BENTLEY PHARMACEUTICALS INC Form 10-Q November 08, 2007

UNITED STATES SECURITIES AND EXCHANGE COMMISSION WASHINGTON, D.C. 20549 FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2007

or

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

For the transition period from to

Commission File Number 1-10581 BENTLEY PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

DELAWARE

(State or other jurisdiction of incorporation or organization)

No. 59-1513162

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

Bentley Park, 2 Holland Way, Exeter, New Hampshire 03833

(Current Address of Principal Executive Offices)

Registrant s telephone number, including area code: (603) 658-6100

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 b NO o Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. (Check one): Large accelerated filer o Accelerated filer b Non-accelerated filer o Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES o NO b

The number of shares of the registrant s common stock outstanding as of November 8, 2007 was 22,326,135.

Bentley Pharmaceuticals, Inc. and Subsidiaries Form 10-Q for the Quarter Ended September 30, 2007 Index

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Bentley Pharmaceuticals, Inc. and Subsidiaries Unaudited Consolidated Balance Sheets

(in thousands, except per share data) Assets	Se	eptember 30, 2007	D	ecember 31, 2006
A55U5				
Current assets:				
Cash and cash equivalents	\$	38,452	\$	12,424
Marketable securities		560		3,177
Receivables, net		31,469		32,963
Inventories Defensed tensor		15,043		16,279
Deferred taxes		1,579 2,437		1,049
Prepaid expenses and other		2,437		1,798
Total current assets		89,540		67,690
Non-current assets:				
Fixed assets, net		55,821		48,556
Drug licenses and related costs, net		17,147		16,026
Restricted cash		1,000		1,000
Deferred taxes		195		240
Other		945		844
Total non-current assets		75,108		66,666
	\$	164,648	\$	134,356
Liabilities and Stockholders Equity				
Current liabilities:				
Accounts payable	\$	15,582	\$	14,566
Accrued expenses		11,276		9,704
Short-term borrowings				247
Current portion of long-term debt				307
Deferred income		998		1,045
Other current liabilities		1,571		1,518
Total current liabilities		29,427		27,387
Non-current liabilities:				
Long-term debt		15,559		
Deferred income		4,757		3,899
Other		4,055		2,739
Total non-current liabilities		24,371		6,638

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Commitments and contingencies

Stockholders equity: Preferred stock, \$1.00 par value, authorized 2,000 shares, issued and		
outstanding, none		
Common stock, \$0.02 par value, authorized 100,000 shares, issued and		
outstanding, 22,323 and 22,262 shares	446	445
Additional paid-in capital	142,092	140,030
Accumulated deficit	(46,952)	(49,016)
Accumulated other comprehensive income	15,264	8,872
Total stockholders equity	110,850	100,331
	\$ 164,648	\$ 134,356

The accompanying Notes to Unaudited Condensed Consolidated Financial Statements are an integral part of these financial statements.

Bentley Pharmaceuticals, Inc. and Subsidiaries Unaudited Consolidated Income Statements

(in thousands, except per share data)	For the Three Months Ended September 30, 2007 2006			For the Nine Months Ended September 30, 2007 2006			
Revenues:							
Net product sales	\$	24,131	\$	22,873	\$ 81,598	\$	75,900
Licensing and collaboration revenues		3,217		2,283	8,320		6,517
6		- ,		,	-)		-)
Total revenues		27,348		25,156	89,918		82,417
Cost of net product sales		14,451		11,778	46,138		37,182
Gross profit		12,897		13,378	43,780		45,235
Operating expenses:		1.000		2 42 5	10.000		11.074
Selling and marketing		4,080		3,495	13,338		11,876
General and administrative		4,098		3,751	12,016		11,320
Research and development		3,017		2,447	9,194		7,850
Litigation settlement				8,932			10,269
Separation costs		846			1,153		
Depreciation and amortization		489		460	1,543		1,341
Total operating expenses		12,530		19,085	37,244		42,656
Income (loss) from operations		367		(5,707)	6,536		2,579
Other income (expenses):							
Interest income		339		223	706		661
Interest expense		(247)		(15)	(348)		(109)
-		. ,		(13)	. ,		
Other, net		(149)			84		36
Income (loss) before income taxes		310		(5,499)	6,978		3,167
Provision for income taxes		911		1,730	4,509		6,607
Net (loss) income	\$	(601)	\$	(7,229)	\$ 2,469	\$	(3,440)
Net (loss) income per common share: Basic	\$	(0.03)	\$	(0.33)	\$ 0.11	\$	(0.16)

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Diluted	\$ (0.03)	\$ (0.33)	\$ 0.11	\$ (0.16)
Weighted average common shares outstanding: Basic	22,354	22,194	22,322	22,107
Diluted	22,354	22,194	22,829	22,107

The accompanying Notes to Unaudited Condensed Consolidated Financial Statements are an integral part of these financial statements.

Bentley Pharmaceuticals, Inc. and Subsidiaries Unaudited Consolidated Statement of Changes in Stockholders Equity

(in thousands)	\$0.02 Pa Commo Shares		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total		
Balance at December 31, 2006	22,262	\$ 445	\$ 140,030	\$ (49,016)	\$ 8,872	\$ 100,331		
Cumulative effect change in accounting from the implementation of FIN 48				(405)		(405)		
Comprehensive income: Net income Other comprehensive income:				2,469		2,469		
Foreign currency translation adjustment					6,392	6,392		
Comprehensive income						\$ 8,861		
Exercise of stock options Purchase of treasury	46	1	191			192		
shares Stock-based	(4)		(52)			(52)		
compensation	19		1,923			1,923		
Balance at September 30, 2007	22,323	\$ 446	\$ 142,092	\$ (46,952)	\$ 15,264	\$ 110,850		
The accompanying Notes to Unaudited Condensed Consolidated Financial Statements are an integral part of these financial statements. 5								

Bentley Pharmaceuticals, Inc. and Subsidiaries Unaudited Consolidated Statements of Cash Flows

(in thousands)	For the Nine Months Ended September 30, 2007 2006					
Cash flows from operating activities:	200	/	2006			
Cash flows from operating activities: Net income (loss)	\$ 2,	469 \$	(3,440)			
Adjustments to reconcile net income (loss) to net cash provided by operating	φ 2,4	+09 φ	(3,440)			
activities:						
Depreciation and amortization	1	959	4,038			
Non-cash charge for inventory write-down and reserves		416	+,050			
Foreign currency gains		(56)				
Stock-based compensation expense		923	1,633			
Change in fair value of derivative instrument		131	1,055			
Loss on disposal of assets		429	50			
Other non-cash items	·	8	50 8			
(Increase) decrease in assets and increase (decrease) in liabilities:		0	0			
Receivables, net	3	507	(3,805)			
Inventories		883	(2,118)			
Deferred income taxes	,	358)	(694)			
Prepaid expenses and other current assets		548)	229			
Other assets		(58)	(6)			
Accounts payable and accrued expenses		(38) 978	1,331			
Deferred income		399	1,351			
Other liabilities		511	7,546			
Other habilities		511	7,540			
Net cash provided by operating activities	16,	593	6,123			
Cash flows from investing activities:						
Additions to fixed assets	(7.	489)	(12,070)			
Additions to drug licenses and related costs	-	780)	(12,070) (1,803)			
Proceeds from the sale of fixed assets	(1,	30	(1,005)			
Purchase of investments		(2)	(2,402)			
Proceeds from investments	2	659	(2,102)			
	2,	007				
Net cash used in investing activities	(6,	582)	(16,275)			
(Continued on following page)						

The accompanying Notes to Unaudited Condensed Consolidated Financial Statements are an integral part of these financial statements.

Bentley Pharmaceuticals, Inc. and Subsidiaries Unaudited Consolidated Statements of Cash Flows (Concluded)

(in thousands)	For the Nine Months Ended September 30,					
		2007		2006		
Cash flows from financing activities: Proceeds from the exercise of stock options	\$	192	\$	150		
Remittance of employee tax liabilities in exchange for common stock tendered to the Company Proceeds from borrowings Repayment of borrowings		(52) 14,807 (554)		(1,907) 1,404 (3,700)		
Net cash provided by (used) in financing activities		14,393		(4,053)		
Effect of exchange rate changes on cash		1,624		21		
Net increase (decrease) in cash and cash equivalents		26,028		(14,184)		
Cash and cash equivalents at beginning of period		12,424		32,384		
Cash and cash equivalents at end of period	\$	38,452	\$	18,200		
Supplemental Disclosures of Cash Flow Information The Company paid cash during the period for: Interest	\$	22	\$	110		
Foreign income taxes	\$	4,099	\$	4,372		
Supplemental Disclosures of Non-Cash Financing and Investing Activities The Company has issued Common Stock as equity-based compensation in lieu of cash during the period as follows:						
Shares		19		14		
Amount	\$	191	\$	182		
Amounts included in accounts payable at end of period for fixed asset and drug license purchases	\$	2,202	\$	3,796		
The accompanying Notes to Unaudited Condensed Consolidated Financial Statem	ents a	ire an inteor	al nart	of these		

The accompanying Notes to Unaudited Condensed Consolidated Financial Statements are an integral part of these financial statements.

Bentley Pharmaceuticals, Inc. and Subsidiaries Notes to Unaudited Condensed Consolidated Financial Statements

History and Operations

Bentley Pharmaceuticals, Inc. and Subsidiaries (which may be referred to as Bentley or the Company), headquartered in the U.S., is an international specialty pharmaceutical company, incorporated in the State of Delaware, focused on:

Specialty Generics: development, licensing and sales of generic and branded generic pharmaceutical products and active pharmaceutical ingredients (API) and the manufacturing of pharmaceuticals for others; and

Drug Delivery: research, development and licensing/commercialization of advanced drug delivery technologies and pharmaceutical products.

Bentley s pharmaceutical product sales and licensing activities are based primarily in Spain, where it has a significant commercial presence and manufactures and markets approximately 180 product presentations (stock keeping units, or SKUs) through three wholly-owned Spanish subsidiaries: Laboratorios Belmac, Laboratorios Davur and Laboratorios Rimafar. Bentley s products are in four primary therapeutic areas: cardiovascular, gastrointestinal, central nervous system and infectious diseases. Although the majority of the Company s sales of these products are currently in the Spanish market, it has recently focused on increasing sales in other European countries and other geographic regions through strategic alliances with companies in these territories. The Company continually adds to its product portfolio in response to increasing market demand for generic and branded generic therapeutic agents and, when appropriate, divests portfolio products considered to be redundant or that have become non-strategic. The Company manufactures its finished dosage pharmaceutical products in its Spanish manufacturing facility which received approval from the U.S. Food and Drug Administration (FDA) in late 2006 for the manufacture of its first U.S. generic product. The Company owns a manufacturing facility in Spain that specializes in the manufacturing of several API products. This facility has also been approved by the FDA for the manufacture of one ingredient for marketing and sale in the U.S. The Company markets its API products through its Spanish subsidiary, Bentley A.P.I. The Company also has an Irish subsidiary, Bentley Pharmaceuticals Ireland Limited, which launched its first product in late 2006.

The Company has U.S. and international patents and other proprietary rights to technologies that facilitate the absorption of drugs. Bentley is developing products that incorporate its drug delivery technologies and has licensed applications of its proprietary CPE-215[®] drug delivery technology to Auxilium Pharmaceuticals, Inc., which launched Testim[®] in the U.S. market in February 2003. Testim, which incorporates Bentley s CPE-215 drug delivery technology, is a gel indicated for testosterone replacement therapy. Bentley continues to seek other pharmaceutical and biotechnology companies to form additional strategic alliances to facilitate the development and commercialization of other products using its drug delivery technologies, including the delivery of insulin to diabetic patients intranasally and the treatment of nail fungus infections topically. In addition, Bentley continues to seek alliances with academic organizations to explore the delivery of macromolecules.

On October 23, 2007 the Company announced a plan to spin-off its drug delivery business, which is subject to a number of conditions. Management expects that shares of the new specialty pharmaceutical drug delivery company, CPEX Pharmaceuticals, Inc. (which may be referred to as CPEX), will be distributed to Bentley stockholders by means of a stock dividend. On the record date, which has not yet been set, each Bentley stockholder will be entitled to receive shares of CPEX in connection with the spin-off of the drug delivery businesses. The spin-off would result in CPEX operating as an independent entity with publicly traded common stock. Bentley would not have any ownership interest in CPEX subsequent to the spin-off.

In connection with the spin-off, CPEX and Bentley expect to enter into a series of agreements, including a separation and distribution agreement, a transition services agreement, an employee matters agreement and a tax allocation agreement. Consummation of the separation is subject to certain conditions, including final approval by the Bentley Board of Directors, approval for listing of CPEX common stock on an exchange, and the effectiveness of the registration statement filed with the Securities and Exchange Commission in connection with the separation. Approval by Bentley s stockholders is not required as a condition to the consummation of the proposed separation.

The Company has incurred and is expected to continue to incur legal, tax and other strategic consulting costs specifically associated with the planned spin-off. These costs totaled \$846,000 and \$1,153,000 in the three and nine months ended September 30, 2007, respectively, and have been reported as *separation costs* within operating expenses in the Company s Unaudited Consolidated Income Statements. Approximately \$307,000 of separation costs incurred during the first two quarters of 2007 were reclassified from *general and administrative* expenses to *separation costs* to conform with the current period presentation.

Basis of Unaudited Condensed Consolidated Financial Statements

The Unaudited Condensed Consolidated Financial Statements of Bentley as of September 30, 2007 and for the three and nine months ended September 30, 2007 and 2006, included herein, have been prepared by the Company, without audit, pursuant to the rules and regulations of the Securities and Exchange Commission. Certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America have been condensed or omitted insofar as such information was disclosed in the Company s consolidated financial statements for the year ended December 31, 2006. These Unaudited Condensed Consolidated Financial Statements should be read in conjunction with the summary of significant accounting policies and the audited consolidated financial statements and notes thereto included in Bentley s Annual Report on Form 10-K for the year ended December 31, 2006, referred to as our 2006 Form 10-K.

In the opinion of management, the accompanying Unaudited Condensed Consolidated Financial Statements as of September 30, 2007 and for the three and nine months ended September 30, 2007 and 2006 are presented on a basis consistent with the audited consolidated financial statements for the year ended December 31, 2006 and contain all adjustments, consisting only of normal recurring adjustments, necessary to present fairly Bentley s financial position as of September 30, 2007 and 2006 and cash flows for the nine months ended September 30, 2007 and 2006. The results of operations for the three and nine months ended September 30, 2007 and 2006. The results of the results to be expected for any subsequent period or for the full year ending December 31, 2007.

Cash and cash equivalents

The Company considers all highly liquid investments with remaining maturities of three months or less when purchased to be cash equivalents for purposes of classification in the Unaudited Consolidated Balance Sheets and the Unaudited Consolidated Statements of Cash Flows. Investments in securities that do not meet the definition of cash equivalents are classified as *marketable securities* in the Unaudited Consolidated Balance Sheets.

Included in *cash and cash equivalents* at September 30, 2007 and December 31, 2006 are approximately \$23,782,000 and \$357,000, respectively, of short-term investments considered to be cash equivalents, as the original maturity dates of such investments were three months or less when purchased.

Fair value of financial instruments

On January 1, 2007, the Company adopted Statement of Financial Accounting Standards (SFAS) No. 157, *Fair Value Measurements* (SFAS No. 157), which provides guidance for measuring the fair value of assets and liabilities, and requires expanded disclosures about fair value measurements. SFAS No. 157 indicates that fair value should be determined based on the assumptions marketplace participants would use in pricing the asset or liability, and provides additional guidelines to consider in determining the market-based measurement. The adoption of SFAS No. 157 did not have a material impact on the Company s Unaudited Condensed Consolidated Financial Statements.

Receivables

Receivables consist of the following (in thousands):

	-	ember 30, 2007	December 31, 2006		
Trade receivables (of which \$0 and \$247, respectively, collateralize short-term borrowings with Spanish financial institutions) VAT receivable	\$	26,443 2,453	\$	27,880 3,151	
Royalties receivable Other		3,065 123		2,261 82	
Less-allowance for doubtful accounts		32,084 (615)		33,374 (411)	
	\$	31,469	\$	32,963	

Inventories

Inventories are stated at the lower of cost or market, cost being determined on the first in, first out (FIFO) method. Reserves for slow moving and obsolete inventories are provided based on historical experience and current product demand.

Balances are comprised of the following (in thousands):

	Sept	December 31, 2006		
Raw materials	\$	10,034	\$	8,669
Finished goods		5,818		7,621
		15,852		16,290
Less allowance for slow moving inventory		(809)		(11)
	\$	15,043	\$	16,279

Included in the Company s inventories at September 30, 2007 and December 31, 2006 are \$137,000 and \$1,338,000, respectively, related to the Company s first U.S. generic product which was launched in late December 2006. The Company has accounted for these goods as consigned inventories that have been shipped to the Company s collaborator. Market price conditions and demand for this product are less favorable than originally estimated. As a result, in the nine months ended September 30, 2007, the Company recorded net adjustments totaling \$1,010,000 to write-down these inventories to their net realizable value and reserve for slow moving inventories. In accordance with its collaboration agreement, the Company is liable for a portion of these adjustments and has therefore recorded a net charge of approximately \$416,000 to *cost of net product sales* in the Unaudited Consolidated Income Statement, reflecting its share of these adjustments.

The Company has received certain payments from its collaborator in anticipation of future sales of the consigned products. As of September 30, 2007 and December 31, 2006, the Company has recorded \$311,000 and \$481,000, respectively, as payments from its collaborator net of adjustments, which have been recorded in *other current liabilities* on the Unaudited Consolidated Balance Sheets.

Fixed assets

Fixed assets consist of the following (in thousands):

	September 30, 2007			December 31, 2006		
Land	\$	3,035	\$	2,875		
Buildings and improvements		25,194		17,538		
Equipment		25,432		20,591		
Furniture and fixtures		2,310		2,138		
Other		338		394		
		56,309		43,536		
Capital in-progress		19,539		20,213		
Less accumulated depreciation		75,848 (20,027)		63,749 (15,193)		
	\$	55,821	\$	48,556		

Depreciation expense of approximately \$271,000 and \$234,000 has been charged to operations as a component of *depreciation and amortization expense* in the Unaudited Consolidated Income Statements for the nine months ended September 30, 2007 and 2006, respectively. Depreciation expense totaling approximately \$3,416,000 and \$2,697,000 has been included in *cost of net product sales* in the Unaudited Consolidated Income Statement during the nine months ended September 30, 2007 and 2006, respectively.

Long-term debt

Long-term debt consists of the following (in thousands):

	September 30, 2007			December 31, 2006		
Loans payable Less-current portion of long-term debt	\$	15,559	\$	307 (307)		
	\$	15,559	\$			

On June 29, 2007, the Company s subsidiary, Laboratorios Belmac (Belmac), entered into a loan agreement with a Spanish financial institution, pursuant to which Belmac borrowed 11,000,000 Euros (approximately \$15,559,000 at September 30, 2007). In accordance with the loan agreement, Belmac will be charged interest on the loan at a variable rate, reset quarterly, equal to the Euro Interbank Offered Rate, plus 0.5%, plus a single, up-front fee of 0.2%. The interest rate under the loan at September 30, 2007 was 5.02%. The principal of the loan will be repaid in quarterly installments of 412,500 Euros (approximately \$583,000) beginning December 31, 2008, with the balance due on December 31, 2013. Maturities on the long-term debt are as follow (in thousands):

	Principal
Year	Payment
2007	\$
2008	583
2009	2,334
2010	2,334
2011	2,334

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2012 and 2013	7,974
Total	\$ 15,559

Pursuant to financial covenants in the loan agreement, Belmac must (i) maintain a net financial debt to net equity ratio of less than 0.33 to 1; (ii) maintain a net financial debt to operating profit ratio of less than 2.75 to 1; and (iii) not have either such ratio increase in any fiscal year by more than 20% over the respective ratio from the prior fiscal year. In addition, Belmac s obligations under the loan agreement have been guaranteed by Bentley and Bentley s other subsidiaries in Spain. Belmac has agreed to pledge assets at the request of the financial institution if Belmac fails to comply with these financial covenants and Belmac has also agreed to not pledge any assets to any other party. The loan may be prepaid at any time without a fee.

In previous years, the Company entered into loan agreements with the Spanish government as a part of government-sponsored research-funding programs. The loans were non-interest bearing and payable in annual installments beginning in 2005. These loans were repaid in full in the nine months ended September 30, 2007. **Stockholders equity**

A substantial amount of the Company s business is conducted in Europe and is therefore influenced by fluctuations in the U.S. Dollar s value in relation to other currencies, specifically the Euro. The exchange rates at September 30, 2007 and December 31, 2006 are as follows:

U.S. Dollars per Euro	September 30, 2007	December 31, 2006
YTD weighted average	1.34	1.26
exchange rate		
Exchange rate	1.41	1.31

The net effect of foreign currency translation on the Company s Unaudited Consolidated Balance Sheet for the three and nine months ended September 30, 2007 was a net increase of \$4,374,000 and \$6,392,000, respectively, and the cumulative historical effect as of September 30, 2007 was an increase of \$15,264,000, as reflected in *accumulated other comprehensive income*. The carrying value of assets and liabilities can be materially affected by changes in foreign currency exchange rates, as can the revenues and expenses.

Supplemental disclosures related to Unaudited Consolidated Statements of Cash Flows

During the nine months ended September 30, 2007, the Chief Executive Officer (CEO), the President, and the Chief Medical Officer (CMO) of the Company were issued an aggregate of 11,150 shares of Bentley Common Stock, before tax withholdings, upon vesting of their respective restricted stock unit awards. At the request of the recipients, the Company withheld approximately 3,783 shares of Common Stock, with a fair market value of approximately \$45,000, in order to satisfy minimum federal and statutory tax withholding requirements. The shares of Common Stock withheld were recorded at fair market value and are held by the Company as treasury shares. As of September 30, 2007 and December 31, 2006, the Company has recorded approximately 853,000 and 849,100 shares, respectively, as treasury stock, with an historical cost of \$10,833,300 and \$10,781,700, respectively, which has been accounted for as a reduction of *additional paid in capital* in the Unaudited Condensed Consolidated Financial Statements.

During the nine months ended September 30, 2006, the CEO and the CMO of the Company and the former CFO of the Company exercised stock options to purchase an aggregate of 650,400 shares of the Company s Common Stock. In satisfaction of the option exercise prices, the Company received an aggregate of approximately 254,300 shares of previously acquired Bentley Common Stock, with a fair market value of approximately \$3,314,000. The Company withheld a total of approximately 144,400 shares of Common Stock, with a fair market value of approximately \$1,900,000, from these employees in order to satisfy minimum federal and statutory tax withholding requirements. The shares of Common Stock acquired by the Company as treasury shares. In addition, in accordance with the separation agreement with the Former CFO, an additional 1,604 shares of Common Stock associated with a grant of restricted stock units became vested and issuable to the Former CFO on September 30, 2006. The Company withheld a total of 584 shares of Common Stock with a fair market value of approximately \$7,000 from the issuance of those shares in order to satisfy minimum federal and statutory tax withholding requirements.

Revenue recognition

Revenue on product sales is recognized when persuasive evidence of an arrangement exists, the price is fixed and final, delivery has occurred and there is a reasonable assurance of collection of the sales proceeds. The Company generally obtains purchase authorizations from its customers for a specified amount of product at a specified price and considers delivery to have occurred when the customer takes possession of the product. The Company provides its customers with a limited right of return. Revenue is recognized upon delivery and a reserve for sales returns is recorded when considered appropriate. The Company has demonstrated the ability to make reasonable and reliable estimates of product returns in accordance with SFAS No. 48, *Revenue Recognition When Right of Return Exists*, (SFAS No. 48) and of allowances for doubtful accounts based on significant historical experience.

Revenue from service, research and development, and licensing agreements is recognized when the service procedures have been completed or as revenue recognition criteria have been met for each separate unit of accounting as defined in Emerging Issues Task Force (EITF) Issue No. 00-21, Accounting for Revenue Arrangements with Multiple Deliverables.

The Company has deferred the recognition of approximately \$5,755,000 and \$4,944,000 of revenues as of September 30, 2007 and December 31, 2006, respectively, for which the earnings process has not been completed.

The Company earns royalty revenues on Auxilium s sales of Testim, which incorporates the Company s CPE-215 permeation enhancement technology. Since 2003, Auxilium has sold Testim to pharmaceutical wholesalers and chain drug stores, which have the right to return purchased product prior to the units being dispensed through patient prescriptions. Historically, customer returns were not able to be reasonably estimated. Therefore, in accordance with SFAS No. 48, the Company deferred the recognition of royalty revenues on product shipments of Testim until the units were dispensed through patient prescriptions. In June 2006, the Company determined that it could reasonably estimate future product returns on sales of Testim based on historical return experience. As a result the Company recorded a change in estimate and recognized its deferred Testim royalties. The Company recognized royalty revenues of \$7,879,000 and \$6,089,000 in the nine months ended September 30, 2007 and 2006, respectively.

Provision for income taxes

On January 1, 2007, the Company adopted the provisions of Financial Standards Accounting Board Interpretation No. 48, Accounting for Uncertainty in Income Taxes (FIN 48) an interpretation of FASB Statement No. 109, Accounting for Income Taxes, (SFAS No. 109). The purpose of FIN 48 is to clarify and set forth consistent rules for accounting for uncertain tax positions in accordance with SFAS No. 109 by requiring the application of a more likely than not threshold for the recognition and derecognition of tax positions. As a result of the implementation of FIN 48, the Company recorded a \$405,000 increase in its non-current liabilities during the quarter ended March 31, 2007 for uncertain tax positions which was accounted for as an increase to the January 1, 2007 accumulated deficit. In order to conform with the balance sheet disclosure requirements of FIN 48, the Company also reclassified its previously recorded liabilities of \$546,000 for uncertain tax positions from accrued expenses to other non-current liabilities during the quarter ended March 31, 2007. The Company had \$935,000 of unrecognized tax benefits at the adoption date, all of which would affect its effective tax rate if recognized. The Company s unrecognized tax benefits decreased by \$272,000 during the nine months ended September 30, 2007 as a result of the expiration of certain foreign tax contingencies. The Company recognizes interest and penalties related to uncertain tax positions as a component of the provision for income taxes. As of the date of adoption, the Company had approximately \$249,000 of accrued penalties and \$51,000 of accrued interest related to its uncertain tax positions. Tax years ranging from 2002 to 2006 remain open to examination by the major taxing authorities in jurisdictions where the Company is subject to taxation, principally the U.S. and Spain.

As a result of reporting taxable income in Spain, the Company recorded provisions for foreign income taxes totaling \$4,509,000 and \$6,607,000 for the nine months ended September 30, 2007 and 2006, respectively. The provisions represented 31% and 57% of the pre-tax income reported in Spain for the nine months ended September 30, 2007 and 2006, respectively. The provisions represented 65% and 209% of consolidated pre-tax income for the nine months ended September 30, 2007 and 2006, respectively.

The Company maintains various agreements by and between Bentley Pharmaceuticals, Inc. and its subsidiaries. Income and expenses resulting from these agreements are eliminated in consolidation; however, the related transactions affect the Company s consolidated income tax provision.

As future operating profits in the U.S. and Ireland cannot be reasonably assured, no tax benefit has been recorded in the Unaudited Consolidated Income Statement for the related losses, which totaled approximately \$7,775,000 and \$8,474,000 for the nine months ended September 30, 2007 and 2006, respectively. The Company has established valuation allowances equal to the full amount of the U.S. and Irish deferred tax assets. Should the Company determine that it is more likely than not that it will realize certain of its net deferred tax assets for which it has previously provided a valuation allowance, an adjustment would be required to reduce the existing valuation allowance. **Basic and diluted net income (loss) per common share**

Basic net income (loss) per common share is based on the weighted average number of shares of Common Stock outstanding during each period. The Company included the dilutive effect of outstanding stock options, as calculated using the treasury stock method and restricted stock units, when determining the diluted net income per common share for the three and nine months ended September 30, 2007 and 2006.

The following is a reconciliation between basic and diluted net income per common share for the nine months ended September 30, 2007. There is no dilutive effect of equity securities on the Company s earnings per share for the three months ended September 30, 2007 and the three and nine months ended September 30, 2006 due to the net losses reported in those periods. Dilutive securities issuable for the nine months ended September 30, 2007 include approximately 507,000 dilutive incremental shares issuable as a result of various stock options and unvested restricted stock units that are outstanding.

For the Nine Months Ended September 30, 2007 (in thousands, except per share data):

		Effect of Dilutive	
Net Income	Basic EPS \$ 2,469	Securities \$	Diluted EPS \$ 2,469
Weighted Average Common	φ 2,105	Ψ	Ψ 2,109
Shares Outstanding Net Income Per Common	22,322	507	22,829
Share	\$ 0.11	\$	\$ 0.11

Excluded from the diluted EPS presentation for the three months ended September 30, 2007 were approximately 3,890,000 shares underlying outstanding stock options and 218,000 shares underlying outstanding restricted stock units as the incremental effect of those shares would be anti-dilutive in that period.

Excluded from the diluted EPS presentation for the nine months ended September 30, 2007 were approximately 1,902,000 shares underlying outstanding stock options at exercise prices greater than the average fair value of the Common Stock for the nine months ended September 30, 2007 as the incremental effect of those shares would be anti-dilutive in that period.

Excluded from the diluted EPS presentation for the three and nine months ended September 30, 2006 were approximately 3,699,000 shares underlying outstanding stock options and 111,000 shares

underlying outstanding restricted stock units as the incremental effect of those shares would be anti-dilutive in those periods.

Share-based compensation

The Company has in effect equity incentive plans (the Plans), pursuant to which directors, officers, employees and consultants of the Company have been awarded grants of restricted stock units and options to purchase the Company s Common Stock. As of September 30, 2007, approximately 4,420,000 shares of Common Stock have been reserved for issuance under the Plans. Approximately 4,108,000 of the shares are outstanding, excluding 50,000 shares underlying restricted stock units, contingently issuable to non-employee directors pursuant to the terms and conditions of the respective restricted stock unit agreements. The balance of approximately 311,000 shares is available for future issuance for any type of award allowed under the plan.

During the nine months ended September 30, 2007, the Company issued approximately 20,200 shares of Common Stock upon the vesting of restricted stock units, approximately 26,000 shares of Common Stock upon exercise of stock options and approximately 18,800 shares of Common Stock as share-based compensation in lieu of cash contributions to the Company s 401(k) Plan. The Company also withheld approximately 4,300 shares upon the vesting of restricted stock units in order to satisfy minimum federal and statutory tax withholding requirements, which were recorded as treasury stock. An additional 30,000 restricted stock units vested during the period and are contingently issuable to non-employee directors pursuant to the terms and conditions of the respective restricted stock unit agreements.

Share-based compensation expense recorded for stock option and restricted stock unit awards to employees and non-employee directors for the three months ended September 30, 2007 and 2006 was approximately \$666,000 and \$598,000, respectively. Share-based compensation expense recorded for stock option and restricted stock unit awards to employees and non-employee directors for the nine months ended September 30, 2007 and 2006 was approximately \$1,670,000 and \$1,424,000, respectively.

The related expenses were recorded in the Company s Unaudited Consolidated Income Statements as follows (in thousands):

	F		ree Mon ded 1ber 30,	iths	F	or the Ni En Septer	ded	
	2	007	20	006	2	007		2006
Cost of net product sales	\$	10	\$	4	\$	25	\$	19
Selling and marketing expenses		5		2		13		10
General and administrative expenses		410		392		1,029		913
Research and development expenses		241		200		603		482
	\$	666	\$	598	\$	1,670	\$	1,424

No related compensation expense was capitalized as the cost of an asset and there was no impact on net cash provided by operating activities or net cash used in financing activities as a result of these share-based transactions.

The Company issued 18,800 and 13,900 shares in the nine months ended September 30, 2007 and 2006, respectively, as matching contributions for the Company s 401(k) Plan. *General and administrative expenses* include approximately \$92,000 and \$87,000 of such non-cash share-based compensation for the nine months ended September 30, 2007 and 2006, respectively. *Research and development expenses* include approximately \$99,000 and \$120,000 of such non-cash share-based compensation for the nine months ended september 30, 2007 and 2006, respectively. *Research and development expenses* include approximately \$99,000 and \$120,000 of such non-cash share-based compensation for the nine months ended September 30, 2007 and 2006, respectively.

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Business segment information

SFAS No. 131, *Disclosures About Segments of an Enterprise and Related Information*, defines how operating segments are determined and requires disclosure of certain financial and descriptive information about a company s operating segments. The Company, headquartered in the U.S., is an international specialty pharmaceutical company which operates in two business segments, specialty generics and drug delivery, and two geographical locations (Europe and the U.S.).

The Company s specialty generics segment is based in Europe and develops and manufactures a growing portfolio of generic and branded generic pharmaceuticals in Europe for the treatment of cardiovascular, gastrointestinal, infectious and central nervous system diseases through its subsidiary, Laboratorios Belmac, and markets these pharmaceutical products through its subsidiaries, Laboratorios Belmac, Laboratorios Davur, Laboratorios Rimafar and Bentley Pharmaceuticals Ireland. The U.S. operations of this segment include any sales of generic pharmaceuticals in the U.S. and continued research and development activities to bring additional generic pharmaceutical products into the U.S. This segment also manufactures and sells active pharmaceutical ingredients through its subsidiary, Bentley A.P.I.

The Company s drug delivery segment is based in both the U.S. and Europe and is focused on the advancement of proprietary drug delivery technologies that enhance or facilitate the absorption of pharmaceutical compounds across various membranes. In the U.S., the Company s activities consist primarily of licensing, product research and development, business development activities, corporate management and administration.

Set forth in the tables below is certain financial information with respect to the Company s business and geographical segments for the three and nine months ended September 30, 2007 and 2006 and as of September 30, 2007 and December 31, 2006. These segments use the same accounting policies as those described in the summary of significant accounting policies in Note 2 of the Company s Annual Report on Form 10-K for the year ended December 31, 2006 (the 2006 Form 10-K).

For the Three Months Ended September 30, 2007 (in thousands):

	Specialty Generics		Drug I		
	Europe	U.S.	Europe	U.S.	Consolidated
Net product sales	\$23,930	\$201	\$	\$	\$24,131
Licensing and collaboration					
revenues	148			3,069	3,217
Total revenues	24,078	201		3,069	27,348
Cost of net product sales	14,291	160			14,451
Gross Profit	9,787	41		3,069	12,897
Selling and marketing expense	4,080				4,080
General and administrative expense	2,021	(8)		2,085	4,098
Research and development expense	341		1,338	1,338	3,017
Separation costs				846	846
Depreciation and amortization					
expense	290	39		160	489
Income (loss) from operations	3,055	10	(1,338)	(1,360)	367
Interest income	188			151	339
Interest expense	(246)			(1)	(247)
Other income (expense), net	(147)			(2)	(149)
Income (loss) before income taxes	2,850	10	(1,338)	(1,212)	310
Provision for income taxes	911				911
Net income (loss)	1,939	10	(1,338)	(1,212)	(601)
Expenditures for fixed assets	3,174			57	3,231
Expenditures for drug licenses	575				575
Income (loss) before income taxes Provision for income taxes Net income (loss) Expenditures for fixed assets	2,850 911 1,939 3,174			(1,212) (1,212)	310 911 (601) 3,231

For the Three Months Ended September 30, 2006 (in thousands):

	Specialty Generics		Drug I	Drug Delivery		
	Europe	U.S.	Europe	U.S.	Consolidated	
Net product sales	\$22,834	\$ 39	\$	\$	\$22,873	
Licensing and collaboration						
revenues	170			2,113	2,283	
Total revenues	23,004	39		2,113	25,156	
Cost of net product sales	11,739	39			11,778	
Gross profit	11,265			2,113	13,378	
Selling and marketing expense	3,495				3,495	
General and administrative expense	1,901		1	1,849	3,751	
Research and development expense	421		1,013	1,013	2,447	
Litigation settlement	7,764	1,168			8,932	
Depreciation and amortization						
expense	270	21		169	460	
Loss from operations	(2,586)	(1,189)) (1,014)	(918)	(5,707)	
Interest income	55			168	223	
Interest expense	(15)				(15)	
Loss before income taxes	(2,546)	(1,189)) (1,014)	(750)	(5,499)	
Provision for income taxes	1,730				1,730	
Net loss	(4,276)	(1,189)) (1,014)	(750)	(7,229)	
Expenditures for fixed assets	4,597			157	4,754	
Expenditures for drug licenses	572			360	932	

For the Nine Months Ended September 30, 2007 (in thousands):

	Specialty Generics		Drug I		
	Europe	U.S.	Europe	U.S.	Consolidated
Net product sales	\$80,997	\$ 601	\$	\$	\$81,598
Licensing and collaboration					
revenues	433			7,887	8,320
Total revenues	81,430	601		7,887	89,918
Cost of net product sales	45,134	1,004			46,138
Gross profit (loss)	36,296	(403)		7,887	43,780
Selling and marketing expense	13,338				13,338
General and administrative expense	6,689	(36)		5,363	12,016
Research and development expense	1,341		3,926	3,927	9,194
Separation costs				1,153	1,153
Depreciation and amortization					
expense	848	117		578	1,543
Income (loss) from operations	14,080	(484)	(3,926)	(3,134)	6,536
Interest income	323			383	706
Interest expense	(339)			(9)	(348)
Other income (expense), net	89			(5)	84
Income (loss) before income taxes	14,153	(484)	(3,926)	(2,765)	6,978
Provision for income taxes	4,509				4,509
Net income (loss)	9,644	(484)	(3,926)	(2,765)	2,469
Expenditures for fixed assets	7,404			85	7,489
Expenditures for drug licenses	1,591	32		157	1,780

For the Nine Months Ended September 30, 2006 (in thousands):

	Specialty Generics		Drug I		
	Europe	U.S.	Europe	U.S.	Consolidated
Net product sales	\$75,861	\$ 39	\$	\$	\$ 75,900
Licensing and collaboration revenues	409			6,108	6,517
Total revenues	76,270	39		6,108	82,417
Cost of net product sales	37,143	39			37,182
Gross profit	39,127			6,108	45,235
Selling and marketing expense	11,876				11,876
General and administrative expense	5,507		68	5,745	11,320
Research and development expense	1,374		3,238	3,238	7,850
Litigation settlement	8,034	2,235			10,269
Depreciation and amortization expense	784	63		494	1,341
Income (loss) from operations	11,552	(2,298)	(3,306)	(3,369)	2,579
Interest income	110			551	661
Interest expense	(109)				(109)
Other income (expense), net	36				36
Income (loss) before income taxes	11,589	(2,298)	(3,306)	(2,818)	3,167
Provision for income taxes	6,607				6,607
Net income (loss)	4,982	(2,298)	(3,306)	(2,818)	(3,440)
Expenditures for fixed assets	11,734			336	12,070
Expenditures for drug licenses	1,128			675	1,803
As of September 30, 2007 (in thousands):					

As of September 30, 2007 (in thousands):

	Specialty Generics		Drug	Delivery		
	Europe	U.S.	Europe	U.S.	Consolidated	
Receivables, net	\$ 28,345	\$	\$	\$ 3,124	\$ 31,469	
Other current assets	44,042	55		13,974	58,071	
Fixed assets	53,174			2,647	55,821	
Drug licenses and related costs	12,357	1,746		3,044	17,147	
Other non-current assets	993			1,147	2,140	
Total assets	138,911	1,801		23,936	164,648	
Current liabilities	25,105	398		3,924	29,427	
Long term debt	15,559				15,559	
Other non-current liabilities	8,812				8,812	
Total liabilities	49,476	398		3,924	53,798	
As of December 31, 2006 (in thousands):						

As of December 31, 2006 (in thousands):

	Specialty Generics		Drug	Delivery		
	Europe	U.S.	Europe	U.S.	Consolidated	
Receivables, net	\$ 30,558	\$ 39	\$	\$ 2,366	\$ 32,963	
Other current assets	21,758	1,338		11,631	34,727	
Fixed assets	45,738			2,818	48,556	
Drug licenses and related costs	10,697	1,833		3,496	16,026	
Other non-current assets	885			1,199	2,084	
Total assets	109,636	3,210		21,510	134,356	
Current liabilities	24,651			2,736	27,387	
Non-current liabilities	6,638				6,638	

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Total liabilities	31,289 18	2,736	34,025

Subsequent event

In accordance with the Company s litigation settlement with Ethypharm S.A. Spain and Ethypharm S.A. France (or Ethypharm) in late 2006, the Company made its first scheduled \$1,000,000 annual payment to Ethypharm in October of 2007. The remaining three annual payments of \$1,000,000 are scheduled to be made in the fourth quarters of 2008, 2009 and 2010.

Recently issued accounting pronouncements

On January 1, 2007, the Company adopted SFAS No. 157, *Fair Value Measurements* (SFAS No. 157), which provides guidance for measuring the fair value of assets and liabilities, and requires expanded disclosures about fair value measurements. SFAS No. 157 indicates that fair value should be determined based on the assumptions marketplace participants would use in pricing the asset or liability, and provides additional guidelines to consider in determining the market-based measurement. The adoption of SFAS No. 157 did not have a material impact on the Company s Unaudited Condensed Consolidated Financial Statements.

In February 2007, the Financial Accounting Standards Board (FASB) issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities, including an amendment of FASB Statement No. 115*, (SFAS No. 159). SFAS No. 159 permits entities to choose to measure many financial instruments and certain other items at fair value that are not currently required to be measured at fair value. SFAS No. 159 also establishes presentation and disclosure requirements designed to facilitate comparisons between entities that choose different measurement attributes for similar types of assets and liabilities. SFAS No. 159 becomes effective for the Company as of January 1, 2008. The Company is currently evaluating the impact of SFAS No. 159 on the Company s consolidated financial statements.

In June 2007, the FASB ratified the consensus reached by the EITF on Issue No. 07-3, "*Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities* (EITF Issue No. 07-3). EITF Issue No. 07-3 states that nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities should be deferred and capitalized. Such amounts should be recognized as an expense as the related goods are delivered or the related services performed. If an entity does not expect the goods to be delivered or services to be rendered, the capitalized advance payment should be charged to expense. EITF Issue No. 07-3 is effective for fiscal years beginning after December 15, 2007 and earlier application is not permitted. The Company often enters into agreements for research and development goods and service. As such, the Company is evaluating the impact that the adoption of EITF Issue No. 07-3 will have on its consolidated financial statements.

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

You should read the following discussion and analysis together with all financial and non-financial information appearing elsewhere in this report and with our consolidated financial statements and related notes included in our 2006 Annual Report on Form 10-K, referred to as our 2006 Form 10-K, which has been previously filed with the SEC. In addition to historical information, the following discussion and other parts of this report contain forward-looking information that involves risks and uncertainties. Our actual results could differ materially from those anticipated by such forward-looking information due to competitive factors and other risks discussed in our 2006 Form 10-K under Item 1A, Risk Factors .

Planned Spin-off

On October 23, 2007, we announced a plan to spin-off our drug delivery business, which is subject to a number of conditions. We expect that shares of the new specialty pharmaceutical drug delivery company, CPEX Pharmaceuticals, Inc. (which may be referred to as CPEX), will be distributed to Bentley stockholders by means of a stock dividend. On the record date, which has not yet been set, each Bentley stockholder will be entitled to receive shares of CPEX in connection with the spin-off of the drug delivery businesses. The spin-off would result in CPEX operating as an independent entity with publicly traded common stock. Bentley would not have any ownership interest in CPEX subsequent to the spin-off.

In connection with the spin-off, CPEX and Bentley expect to enter into a series of agreements, including a separation and distribution agreement, a transition services agreement, an employee matters agreement and a tax allocation agreement. Consummation of the separation is subject to certain conditions, including final approval by the Bentley Board of Directors, approval for listing of CPEX common stock on an exchange, and the effectiveness of the registration statement filed with the Securities and Exchange Commission in connection with the separation. Approval by Bentley s stockholders is not required as a condition to the consummation of the proposed separation.

We have incurred and expect to continue to incur legal, tax and other strategic consulting costs specifically associated with the planned spin-off. These costs totaled \$846,000 and \$1,153,000 in the three and nine months ended September 30, 2007, respectively, and have been reported as *separation costs* within operating expenses in the Unaudited Consolidated Income Statements.

Overview

We are a specialty pharmaceutical company focused on:

Specialty Generics: development, licensing and sales of generic and branded generic pharmaceutical products and active pharmaceutical ingredients and the manufacturing of pharmaceuticals for ourselves and others in Spain, other parts of Europe and international markets, including the U.S. market; and

Drug Delivery: research, development and licensing/commercialization of advanced proprietary drug delivery technologies for new and existing pharmaceutical products.

Generic Pharmaceuticals

Our pharmaceutical product sales activities are based in Spain, where we have a significant commercial presence and we manufacture and market approximately 180 product presentations or SKUs in four primary therapeutic areas: cardiovascular, gastrointestinal, central nervous system and infectious diseases. Revenues derived from our top three product lines, represented approximately 30% of our net product revenues in the three months ended September 30, 2007. We market our branded generic and generic products to physicians, pharmacists and hospitals through our three separate sales and marketing

organizations based in Spain: Laboratorios Belmac, Laboratorios Davur and Laboratorios Rimafar. In past years we expanded our geographic sales to countries outside of Spain including the U.S. and several countries in the European Union. As of September 30, 2007 approximately 28% of our net product sales were derived from sales outside of Spain. Our generic simvastatin product, which is manufactured at our FDA approved finish dosage facility in Spain, was launched in the U.S. in December of 2006. The launch of our first U.S. generic product marked a significant strategic milestone for us; however, due to market price conditions and limited demand, sales of our generic simvastatin have been determined to be less favorable than our initial projections. As a result, we have recorded net charges of approximately \$416,000 to *cost of net product sales* for inventory write-downs and obsolescence reserves in the nine months ended September 30, 2007.

While the pricing of our pharmaceutical products is influenced by market forces (size of the market, number of competitors, etc.), our pricing in Spain and other countries is also subject to governmental price controls. The majority of our products are subject to price controls set in place by the Spanish government. The Spanish government enacted legislation effective March 1, 2007 which reduced the amount reimburses for pharmaceutical products. As a result of the legislation our sales force began marketing our products at lower selling prices in Spain as early as February 2007. We also experienced reduced sales levels in the beginning of the first quarter of 2007 as Spanish wholesalers and pharmacies minimized order quantities until they were able to purchase our products at the new lower prices. Once we began selling at the new prices we experienced an increase in the number of our units sold. While the increased unit volume has substantially offset the impact of the reduced selling prices on our net product sales, our gross margins have decreased from 51% in the nine months ended September 30, 2006 to 44% in the nine months ended September 30, 2007 (excluding inventory write-downs associated with our U.S. generic simvastatin discussed above). We have implemented strategies to mitigate lower selling prices, including strategies to reduce manufacturing costs and increase sales volumes. We are seeking to continue expanding our product sales in other geographic regions, including the U.S., through strategic alliances. We are targeting markets that offer compatible regulatory approval regimes and attractive product margins. In addition, we expect to grow our business by developing and acquiring rights to market additional products to sell through our sales organization and our strategic alliances. We continually acquire rights to new products in response to increasing market demand for generic and branded generic therapeutic products.

We also manufacture and market active pharmaceutical ingredients, or API, through our subsidiary, Bentley A.P.I. Our API facility has been approved by the FDA for the manufacture of one ingredient for marketing and sale in the U.S. In addition, our Spanish pharmaceutical product manufacturing facility produces pharmaceutical products that are marketed by other pharmaceutical companies both in Spain and in other international markets, including the U.S. *Drug Delivery Technologies and Products*

We develop and co-develop products that incorporate our drug delivery technologies. We have licensed applications of our proprietary CPE-215 drug delivery technology to Auxilium Pharmaceuticals, Inc., which launched Testim, the first product incorporating our CPE-215 drug delivery technology, in the United States in February 2003. Testim is a gel indicated for testosterone replacement therapy. Testim is also approved for marketing in 15 European countries and Canada. On August 29, 2007, we received a new patent from the European Patent Office, effectively extending patent coverage for Testim through April 2023 in covered territories. We are in discussions with other pharmaceutical and biotechnology companies to form additional strategic alliances to facilitate the development and commercialization of other products using our drug delivery technologies, including the delivery of insulin to diabetic patients intranasally and the treatment of nail fungus infections topically. In addition, we continue to seek alliances with academic organizations to explore the delivery of macromolecules.

Research and Development Focus

Our U.S. research and development activities are primarily focused on the development of NasulinTM, our intranasal insulin product candidate. In 2004 we concluded a Phase IIA study of Nasulin in

Type I diabetic patients using our CPE-215 technology. The full results of that trial were published in 2006 in the journal *Diabetes Technology & Therapeutics*, Volume 8, Number 1. In 2006, we completed an additional Phase I study in Ireland and advanced our Phase IIA studies in the U.S. In the first quarter of 2007 we completed preparations for a Phase II study in India which began in the second quarter of 2007. Portions of the results from our U.S. and Irish studies were presented at the American Diabetes Association 67th Sessions in Chicago, IL in June 2007. We expect the U.S. clinical development programs for Nasulin to continue and expand both outside and inside the U.S. We are also continuing our clinical programs to support our strategy for the distribution of our generic pharmaceutical products in other countries, including the U.S. We expect to continue to invest our resources to conduct clinical trials and support the required regulatory submissions for our clinical programs. As a result, we expect to incur increased costs for product formulation, research and clinical development efforts. *Effect of Foreign Currency Fluctuations*

A substantial amount of our business is conducted in Europe and, therefore our results, which are measured in U.S. Dollars, are influenced by fluctuations in the U.S. Dollar s value in relation to other currencies, specifically the Euro. An increase in the weighted average value of the Euro in relation to the U.S. Dollar over the prior year third quarter, had the following impact on the results of our operations when reported in U.S. Dollars: (1) total revenues were increased by approximately \$1,835,000, (2) gross profit was increased by approximately \$765,000, (3) operating expenses and other income (expense) were increased by approximately \$579,000, (4) provision for income taxes was increased by approximately \$82,000, which resulted in (5) an aggregate decrease in net loss of approximately \$104,000. An increase in the weighted average value of the Euro in relation to the U.S. Dollar over the first nine months of the prior year, had the following impact on the results of our operations when reported in U.S. Dollar over the first nine months of the prior year, had the following impact on the results of our operations when reported in U.S. Dollar over the first nine months of the prior year, had the following impact on the results of our operations when reported in U.S. Dollars: (1) total revenues were increased by approximately \$6,100,000, (2) gross profit was increased by approximately \$2,745,000, (3) operating expenses and other income (expense) were increased by approximately \$1,834,000, (4) provision for income taxes was increased by approximately \$357,000, which resulted in (5) an aggregate increase in net income taxes was increased by approximately \$357,000, which resulted in (5) an aggregate increase in net income of approximately \$554,000.

This section includes constant currency measures. Constant currency removes from financial data the impact of changes in exchange rates between the U.S. Dollar and other currencies, particularly the Euro, by translating current period financial data into U.S. Dollars using the same foreign currency exchange rates that were used to translate the financial data for the previous period. We believe presenting certain results on a constant currency basis is useful to investors because it allows a more meaningful comparison of the performance of our European operations from period to period.

RESULTS OF OPERATIONS:

Three Months Ended September 30, 2007 versus Three Months Ended September 30, 2006

<u>Revenues by Segment</u>

	For the 2	Change				
(in thousands)	2007	%	2006	%	\$	%
Specialty Generics Net product sales Licensing and collaboration revenues	\$24,131 148	88% 1%	\$ 22,873 170	91% 1%	\$ 1,258 (22)	5% -13%
	24,279	89%	23,043	92%	1,236	5%
Drug Delivery Licensing and collaboration revenues	3,069	11%	2,113	8%	956	45%

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Total revenues	\$ 27,348	100%	\$25,156	100%	\$ 2,192	9%
		22				

Total revenues for the three months ended September 30, 2007 increased \$2,192,000, or 9% from the same period in the prior year. Our specialty generics business experienced increased demand when compared to the comparable quarter of 2006. However, price reductions in Spain have resulted in net product sales that are consistent with the comparable period of 2006 when expressed in constant currency. Our drug delivery licensing revenues grew to \$3,069,000 in the third quarter of 2007 due to increased royalties earned on sales of Testim. Based on industry sources, Testim was reported to capture approximately 21% of all testosterone gel replacement prescriptions in the U.S. market as of September 30, 2007, compared to approximately 18% as of September 30, 2006.

Our revenues are generated through our primary sales channels of branded generic pharmaceuticals, generic pharmaceuticals and sales to licensees and others, as well as licensing and collaboration arrangements. The following is a summary of our revenues by sales channel and top-selling product lines:

For the three months ended September 30, 2007:

(in thousands)	Reve	Revenues Within Spain		Revenues	01 of	
Product Line	Branded Generics	Generics	Other	Outside of Spain	Total	% of Total Revenues
Omeprazole	\$ 406	\$ 4,091	\$	\$	\$ 4,497	16%
Enalapril	1,227	348			1,575	6%
Simvastatin	153	1,041			1,194	4%
Lansoprazole	805	294			1,099	4%
Paroxetine	297	795			1,092	4%
All other products	2,624	2,603	105	426	5,758	21%
Sales to licensees and						
others			3,075	5,841	8,916	33%
Licensing and						
collaborations			148	3,069	3,217	12%
Total Revenues	\$ 5,512	\$ 9,172	\$ 3,328	\$ 9,336	\$27,348	100%
% of Q3 2007 Revenues	20%	34%	12%	34%	100%	

For the three months ended September 30, 2006:

(in thousands)	Reve	Revenues Within Spain				% of
Product Line	Branded Generics	Generics	Other	Outside of Spain	Total	Total Revenues
Omeprazole	\$ 671	\$ 3,896	\$	\$	\$ 4,567	18%
Simvastatin	457	1,371			1,828	7%
Enalapril	1,241	347			1,588	6%
Lansoprazole	633	219			852	4%
Paroxetine	319	774			1,093	4%
All other products	2,408	2,580	301	473	5,762	23%
Sales to licensees and						
others			2,642	4,541	7,183	29%
Licensing and						
collaborations			170	2,113	2,283	9%

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Total Revenues	\$ 5,729	\$ 9,187	\$ 3,113	\$	7,127	\$25,156	100%
% of Q3 2006 Revenues <u>Branded Generic Pharmac</u>	23% ceutical Product	37%	12%		28%	100%	
	For	the Three Mon	ths Ended Se	pten	nber 30,	Chang	ge
(in thousands)	2007	%	2006	-	%	\$	%
Branded Generic Product							
Sales:							
Enalapril	\$ 1,227	22%	\$ 1,241		22%	\$ (14)	-1%
Lansoprazole	805	15%	633		11%	172	27%
Codeisan	621	11%	588		10%	33	6%
Ibuprofen	549	10%	354		6%	195	55%
Mio Relax	465	8%	397		7%	68	17%
All other branded generic							
products	1,845	34%	2,516		44%	(671)	- 27%
Total branded generic sales	\$ 5,512	100%	\$ 5,729		100%	\$ (217)	- 4%
		23					

Sales of our branded generic pharmaceutical products decreased by 8% in constant currency when compared to the three months ended September 30, 2006 due to the recent price reductions in Spain. Excluded from the top five branded generic products listed above are branded generic sales of omeprazole, which decreased approximately \$265,000, or 39%, and sales of branded generic simvastatin, which decreased approximately \$304,000, or 67%, primarily due to the price reductions. The impact of price reductions was partially offset by increased unit volume in the third quarter of 2007, primarily from sales of ibuprofen and lansoprazole. While we expect to continue to develop, acquire, launch and support new and existing branded generic products, our growth strategy is also focused on sales of generic products and sales outside of Spain.

Generic Pharmaceutical Products

	For the	Three Months	Change			
(in thousands)	2007	%	2006	%	\$	%
Generic Product Sales:						
Omeprazole	\$4,091	45%	\$3,896	43%	\$ 195	5%
Simvastatin	1,041	11%	1,371	15%	(330)	-24%
Paroxetine	795	9%	774	8%	21	3%
Pentoxifylline	682	7%	654	7%	28	4%
Trimetazidine	636	7%	586	6%	50	9%
All other generic products	1,927	21%	1,906	21%	21	1%
Total generic sales	\$9,172	100%	\$9,187	100%	\$ (15)	-0%

Sales of our generic pharmaceutical products remained constant when compared to the three months ended September 30, 2006, but decreased by 5% in constant currency as a result of the recent price reductions in Spain. While we also experienced an increased unit volume in our generic sales, primarily from sales of omeprazole and simvastatin, the increase was not enough to offset the effect of the price reductions. We expect to continue to increase our generic drug portfolio and increase our generic drug sales in Spain as products patent protection rights expire in the future.

Sales to Licensees and Others

	For the Three	Months Ended		
	Septem	Chan	ge	
(in thousands)	2007	2006	\$	%
Specialty generics	\$ 8,916	\$ 7,183	\$1,733	24%

In addition to manufacturing and selling our own branded generic and generic products, we license the right to market products to others within and outside of Spain. These license agreements are usually accompanied by long-term exclusive supply agreements, whereby our licensees purchase the licensed products from our manufacturing facility. These purchases are recorded as *net product sales* in our Unaudited Consolidated Income Statements. As of September 30, 2007, our Spanish operations have executed 213 license agreements for product registrations, of which 28 with customers in Spain and 104 with customers outside of Spain, cover actively marketed products that are generating revenues. The remaining licenses (1 with a customer in Spain, 11 with customers in Ireland and 69 with customers outside of Spain and Ireland) are for products that are awaiting regulatory approvals. Additionally, we have 15 contract manufacturing agreements in effect in Spain and 6 contract manufacturing agreements in effect in other countries. Our clients market these products under their own names and with their own labeling. Many of the products we manufacture for others use the same active ingredients that are used in our own marketed products. Sales to licensees and others in the three months ended September 30, 2007 increased \$1,733,000 when compared to the third quarter of 2006; however, sales to licenses and others increased by 19% in constant currency. Sales to our licensees and contract manufacturing customers are usually of larger quantities and occur on a less frequent basis than our normal sales in Spain. Therefore, the shipment of one order, or delayed shipment of one order, could cause significant

fluctuations from quarter to quarter.

Licensing and Collaboration Revenues

	For the Three Months Ended September 30, Cl						ge	
(in thousands)	2007		2006		\$		% %	
Specialty generics	\$	148	\$	170	\$	(22)	-13%	
Drug delivery		3,069		2,113		956	45%	
Total	\$	3,217	\$	2,283	\$	934	41%	

Licensing and collaboration revenues increased by 41% and accounted for 12% and 9% of total revenues for the three months ended September 30, 2007 and 2006, respectively. Our licensing and collaboration revenues are primarily royalties earned from sales of Testim. Testim royalties increased 46% from \$2,107,000 in the three months ended September 30, 2006 to \$3,069,000 in the three months ended September 30, 2007 as a result of increased market share.

Gross Profit

	For the Three Months Ended September 30, Chan						
(in thousands)		2007	,	2006	\$	%	
Specialty generics Drug delivery	\$	9,828 3,069	\$	11,265 2,113	\$(1,437) 956	-13% 45%	
Total	\$	12,897	\$	13,378	\$ (481)	-4%	

Gross profit decreased by approximately \$481,000, or 4% when compared to the three months ended September 30, 2006. Despite an increase in unit volume, gross profit reported by our specialty generics business decreased by 13% when compared to the same quarter of the prior year. Our gross margins on net product sales decreased from 49% to 40% in the three months ended September 30, 2006 and 2007, respectively, as a result of the price reductions. We expect our margins to gradually improve over time as we continue to implement our strategies to mitigate the impact of the price reductions.

Selling and Marketing Expenses

		Septem	ber 30,		Change		
(in thousands)		2007		2006	\$	%	
Specialty generics	\$	4,080	\$	3,495	\$ 585	17%	
Selling and marketing expenses for the three m	nonths e	nded Septembe	r 30, 2007	increased 1	7% from the	same	
period in the prior year, or 8% when expressed in	constan	t currency due	to increase	d sales volu	ime. As a perc	centage of	
net product sales, selling and marketing expenses	increase	ed from 15% to	17% in the	e three mon	ths ended		
September 30, 2006 and 2007, respectively.							

General and Administrative Expenses

(in thousands)	September 30,					Change	
		2007		2006		\$	%
Specialty generics	\$	2,013	\$	1,901	\$	112	6%
Drug delivery		2,085		1,850		235	13%

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Total	\$	4,098	\$	3,751	\$ 347	9%	
General and administrative expenses increased	General and administrative expenses increased 9% when compared to the same period in the prior year. Increases						
in drug delivery headcount and outside professional service costs included in general and administrative expenses							
were partially offset by approximately \$600,000 of reduced severance costs related to							

a change in our Chief Financial Officer in September 2006. Increased general and administrative expenses in our specialty generics business include approximately \$137,000 due to fluctuations in foreign currency rates. Total general and administrative expenses as a percent of total revenues remain consistent at 15% for the three months ended September 30, 2007 and 2006.

Research and Development Expenses

	For the Three Months Ended September 30, Chang						
(in thousands)	2007		2006		\$	%	
Specialty generics Drug delivery	\$	341 2,676	\$	421 2,026	\$ (80) 650	-19% 32%	
Total	\$	3,017	\$	2,447	\$ 570	23%	

Research and development expenses have increased by approximately \$570,000 compared to the third quarter of 2006 primarily from increased costs to support our Nasulin clinical program. We plan to increase research and development costs as we continue to conduct our Nasulin clinical trials throughout 2007. Although cost estimates and timing of our trials are subject to change, we expect consolidated research and development expenses for 2007 to be approximately \$13,000,000 to \$16,000,000.

Litigation Settlement Expenses

	For the Three Months Ended				
	Sept	Change			
(in thousands)	2007	2006	\$	%	
Specialty generics	\$	\$ 8,932	\$(8,932)	*	

* Not meaningful

Litigation settlement expenses for the three months ended September 30, 2006 include \$7,546,000 representing the present value of our loss contingency stemming from litigation for which we reached an agreement on settlement terms. In addition, we incurred litigation defense costs of \$1,386,000 in the three months ended September 30, 2006 associated with the settled claim in late 2006.

Separation Costs

	For the Three Months Ended					
	September 30,					
(in thousands)	2007	2006	\$	%		
Drug delivery	\$ 846	\$	\$846	*		

* Not meaningful

As noted above, we have incurred legal, tax and other strategic consulting costs specifically associated with a planned spin-off of the drug delivery business. These costs include the services of lawyers, accountants, tax and compensation consultants needed to effectively complete the spin. Separation costs for the three months ended September 30, 2007 were \$846,000. We expect to continue to incur these costs as we proceed with the planned spin-off and other strategic alternatives.

Provision for Income Taxes

	For the Three Months Ended September 30,							
		20	07			20	06	
(in thousands)	Spain	Ireland	<i>U.S.</i>	Consol.	Spain	Ireland	<i>U.S.</i>	Consol.
Income								
(loss) before								
income taxes	\$3,008	\$(1,496)	\$(1,202)	\$ 310	\$(2,545)	\$(1,015)	\$(1,939)	\$(5,499)
Provision								
(benefit) for								
income taxes	911	(187)	(306)	418	1,730	(126)	(690)	914
Valuation		107	206	40.2		126	(00)	016
allowance		187	306	493		126	690	816
Net provision for								
income taxes	911			911	1,730			1,730
income taxes	<i><i>у</i>11</i>			<i><i>у</i>11</i>	1,750			1,750
Net income (loss)	\$2,097	\$(1,496)	\$(1,202)	\$(601)	\$(4,275)	\$(1,015)	\$(1,939)	\$(7,229)
Effective tax rate	30%	0%	0%	294%	68%	0%	0%	31%

As a result of reporting taxable income in Spain in 2007, we recorded a provision for foreign income taxes totaling \$911,000 for the three months ended September 30, 2007. This represented 30% of the pre-tax income reported in Spain of \$3,008,000. As future operating profits in the U.S and Ireland cannot be reasonably assured, no tax benefit has been recorded for the related losses, which totaled approximately \$2,698,000 for the three months ended September 30, 2007. Accordingly, we have established valuation allowances equal to the full amount of the U.S. and Irish deferred tax assets. The provision represented 294% of consolidated pre-tax income for the three months ended September 30, 2007. The current statutory tax rate in Spain of 32.5% is expected be reduced to 30% effective January 1, 2008 in accordance with Spanish governmental regulations.

We recorded a provision for foreign income taxes totaling \$1,730,000 for the three months ended September 30, 2006, which represented 68% of the Spanish pre-tax loss of \$2,545,000. This effective tax rate was significantly above the 2006 Spanish statutory tax rate of 35% primarily due to a \$7,546,000 loss contingency recorded in September 2006 for litigation proceedings in Spain for which a \$2,746,000 tax benefit was not recognized in the 2006 period. The \$1,730,000 provision for income taxes represented 31% of the consolidated pre-tax loss in the three months ended September 30, 2006. The tax benefit of the loss contingency was subsequently recognized in the fourth quarter of 2006.

Should we determine that it is more likely than not that we will realize certain of our net deferred tax assets for which we have previously provided a valuation allowance, an adjustment would be required to reduce the existing valuation allowance. In addition, we operate within multiple taxing jurisdictions and are subject to audit in those jurisdictions. These audits can involve complex issues, which may require an extended period of time for resolution. No additional potential tax contingencies were considered to be probable and reasonably estimable as of September 30, 2007. However, there is the possibility that the ultimate resolution of such potential contingencies could have an adverse effect on our consolidated financial statements in the future.

Net (Loss) Income

	For the Three Months Ended					
	September 30,				Change	
(in thousands)		2007		2006	\$	%
Specialty generics	\$	1,949	\$	(5,465)	\$ 7,414	136%

Drug delivery	(2,550)		(1,764)	(786)	-45%
Total	\$	(601)	\$ (7,229)	\$ 6,628	92%

We reported income from operations of \$367,000 in the three months ended September 30, 2007 compared to loss from operations of \$5,707,000 in the three months ended September 30, 2006. The combination of income from operations of \$367,000 and the net non-operating expense of \$57,000, and the provision for income taxes of \$911,000, resulted in net loss of \$601,000, or \$(0.03) per basic common

share on 22,354,000 weighted average basic common shares outstanding in the three months ended September 30, 2007, compared to net loss of \$7,229,000, or \$(0.33) per basic common share on 22,194,000 weighted average basic common shares outstanding in the same period of the prior year.

Nine Months Ended September 30, 2007 versus Nine Months Ended September 30, 2006

Revenues by Segment

	For the	Nine Months	Ended Septembe	er 30,	Chan	ige
(in thousands)	2007	%	2006	%	\$	%
Specialty Generics Net product sales Licensing and	\$81,598	91%	\$75,900	92%	\$5,698	8%
collaboration revenues	433	*	409	*	24	6%
	82,031	91%	76,309	92%	5,722	7%
Drug Delivery Licensing and collaboration revenues	7,887	9%	6,108	8%	1,779	29%
Total revenues	\$89,918	100%	\$82,417	100%	\$7,501	9%

* Less than 1%

Revenues. Set forth below is a summary of our revenues by sales channel and top-selling product lines: For the nine months ended September 30, 2007:

(in thousands)	Rev	Revenues Within Spain			Revenues		
Product Line	Branded Generics	Generics	Other	Outside of Spain	Total	% of Total Revenues	
Omeprazole	\$ 1,367	\$11,916	\$	\$	\$13,283	15%	
Enalapril	3,778	1,112			4,890	5%	
Simvastatin	723	3,631			4,354	5%	
Paroxetine	1,112	2,485			3,597	4%	
Lansoprazole	2,571	895			3,466	4%	
All other products	8,964	9,824	472	2,540	21,800	24%	
Sales to licensees and							
others			10,062	20,146	30,208	34%	
Licensing and							
collaborations			433	7,887	8,320	9%	
Total Revenues	\$18,515	\$29,863	\$10,967	\$30,573	\$89,918	100%	
% of YTD 2007							
Revenues	21%	33%	12%	34%	100%		
For the nine months en	nded September 3	0, 2006:					
(in thousands)	Rev	enues Within S _l	pain	Revenues		% of	

Branded	Outside of

Total

Product Line	Generics	Generics	Other	Spain	Total	Revenues
Omeprazole	\$ 2,012	\$12,589	\$	\$	\$14,601	18%
Enalapril	3,538	1,477			5,015	6%
Simvastatin	1,383	4,334			5,717	7%
Paroxetine	1,094	2,389			3,483	4%
Lansoprazole	1,958	671			2,629	3%
All other products	7,693	8,172	782	1,100	17,747	22%
Sales to licensees and others Licensing and			9,553	17,155	26,708	32%
collaborations			409	6,108	6,517	8%
Total Revenues	\$17,678	\$29,632	\$10,744	\$24,363	\$82,417	100%
% of YTD 2006 Revenues	21%	36%	<i>13%</i> 29	30%	100%	

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Total revenues for the nine months ended September 30, 2007 increased 9% to \$89,918,000 from the same period in 2006, or 2% when expressed in constant currency. Favorable fluctuations in foreign currency rates increased year-to-date 2007 revenues by approximately \$6,100,000 when compared to the same nine month period of 2006. In addition to the effect of favorable currency rates, current period growth was driven primarily by increased product sales to our licensees and others of approximately \$1,366,000 (net of currency fluctuations) and approximately \$1,790,000 of increased royalty revenue from the sales of Testim. These increases, along with increased API sales, were partially offset by the effect price reductions in Spain that were implemented in the first quarter of this year. *Branded Generic Pharmaceutical Products*

	For the	Change				
(in thousands)	2007	%	2006	%	\$	%
Branded Generic Product						
Sales:						
Enalapril	\$ <i>3</i> ,778	20%	\$ 3,538	20%	\$ 240	7%
Codeisan	2,630	14%	2,051	12%	579	28%
Lansoprazole	2,571	14%	1,958	11%	613	31%
Ibuprofen	1,676	9%	1,097	6%	579	53%
Omeprazole	1,367	8%	2,012	11%	(645)	-32%
All other branded generic						
products	6,493	35%	7,022	40%	(529)	-8%
Total branded generic						
sales	\$18,515	100%	\$17,678	100%	\$ 837	5%

Sales of our branded generic pharmaceutical products during the nine months ending September 30, 2007 increased 5% when compared to the same period in 2006. Excluding the effect of fluctuations in foreign currency exchange rates, sales of our branded generic pharmaceutical products decreased 2% when compared to the nine months ending September 30, 2006 as a result of price reductions in Spain. Among products most affected by the price reductions was our branded generic omeprazole, sales of which decreased 32% despite consistent unit volume. Increased unit volume in the nine months ended September 30, 2007, primarily from sales of our enalapril, codeisan and lansoprazole, helped offset the impact of price reductions.

Generic Pharmaceutical Products

	For the	Change				
(in thousands)	2007	%	2006	%	\$	%
Generic Product Sales:						
Omeprazole	\$11,916	40%	\$12,589	42%	\$(673)	-5%
Simvastatin	3,631	12%	4,334	15%	(703)	-16%
Paroxetine	2,485	8%	2,389	8%	96	4%
Trimetazidine	2,181	7%	1,679	6%	502	30%
Pentoxifylline	2,038	7%	1,932	6%	106	5%
All other generic products	7,612	26%	6,709	23%	903	13%
Total generic sales	\$29,863	100%	\$29,632	100%	\$ 231	1%

Sales of our generic pharmaceutical products increased 1% during the nine months ending September 30, 2007 when compared to the same period 2006. Excluding the effect of fluctuations in foreign currency exchange rates, sales of our branded generic pharmaceutical products decreased 6% due to the recent price reductions in Spain. Generic sales of omeprazole and simvastatin, which were among the products more affected by the price reductions, decreased

approximately \$1,376,000. Increased unit volume in the nine months ended September 30, 2007, primarily from sales of omeprazole, simvastatin and trimetazidine, helped offset the impact of price reductions.

Sales to Licensees and Others

	For the Nine M Septeml	Char	nge	
(in thousands)	2007	2006	\$	~ %
Specialty generics	\$ 30,208	\$ 26,708	\$3,500	13%
Sales to licensees and others in the nine month same nine month period of the prior year. An incr relation to the U.S. Dollar, had the effect of incre approximately \$2,134,000. See the explanation up September 30, 2007.	rease in the weighted ave asing our revenues from	erage value of the Eu sales to licensees an	aro over the pas and others by	t year, in

Licensing and Collaboration Revenues

(in thousands)		Chan	ge			
		2007	, ,	2006	\$	%
Specialty generics	\$	433	\$	409	\$ 24	6%
Drug delivery		7,887		6,108	1,779	29%
Total	\$	8,320	\$	6,517	\$ 1,803	28%

Licensing and collaboration revenues accounted for 9% of total revenues in the nine months ended September 30, 2007 and totaled \$8,320,000. These revenues included increased Testim royalties of approximately \$1,790,000 in the nine months ended September 30, 2007. See the explanation under *Licensing and Collaboration Revenues* for the three months ended September 30, 2007.

Gross Profit

September 30,					Change	
2007		2006		\$	%	
\$	35,893 7.887	\$	39,127 6 108	\$ (3,234) 1 770	-8% 29%	
\$	43,780	\$	45,235	\$(1,455)	-3%	
		Septem 2007 \$ 35,893 7,887	September 30, 2007 \$ 35,893 \$ 7,887	2007 2006 \$ 35,893 \$ 39,127 7,887 6,108	September 30, Chang 2007 2006 \$ \$ 35,893 \$ 39,127 \$ (3,234) 7,887 6,108 1,779	

Gross profit decreased by approximately \$1,455,000, or 3%, in the nine months ended September 30, 2007 when compared to the nine months ended September 30, 2006. Gross margins on net product sales were 43% in the nine months ended September 30, 2007 versus 51% in the nine months ended September 30, 2006. We have recorded net adjustments totaling \$1,010,000 to write-down our U.S. generic inventory to its net realizable value and reserve for slow moving inventories. In accordance with our collaboration agreement, we are liable for a portion of these adjustments and have therefore recorded a net charge of approximately \$416,000 to *cost of net product sales* in the nine months ended September 30, 2007. Excluding these inventory adjustments, our gross margins on net product sales decreased from 51% to 44% in the nine months ended September 30, 2006 and 2007, respectively, as a result of price reductions in Spain. See the explanation under *Gross Profit* for the three months ended September 30, 2007.

Selling and Marketing Expenses

	For the Nine Months Ended					
	September 30,		Change			
(in thousands)	2007	2006	\$	%		

Specialty generics\$ 13,338\$ 11,876\$ 1,46212%Selling and marketing expenses for the nine months ended September 30, 2007 increased 12% from the sameperiod in the prior year; however, selling and marketing expenses increased 4% when expressed in

constant currency. Selling and marketing expenses as a percentage of net product sales remained relatively constant at 16% in the nine months ended September 30, 2007 and 2006.

General and Administrative Expenses

		Septem	ıber 30,		Chan	ge
(in thousands)		2007		2006	\$	%
Specialty generics	\$	6,653	\$	5,507	\$1,146	21%
Drug delivery		5,363		5,813	(450)	-8%
Total	\$	12,016	\$	11,320	\$ 696	6%

General and administrative expenses for the nine months ended September 30, 2007 increased 6% from the same period in the prior year. The \$1,146,000 change in our specialty generics business reflects an increase of \$412,000 from fluctuations in foreign currency exchange rates and approximately \$407,000 of intellectual property filing and maintenance costs incurred to support our continued revenue growth. The \$450,000 decrease in our drug delivery business reflects reduced strategic consulting expenses compared to the same period in 2006. General and administrative expenses as a percentage of total revenues decreased to 13% for the nine months ended September 30, 2007 compared to 14% for the nine months ended September 30, 2006.

Research and Development Expenses

	For the Nine Months Ended September 30, Chan						
(in thousands) Specialty generics Drug delivery	\$	2007 1,341 7,853		2 006 1,374 6,476	\$ \$ (33) 1,377	% -2% 21%	
Total	\$	9,194	\$	7,850	\$ 1,344	17%	

Research and development expenses for the nine months ended September 30, 2007 increased 17% from the same period in the prior year. The increase is directly attributed to the advancement of our research and development programs in the Drug Delivery segment of our business. See the explanation under *Research and Development Expenses* for the three months ended September 30, 2007. We expect to continue to incur increased costs to support our clinical programs for the remainder of 2007.

Litigation Settlement Expenses

	For the Nine Months Ended					
(in thousands)	Septe	Change				
	2007	2006	\$	%		
Specialty generics	\$	\$ 10,269	\$(10,269)	*		

* Not meaningful

We incurred litigation settlement and defense costs of \$10,269,000 in the nine months ended September 30, 2006 associated with a claim settled in late 2006.

Separation Costs

	For the Nine M	onths Ended		
	Septemb	er 30,	Cha	nge
(in thousands)	2007	2006	\$	%

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Drug delivery	\$ 1,153	\$ \$1,153	*
* Not meaningful	32		

Separation costs for the nine months ended September 30, 2007 totaled \$1,153,000, primarily for external advisors to the Company incurred in connection with our planned spin-off of the drug delivery business. See the explanation under *Separation Costs* for the three months ended September 30, 2007.

Provision for Income Taxes

For the Nine Months Ended September 30,								
		20	07			20	06	
(in thousands)	Spain	Ireland	<i>U.S.</i>	Consol.	Spain	Ireland	<i>U.S.</i>	Consol.
Income (loss) before income taxes Provision (benefit) for	\$ 14,753	\$ (4,526)	\$(3,249)	\$ 6,978	\$ 11,630	\$ (3,347)	\$(5,116)	\$ 3,167
income taxes Valuation	4,509	(566)	(888)	3,055	6,607	(418)	(1,863)	4,326
allowance		566	888	1,454		418	1,863	2,281
Net provision for income taxes	4,509			4,509	6,607			6,607
Net income (loss)	\$10,244	\$(4,526)	\$(3,249)	\$ 2,469	\$ 5,023	\$(3,347)	\$(5,116)	\$(3,440)
Effective tax rate	31%	0%	0%	65%	57%	0%	0%	209%

We have recorded provisions for foreign income taxes totaling \$4,509,000 and \$6,607,000 for the nine months ended September 30, 2007 and 2006, respectively. The provisions represented 31% and 57% of the pre-tax income reported in Spain of \$14,753,000 and \$11,630,000 for the nine months ended September 30, 2007 and 2006, respectively. The 2006 effective tax rate for Spain is higher than that for 2007 primarily due to the \$7,546,000 loss contingency recorded in Spain in September 2006 for which no tax benefit was recorded in that period. We subsequently recorded a tax benefit of \$2,746,000 in the *provision for income taxes* upon finalization of the litigation settlement in the fourth quarter of 2006. As future operating profits in the U.S and Ireland cannot be reasonably assured, no tax benefit has been recorded for the related losses, which totaled approximately \$7,775,000 and \$8,463,000 for the nine months ended September 30, 2007 and 2006, respectively. Accordingly, we have established valuation allowances equal to the full amount of the U.S. and Irish deferred tax assets. Consequently, the provisions represented 65% and 209% of consolidated pre-tax income for the nine months ended September 30, 2007 and 2006, respectively.

Net Income (Loss)

	For the Ni	ne Months		
	Ended Sep	tember 30,	Change	
(in thousands, except per share data)	2007	2006	\$	%
Specialty generics	\$ 9,160	\$ 2,684	\$ 6,476	241%
Drug delivery	(6,691)	(6,124)	(567)	-9%
Total net income (loss)	\$ 2,469	\$ (3,440)	\$ 5,909	172%

Net income (loss) per common share:

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Basic	\$ 0.11	\$ (0.16)	\$ 0.27	169%
Diluted	\$ 0.11	\$ (0.16)	\$ 0.27	169%
Weighted average common shares outstanding: Basic	22,322	22,107	215	1%
Diluted	22,829	22,107	722	3%

We reported net income of \$2,469,000 in the nine months ended September 30, 2007 compared to the net loss of \$3,440,000 in the nine months ended September 30, 2006. The combination of income from operations of \$6,536,000 and the non-operating items, primarily a provision for income taxes of \$4,509,000 and the net of other income and expenses totaling \$442,000 resulted in net income of \$2,469,000, or \$0.11 per basic common share (\$0.11 per diluted common share) on 22,322,000 weighted average basic common

2	2
2	2

shares outstanding (22,829,000 weighted average diluted common shares outstanding) in the period ended September 30, 2007, compared to net loss of \$3,440,000, or \$(0.16) per basic common share on 22,107,000 weighted average basic common shares outstanding in the period ended September 30, 2006.

LIQUIDITY AND CAPITAL RESOURCES:

Total assets increased from \$134,356,000 at December 31, 2006 to \$164,648,000 at September 30, 2007, and stockholders equity increased from \$100,331,000 at December 31, 2006 to \$110,850,000 at September 30, 2007. The \$10,519,000 increase in stockholders equity during the nine months ended September 30, 2007 primarily reflects the effect of fluctuations in the Euro/U.S. Dollar exchange rate, which resulted in a net increase of \$6,392,000 to our stockholders equity, net income of \$2,469,000 and \$1,923,000 of stock-based compensation increasing additional paid-in capital.

Cash, cash equivalents and marketable securities increased by approximately 150% or \$23,411,000 from \$15,601,000 at December 31, 2006 to \$39,012,000 at September 30, 2007. Sources of cash include loan proceeds of \$14,807,000 included in cash flows from financing activities, net income of \$2,469,000 and approximately \$7,810,000 of non-cash expenses included in cash flows from operating activities. Uses of cash included additions to fixed assets totaling \$7,489,000 and additions to drug licenses totaling \$1,780,000. Cash and cash equivalents at September 30, 2007 include approximately \$23,782,000 of short-term liquid investments considered to be cash equivalents.

Receivables decreased by approximately 5% from \$32,963,000 at December 31, 2006 to \$31,469,000 at September 30, 2007. When expressed in constant currency, receivables decreased \$3,507,000, or 11%, due to a combination of lower cyclical sales in the third quarter and the timing of collections on net product sales outside of Spain, which generally have longer negotiated collection terms. We have not experienced any material delinquencies on any of our receivables that have had a material effect on our financial position, results of operations or cash flows.

Inventory balances decreased by approximately \$1,236,000 from \$16,279,000 at December 31, 2006 to \$15,043,000 at September 30, 2007. Fluctuations in foreign currency had the effect of increasing inventories by approximately \$1,062,000. The constant currency decrease of \$2,298,000 was primarily due to inventory adjustments totaling \$1,010,000 to write-down U.S. generic product inventories to their net realizable value and reserve for slow moving inventories and lower finished good inventories due to the timing of product orders.

The combined total of accounts payable and accrued expenses increased from \$24,270,000 at December 31, 2006 to \$26,858,000 at September 30, 2007. The \$2,588,000 increase was primarily attributed to fluctuations in foreign currency exchange rates, which increased the balances by approximately \$1,610,000, as well as approximately \$1,197,000 of increased drug delivery payables and accrued expenses, which include accrued separation costs and accrued compensation.

We repaid all of our short-term borrowings and current portion of long-term debt outstanding at December 31, 2006 during the nine months ended September 30, 2007. Our short-term borrowings and current portion of long-term debt totaled \$554,000 at December 31, 2006.

On June 29, 2007, we entered into an 11,000,000 Euro loan agreement with a Spanish financial institution. As a result, we recorded long-term debt of \$14,807,000 (\$15,559,000 at September 30, 2007 due to changes in foreign currency rates).

Operating activities for the nine months ended September 30, 2007 provided net cash of \$16,593,000, an increase of \$10,470,000 when compared to the nine months ended September 30, 2006. Changes in working capital, accounts receivable and inventory in particular, contributed to approximately \$11,313,000 of this increase.

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Investing activities, primarily capital expenditures to expand the capacity of our manufacturing facilities in Spain, along with additions to drug licenses and related costs, required cash totaling \$9,269,000 during the nine months ended September 30, 2007. In addition, approximately \$2,659,000 of short-term marketable securities matured during the nine months ended September 30, 2007.

Financing activities during the nine months ended September 30, 2007 provided net cash of \$14,393,000, and represented mainly cash proceeds from borrowings totaling \$14,807,000, as described above. These proceeds were partially offset by net repayment of borrowings totaling \$554,000.

<u>Seasonality</u>. In the past, we have experienced lower sales in the third calendar quarter and higher sales in the fourth calendar quarter due to seasonality of our pharmaceutical business. The extent of such variations is dependent upon the severity of the cough, cold and flu season. As we market more pharmaceutical products whose sales are seasonal, seasonality of sales may become more significant.

Effect of Inflation and Changing Prices. Neither inflation nor changing prices has materially impacted our net product sales or income from operations for the periods presented.

Liquidity. We plan to continue making improvements to our manufacturing facilities during 2007 that include the acquisition of additional manufacturing equipment and expansion of our manufacturing facilities, in order to increase manufacturing efficiencies and accommodate our expected growth. We have completed capital additions of \$7,489,000 in the nine months ended September 30, 2007. Due to delays in timing of planned capital projects, we currently expect to invest \$11,000,000 to \$13,000,000 in 2007 (primarily in our manufacturing facilities), compared to our previous estimate of \$13,000,000 to \$16,000,000. We expect to complete the balance of these capital investments in 2008. We also plan to invest \$13,000,000 to \$16,000,000 in research and development activities in 2007, primarily to support the continued development of Nasulin, our intranasal insulin product. We plan to finance the remaining capital expenditures and research and development investments from a combination of cash flows from operations and existing cash balances (including the \$14,807,000 of proceeds we received from our recent loan agreement). In accordance with our litigation settlement with Ethypharm S.A. Spain and Ethypharm S.A. France (or Ethypharm) in late 2006, we made a scheduled \$1,000,000 annual payment to Ethypharm in October of 2007. The remaining three annual payments of \$1,000,000 are scheduled to be made in the fourth quarters of 2008, 2009 and 2010. These amounts are expected to be paid with our operating cash flows.

As discussed above, we have cash and cash equivalents totaling approximately \$38,452,000 as of September 30, 2007, which we believe is sufficient to fund our operations for the foreseeable future. Although we generate positive cash flow from operations, (approximately \$16,593,000 in the nine months ended September 30, 2007), there can be no assurance that changes in our research and development plans, capital expenditures and/or acquisitions, or other events affecting our operations will not result in the earlier depletion of our funds. We continue to search both domestically and internationally for opportunities that will enable us to continue expanding our business and explore alternative financing sources for these activities, including the possibility of public and/or private offerings of debt and equity securities. In appropriate situations, we may seek financial assistance from other sources, including contribution by others to joint ventures and other collaborative or licensing arrangements for the development, testing, manufacturing and marketing of products under development.

Critical Accounting Policies and Estimates

Our significant accounting policies are more fully described in Note 2 to our consolidated financial statements in our 2006 Form 10- K. Certain of our accounting policies are particularly important to the portrayal of our financial position, results of operations and cash flows and require the application of significant judgment by our management; as a result they are subject to an inherent degree of uncertainty. In applying those policies, our management uses its judgment to determine the appropriate assumptions to be used in the determination of certain estimates. Those estimates are based on our historical experience, terms of existing contracts, our observation of trends in the industry, information provided by our customers and

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information available from other outside sources, as appropriate. We have reviewed our critical accounting policies and estimates discussed in our 2006 Form 10-K and have determined that, with the exception of our critical accounting policies for the *provision for income taxes, inventories* and *clinical trial expenses* noted below, those policies remain our most critical accounting policies for the quarter ended September 30, 2007. We did not make any changes to those policies during the nine months ended September 30, 2007. *Provision for income taxes*

We have provided for current and deferred U.S. federal, state and foreign income taxes for the current and all prior periods presented. Current and deferred income taxes have been provided with respect to jurisdictions where certain of our subsidiaries produce taxable income. We have provided a valuation allowance with respect to the remainder of our deferred income taxes, consisting primarily of net operating loss carryforwards in the U.S. and Ireland, because of uncertainty regarding their realization. Should we determine that it is more likely than not that we will realize certain of our net deferred tax assets for which we have previously provided a valuation allowance, an adjustment would be required to reduce the existing valuation allowance.

Effective January 1, 2007, we account for uncertain tax positions in accordance with Financial Accounting Standards Board Interpretation No. 48, *Accounting for Uncertainty in Income Taxes* (FIN 48), an interpretation of FASB Statement No. 109, *Accounting for Income Taxes*. As a result of the implementation of FIN 48, we recorded a \$405,000 increase in our non-current liabilities for uncertain tax positions which was accounted for an increase to the January 1, 2007 accumulated deficit. The application of income tax law is inherently complex. Income tax laws and regulations are voluminous and often ambiguous. As such, we are required to make many subjective assumptions and judgments regarding our income tax exposures. Interpretations and guidance surrounding income tax laws and regulations, results of operations or cash flows. In addition, as we operate within multiple taxing jurisdictions, we are subject to audit in those jurisdictions. The ultimate resolution of tax audits may require an extended period of time. Although we believe an adequate provision has been made for uncertain tax position, results of operations or cash flows could have an adverse effect on our financial position, results of operation of such positions could have an adverse effect on our financial position, results of operation of such positions could have an adverse effect on our financial position, results of operations for income taxes in our Notes to Unaudited Condensed Consolidated Financial Statements in Item 1 for additional information regarding our uncertain tax positions. *Inventories*

Inventories are stated at the lower of cost or market, cost being determined on the first-in, first-out method. We analyze our inventory on a quarterly basis and write-down inventory that has a cost basis in excess of its expected net realizable value. The determination of whether or not inventory costs will be realized requires management estimates. Actual results may differ from those estimates and require inventory to be written-down, resulting in a new cost basis until sold. Reserves for slow moving or obsolete inventories are provided based on historical experience and forecasted demand.

Clinical trial expenses

Clinical trial expenses, which are reflected in research and development expenses, result from obligations under contract with vendors, consultants, and clinical sites in connection with conducting clinical trials. The financial terms of these contracts are subject to negotiations which vary from contract to contract and may result in cash flows which are not consistent with the periods in which materials or services are provided. These costs are capitalized upon payment and expensed according to the progress of each trial as measured by patient progression and the timing of various aspects of the trial. The progress of the trials, including the level of services performed, is determined for financial reporting purposes based upon judgments made after discussions with internal personnel as well as outside service providers.

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Important Factors That May Affect Future Results

This Quarterly Report on Form 10-Q contains forward-looking statements. These forward-looking statements appear principally in the section entitled Management s Discussion and Analysis of Financial Condition and Results of Operations. Forward-looking statements may appear in other sections of this report, as well. Generally, the forward-looking statements in this report include such words as expect, believe, continue, anticipate, estimate, will, could, opportunity, future, project, and similar expressions.

The forward-looking statements include statements about our:

Strategic plans;

Sales growth;

Anticipated sources of future revenues;

Anticipated 2007 expenses, margins and operating performance;

Anticipated expenses associated with the planned spin-off transaction;

Expected launch of new products;

Anticipated expenses and spending;

Planned and continuing clinical trials;

Anticipated regulatory changes and approvals; and

The sufficiency of capital resources to fund our operations.

These forward-looking statements are based on our current expectations, beliefs, assumptions, estimates, forecasts and projections for our business and the industry and markets in which we compete. These statements are not guarantees of future performance and involve certain risks, uncertainties and assumptions that are difficult to predict. Therefore, actual outcomes and results may differ materially from what is expressed in such forward-looking statements. We caution investors not to place undue reliance on the forward-looking statements contained in this report. These statements speak only as of the date of this report, and we do not undertake any obligation to update or revise them, except as required by law. We refer you to our description of the risk factors related to our business, which are contained in the section entitled Risk Factors in our 2006 Form 10-K. As a result of these and other factors, we may experience material fluctuations in our future operating results, which could materially affect our business, financial position, and stock price.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Foreign Currency. A substantial amount of our business is conducted in Europe and, therefore our results, which are measured in U.S. Dollars, are influenced by fluctuations in the U.S. Dollar s value in relation to other currencies, specifically the Euro. The exchange rates at September 30, 2007 and December 31, 2006 are as follows:

U.S. Dollars per Euro	September 30, 2007	December 31, 2006
YTD weighted average	1.34	1.26
exchange rate		
Exchange rate	1.41	1.31

The net effect of foreign currency translation on our Unaudited Consolidated Balance Sheet for the nine months ended September 30, 2007 was a net increase of \$6,392,000 and the cumulative historical effect as of September 30, 2007 was an increase of \$15,264,000, as reflected in *accumulated other comprehensive income*. The carrying values of assets and liabilities can be materially impacted by foreign currency translation, as can the translated amounts of

revenues and expenses.

We have relied primarily upon financing activities to fund our operations in the U.S. In the event that we are required to fund U.S. operations or cash needs with funds generated in Europe or cash requirements in Europe with U.S. funds, currency rate fluctuations in the future could have a significant impact on us. We entered into a cash flow hedge in 2006 designed to reduce the effect of fluctuations in foreign

currency on a litigation settlement liability. However, at this time, we do not anticipate using any similar hedging transaction or otherwise altering our business plans and practices to compensate for future currency fluctuations affecting any other balances.

Interest Rates. The interest rate on our long-term borrowings at September 30, 2007 was 5.02% and the amount of borrowings outstanding is \$15,559,000 as of September 30, 2007. The interest rate on our long-term debt is variable and reset quarterly. The effect of an increase in interest rates of one percentage point (one hundred basis points) to an average of 6.02% on long-term borrowings would have the effect of increasing interest expense by approximately \$155,600 annually; however, no payments are due under the loan agreement until December 31, 2008.

Item 4. Controls and Procedures

Bentley maintains disclosure controls and procedures that are designed to ensure that information required to be disclosed in Bentley s reports that are filed or submitted under the Securities Exchange Act of 1934, as amended (the

Exchange Act) with the Securities and Exchange Commission is recorded, processed, summarized and reported within the time periods required for each report and that such information is reported to Bentley s management, including its principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure.

Bentley s management carried out an evaluation, with the participation of Bentley s principal executive officer and principal financial officer, of the effectiveness of Bentley s disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of the end of the period covered by this quarterly report. Based on that evaluation, Bentley s principal executive officer and principal financial officer concluded that Bentley s disclosure controls and procedures were effective as of September 30, 2007.

There was no change in Bentley s internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) identified in connection with the evaluation of Bentley s internal controls that occurred during the quarter ended September 30, 2007 that has materially affected, or is reasonably likely to materially affect, Bentley s internal control over financial reporting.

PART II. OTHER INFORMATION

Item 6. Exhibits

The Exhibits filed as part of this report are listed on the Exhibit Index immediately preceding the exhibits, which Exhibit Index is incorporated herein by reference.

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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.

BENTLEY PHARMACEUTICALS, INC.

Registrant

November 8, By: /s/ James R. Murphy 2007

James R. Murphy Chairman of the Board of Directors and Chief Executive Officer (Principal Executive Officer)

November 8, By: /s/ Richard P. Lindsay 2007

Richard P. Lindsay Vice President, Chief Financial Officer, Secretary and Treasurer (Principal Financial Officer) **Exhibit Index**

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Exhibit Number		Description of Exhibit
10.1	*	Employment Agreement dated as of August 20, 2007 by and between Bentley Pharmaceuticals, Inc. and James R. Murphy.
31.1	*	Certification of the Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	*	Certification of the Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	*	Certification of the Chief Executive Officer pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	*	Certification of the Chief Financial Officer pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

* Filed herewith.