneumonia or acute exacerbation of chronic bronchitis, our partner, Forest Laboratories Holdings Limited, or Forest Laboratories, has the contractual right to delay launch of faropenem medoxomil following such initial FDA approval;
- if any FDA approval of faropenem medoxomil does not include approval of faropenem medoxomil having at least an 18 month shelf-life, then Forest Laboratories has the contractual right to delay launch of faropenem

medoxomil following such initial FDA approval until sufficient supplies of faropenem medoxomil having at least an 18 month shelf-life are available;

- if the FDA's inspections of the manufacturing facilities for faropenem medoxomil drug substance or faropenem medoxomil tablets or the proposed packaging operations for faropenem medoxomil products reveal problems with the manufacturer or the manufacturer's facilities, then the FDA may impose restrictions on operations, including new manufacturing requirements, which would be costly and time consuming and require further FDA review and approval; and
- the supply chain for faropenem medoxomil for the U.S. market is a complex process with highly interactive components consisting of the manufacture of faropenem medoxomil drug substance, the manufacture of faropenem medoxomil tablets, the packaging and labeling of faropenem medoxomil, and the distribution in the U.S. We rely on third parties for each of these activities, including management of the supply chain. Any failure in the complex execution that would influence the ability to establish or manage these manufacturing, packaging and distribution relationships in an effective or timely manner could prevent us from achieving or maintaining market acceptance of faropenem medoxomil.

Any one or a combination of these events could significantly delay or prevent our ability to commercialize faropenem medoxomil. If we are not successful in commercializing faropenem medoxomil, or are significantly delayed in doing so, our business will be materially harmed.

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 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 products 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.

Daiichi Asubio owns a portfolio of patents related to faropenem compounds, including the faropenem parent compound, faropenem medoxomil and other faropenem prodrugs. We have licensed from Daiichi Asubio 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 Daiichi Asubio patents. Beginning in 2008, when the Daiichi Asubio 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 the faropenem medoxomil NDA, 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.

We have limited manufacturing capabilities and will depend on third parties to manufacture faropenem medoxomil and future products. If these manufacturers fail to meet our or Forest Laboratories' 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 and our partner Forest Laboratories 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 Tropon as our sole suppliers of faropenem medoxomil drug substance and faropenem medoxomil tablets, respectively. Pursuant to the terms of our collaboration agreement with Forest Laboratories, Forest Laboratories agreed to assume responsibility for supply chain management for faropenem medoxomil and has entered into a direct relationship with both Nippon Soda and Tropon as its sole supplier of faropenem medoxomil drug substance. However, if our agreement with Forest Laboratories terminates for any reason, then the Nippon Soda and Tropon obligations will revert directly to us. We and Forest Laboratories are contractually bound to purchase all of our requirements from these parties and we expect Nippon Soda and Tropon will be our and Forest Laboratories' sole suppliers of faropenem medoxomil drug substance and tablets for the

foreseeable future. Nippon Soda and Tropon may terminate these supply agreements for a number of reasons, such as:

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

Tropon and 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. Neither we nor Forest Laboratories has control over compliance by Tropon and 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.

Reliance on a third party manufacturer entails risks 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. The full results of this review are unknown at this time although no 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 and Forest Laboratories 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.

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 are developing faropenem medoxomil for pediatric use in conjunction with our strategic partner, Forest Laboratories. We have developed a prototype oral liquid formulation, have initiated a Phase II trial in acute otitis media (middle ear infection) and are considering conducting studies in tonsillitis/pharyngitis. Our ability to successfully develop and market this product candidate for pediatric use is subject to various risks, including the following:

- Pre-clinical testing and clinical trials are protracted, expensive and uncertain processes. It might take us and our partner several years to complete the testing process, 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 not completed any clinical trials in children to date. A clinical trial conducted by Bayer for tonsillitis/pharyngitis in adults did not meet its primary end point.
- Any regulatory approval we ultimately obtain may be limited or subject to post-approval commitments that render the product not commercially viable.
- Any NDA or other marketing authorization applications that we may file might be denied by the FDA and analogous foreign regulators. 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 abandon further development of faropenem medoxomil for adult use, it may be difficult to obtain FDA approval for a pediatric indication.
- 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 or might be uneconomical to market commercially.
- Third parties might 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 potential market might change such that our sales revenue is less than initially contemplated.
- Because of our relationship with our partner, Forest Laboratories, we are dependent on Forest Laboratories to commercialize faropenem medoxomil.

Any failure to obtain regulatory approval of faropenem medoxomil for pediatric use or to effectively market an approved product 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.

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, at the appropriate time and as resources allow, 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 are 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 assure you 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 existing product

candidate, REP8839, is in 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.

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 pediatric use and for certain indications for adults and we have commenced 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. 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, which is based in Connecticut, the services of which we highly depend upon in order to conduct our clinical programs and obtain regulatory approvals.

Competition for qualified personnel in the biotechnology and pharmaceuticals field is intense. We will need to hire additional personnel as we expand our clinical development and commercial activities. We may not be able to attract and retain quality 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 employment at any time without notice and without cause or good reason.

If product liability lawsuits are successfully brought against us or our partner Forest Laboratories, 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 with them. We have also agreed to indemnify Forest Laboratories from claims arising from our development, manufacture, use, handling, storage, promotion, marketing or sale of any product, except as related to certain faropenem medoxomil products in the U.S. with respect to which Forest Laboratories has agreed to bear a substantial portion of any product liability claims. 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 $5.0 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 assure you 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 Daiichi Asubio 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, with a right to sublicense certain rights to Forest Laboratories under our collaboration with Forest Laboratories. Either we or Daiichi Asubio 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 Daiichi Asubio regarding the future development plans for faropenem medoxomil. If there is any dispute between us and Daiichi Asubio 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 Daiichi Asubio 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 products 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. Our collaboration with Forest Laboratories does not cover any markets outside of the U.S. and Canada. 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 and Forest Laboratories 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 or Forest Laboratories 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, Forest Laboratories may experience a significant drop in the sales of the affected products and our product royalty will be reduced, our reputation in the marketplace may suffer and we may become the target of lawsuits, including class action suits. Moreover, if we or Forest Laboratories 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 and our royalties 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 or Forest Laboratories fail to comply with any of these regulations, we or they 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 assure 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 assure 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 Report on Form 10-K to be 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 National 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.

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, Forest Laboratories will market that product candidate directly to primary care physicians in the U.S. but will rely on us to market to physician specialists, such as otolaryngologists. If faropenem medoxomil is approved by the FDA for pediatric use and if we exercise our option, we would be responsible for marketing faropenem medoxomil to pediatricians in the U.S. Although Forest Laboratories will provide some funding, 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 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, such as Forest Laboratories, 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.

Reimbursement may not be available for our product candidates, which could diminish our sales or affect our ability to sell our 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, 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 go 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 is not included on these preferred drug lists, physicians may not be inclined to prescribe it 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 94 employees as of September 30, 2006. 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.

If we do not find collaborators for our future product candidates, we may have to reduce or delay our rate of product development and commercialization and/or increase our expenditures.

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 able to identify and reach agreement with collaborators for our product candidates, those relationships will also 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 products may not commit sufficient resources to the marketing and distribution of our products, limiting our potential revenues from the commercialization of these products; and
- disputes may arise delaying or terminating the research, development or commercialization of our product candidates, or result in significant litigation or arbitration.

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.

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, 2006, we have exclusively licensed from Daiichi Asubio 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 Daiichi Asubio and Forest Laboratories. Although Daiichi Asubio and Forest Laboratories have agreed to cooperate with us in such efforts, if requested, we cannot be assured that Daiichi Asubio and Forest Laboratories 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.

Daiichi Asubio owns a portfolio of patents related to faropenem compounds, including the faropenem parent compound, faropenem medoxomil and other faropenem prodrugs. We have licensed from Daiichi Asubio 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 Daiichi Asubio patents. Beginning in 2008, when the Daiichi Asubio 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 the

faropenem medoxomil NDA, 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 may be 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 may be 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;
- 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. Recently, 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 recent 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 will be 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 approximately 66% 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 new compliance initiatives.

As a public company, we will 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 National 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 will increase 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, commencing in fiscal 2007, 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 will 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.

Substantially all of our stockholders that owned shares prior to our initial public offering that was completed on July 3, 2006 are subject to lock-up agreements with the underwriters of the offering that restrict the stockholders' ability to transfer shares of our common stock for at least 180 days from the effective date of the offering, or until December 25, 2006. Subject to certain limitations, approximately 72% of our total outstanding shares will be eligible for sale upon expiration of the lock-up period. In addition, shares issuable upon exercise of options and warrants vested as of the expiration of the lock-up period will be eligible for sale at that time. Sales of stock by these stockholders could have a material adverse effect on the trading 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, subject to the 180-day lock-up arrangement described above. 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 that 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, with our initial public offering, our most recent private placement and other transactions that have occurred over the past three years, we have triggered an “ownership change” limitation. We are in the process of performing an analysis to determine to what extent our ability to utilize our net operating loss carryforwards is limited. We may also experience ownership change in the future as a result of subsequent shifts in our stock ownership.

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.

On various dates during July 2006 and before the Company filed a Form S-8 covering the shares issuable under the Company's equity incentive plans, the Company issued an aggregate of 1,275 shares of common stock upon the exercise of outstanding stock options. The weighted average exercise price of such options was $0.613 for aggregate purchase price of approximately $1 thousand. The exercise of the options was deemed to be exempt from registration under the Securities Act of 1933 (the "Securities Act") by virtue of Rule 701 in that they were offered and sold pursuant to a written compensatory benefit plan, as provided in Rule 701.

Use of Proceeds from the Sale of Registered Securities.

After deducting expenses of the initial public offering of our common stock in July and August 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, 2006, we have used approximately $8.5 million of 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. The remainder of the net proceeds from the Offering are invested in various interest-bearing instruments and accounts or marketable securities. There has been no material change in the planned use of proceeds from the Offering as described in our final prospectus filed with the SEC pursuant to Rule 424(b) with respect to the Offering.

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.

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

Not applicable.

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

On June 27, 2006 our stockholders holding more than a majority of the then outstanding preferred stock adopted resolutions by written consent approving the automatic conversion of all then outstanding preferred stock into common stock in connection with the closing of our initial public offering, which was effective July 3, 2006. The results of the voting from the stockholders who returned written consents to us is as follows:

For: 53,473,160 shares of preferred stock

Against: None

Item 5. ***Other Information***

Not applicable.

Item 6. ***Exhibits***

The following documents are being filed as part of this report:

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 9, 2006

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 (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 9, 2006

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 (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 9, 2006

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, 2006, 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 9, 2006

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.