

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

FORM 6-K

**REPORT OF FOREIGN PRIVATE ISSUER
PURSUANT TO RULE 13a-16 OR 15d-16 UNDER
THE SECURITIES EXCHANGE ACT OF 1934**

For the month of November 2009

**001-33444
(Commission File Number)**

Eurand N.V.

(Exact Name of Registrant as Specified in Its Charter)

Not Applicable

(Translation of registrant's name into English)

**Olympic Plaza
Fred. Roeskestraat 123
1076 EE Amsterdam, The Netherlands**
(Address of principal corporate office)

Indicate by check mark whether the registrant files or will file annual reports under cover Form 20-F or Form 40-F:
Form 20-F Form 40-F

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T
Rule 101(b)(1):

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T
Rule 101(b)(7):

Indicate by check mark whether the registrant by furnishing the information contained in this Form is also thereby
furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of
1934: Yes No

If "Yes" is marked, indicate below the file number assigned to the registrant in connection with Rule 12g3-2(b): 82-

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PART I. UNAUDITED CONDENSED FINANCIAL INFORMATION

Unaudited Condensed Consolidated Financial Statements

EURAND N.V.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands of euros)

	September 30, 2009 (Unaudited)	December 31, 2008 (Note 2)
Assets		
Current Assets		
Cash and cash equivalents	16,730	19,146
Marketable securities	14,582	3,592
Accounts receivable, less allowance for doubtful accounts of €32 and €275, respectively	14,405	13,335
Inventories, net	14,674	13,923
Prepaid expenses and other current assets	8,066	6,093
Deferred income taxes	1,648	1,693
Total current assets	<u>70,105</u>	<u>57,782</u>
Property, plant and equipment, net of accumulated depreciation of €1,144 and €67,476, respectively	35,024	37,294
Goodwill	26,654	27,000
Other intangible assets, net of accumulated amortization of €5,372 and €4,425, respectively	6,539	7,784
Deferred income taxes	403	432
Other non current assets	23	3,667
Total non current assets	<u>68,643</u>	<u>76,177</u>
Total assets	<u><u>138,748</u></u>	<u><u>133,959</u></u>

EURAND N.V.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands of euros, except share and per share amounts)

	September 30, 2009 (Unaudited)	December 31, 2008 (Note 2)
<i>Liabilities and shareholders' equity</i>		
<i>Current Liabilities</i>		
Short-term borrowings	-	186
Accounts payable	8,661	9,152
Income taxes payable	2,170	129
Accrued expenses and other current liabilities	16,608	11,606
Total current liabilities	27,439	21,073
Employee severance indemnities	4,043	4,081
Other non-current liabilities	3,284	2,997
Deferred income taxes	2,873	3,706
Total non-current liabilities	10,200	10,784
Commitments and contingencies (Note 10)		
<i>Shareholders' equity</i>		
Ordinary shares par value €0.01, authorized 130,000,000 shares as of September 30, 2009 and December 31, 2008, 45,845,216 and 45,751,997 issued and outstanding as of September 30, 2009 and December 31, 2008, respectively	458	458
Additional paid-in capital	136,728	134,643
Accumulated deficit	(40,352)	(38,382)
Accumulated other comprehensive income	4,275	5,383
Total shareholders' equity	101,109	102,102
Total liabilities and shareholders' equity	138,748	133,959

See accompanying notes to unaudited condensed consolidated financial statements

EURAND N.V.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands of euros, except share and per share amounts)

	For the three months ended		For the nine months ended	
	September 30, 2009	September 30, 2008	September 30, 2009	September 30, 2008
Product sales	25,053	20,131	73,151	60,675
Royalties	2,815	2,013	8,113	5,370
Development fees	2,723	2,407	9,035	6,787
Revenues	<u>30,591</u>	<u>24,551</u>	<u>90,299</u>	<u>72,832</u>
Cost of goods sold	(15,517)	(14,078)	(45,327)	(39,632)
Research and development expenses attributable to development fees	(981)	(1,340)	(4,804)	(3,675)
Other research and development expenses	(5,492)	(3,404)	(13,392)	(9,499)
Selling, general and administrative costs	(7,855)	(7,423)	(24,505)	(23,256)
Income from litigation settlement	-	24,404	-	24,404
Amortization of intangibles	(336)	(213)	(1,038)	(1,078)
Operating income	<u>410</u>	<u>22,497</u>	<u>1,233</u>	<u>20,096</u>
Interest income, net	110	87	238	306
Foreign exchange gain (loss), net	7	28	(290)	59
Income before taxes	<u>527</u>	<u>22,612</u>	<u>1,181</u>	<u>20,461</u>
Income tax expense	(921)	(2,378)	(3,151)	(4,042)
Net income (loss)	<u>(394)</u>	<u>20,234</u>	<u>(1,970)</u>	<u>16,419</u>
Net income (loss) per share:				
Basic net profit (loss) per share	<u>€(0.01)</u>	<u>€0.45</u>	<u>€(0.04)</u>	<u>€0.37</u>
Diluted net profit (loss) per share	<u>€(0.01)</u>	<u>€0.43</u>	<u>€(0.04)</u>	<u>€0.35</u>
Weighted average shares used to compute basic net profit (loss) per share	<u>45,775,720</u>	<u>45,062,378</u>	<u>45,761,056</u>	<u>44,689,409</u>
Weighted average shares used to compute diluted net profit (loss) per share	<u>45,775,720</u>	<u>46,622,060</u>	<u>45,761,056</u>	<u>46,437,140</u>

See accompanying notes to unaudited condensed consolidated financial statements

EURAND N.V.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS'
EQUITY
Nine months ended September 30, 2009 and 2008
(In thousands of euros, except share amounts)

	Common Stock		Additional Paid-In Capital	Accumulat ed Deficit	Accumulat ed Other Comprehe nsive Income	Total Shareholders' Equity
	Shares	Amount				
As at December 31, 2007	44,034,114	440	130,858	(52,011)	1,780	81,067
Comprehensive loss:						
Net profit				16,419		16,419
Cumulative exchange translation adjustment					3,028	3,028
Comprehensive income						19,447
Shares issuance	26,100	-				-
Exercise of stock options	1,136,324	12	1,797			1,809
Stock option compensation			1,050			1,050
As at September 30, 2008	45,196,538	452	133,705	(35,592)	4,808	103,373
As at December 31, 2008	45,751,997	458	134,643	(38,382)	5,383	102,102
Comprehensive loss:						
Net loss				(1,970)		(1,970)
Cumulative exchange translation adjustment					(1,108)	(1,108)
Comprehensive income						(3,078)
Tax benefit of stock options plan			6			6
Exercise of stock options	93,219	-	296			296
Stock option compensation			1,783			1,783
As at September 30, 2009	45,845,216	458	136,728	(40,352)	4,275	101,109

EURAND N.V.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands of euros)

	For the nine months ended	
	September 30, 2009	September 30, 2008
<i>Operating Activities</i>		
Net profit (loss)	(1,970)	16,419
Adjustments to reconcile net profit (loss) to net cash provided by operating activities:		
Depreciation	5,233	4,988
Amortization	1,038	1,078
Loss on disposal of property, plant and equipment	-	193
Unrealized foreign exchange losses	53	1,646
Stock option compensation expense	1,783	1,050
Deferred income taxes	126	193
Changes in operating assets and liabilities:		
Accounts receivable, net	(1,735)	1,872
Inventories, net	(1,023)	(3,042)
Prepaid expenses and other current assets	(1,872)	(4,315)
Other non-current assets	3,476	(3,476)
Accounts payable	(430)	(217)
Accrued expenses and other current liabilities	6,906	(922)
Other non-current liabilities	888	(123)
Income taxes	(162)	2,816
Cash provided by operating activities	12,311	18,160
<i>Investing Activities</i>		
Purchase of marketable securities	(16,662)	-
Maturity of marketable securities	5,912	-
Purchases of property, plant and equipment	(3,810)	(5,506)
Cash used in investing activities	(14,560)	(5,506)
<i>Financing Activities</i>		
Borrowings on long term credit facility	-	6,000
Repayment of borrowings on long term credit facility	-	(6,000)
Repayment of principal on long term debt	-	(375)
Net changes in short term borrowings	(186)	(181)
Exercise of stock options	296	1,809
Cash provided by financing activities	110	1,253
Effect of exchange rates on cash	(277)	163
Increase (decrease) in cash and cash equivalents	(2,416)	14,070
Cash and cash equivalents at beginning of period	19,146	12,541
Cash and cash equivalents at end of period	16,730	26,611

EURAND N.V.
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(In thousands of euros, except share and per share data)

1. Company Overview

We are a holding company formerly known as Eurand B.V. Prior to that, we were known as Eurand Pharmaceuticals Holdings B.V., a private limited liability company incorporated in The Netherlands. We were converted into a Dutch public limited liability company by notarial deed of conversion on November 30, 2006. In May 2007, we completed an initial public offering of our ordinary shares in the United States and our ordinary shares began trading on the NASDAQ Global Market. Our principal executive offices are located at Olympic Plaza, Fred. Roeskestraat 123, 1076 EE Amsterdam, The Netherlands, telephone +31 20-673 2744, and we have operating subsidiaries organized in the United States, Italy, France and Ireland.

We are a specialty pharmaceutical company that develops, manufactures and commercializes enhanced pharmaceutical and biopharmaceutical products, utilizing proprietary pharmaceutical technologies to develop products that we believe will have advantages over existing products or will address unmet medical needs. Through collaboration arrangements, we have applied our technologies to drug products in a range of therapeutic areas, including cardiovascular, gastrointestinal, pain, nutrition and respiratory. We are developing and commercializing a portfolio of products to address cystic fibrosis and gastrointestinal disorders which we are promoting in the United States with our own sales and marketing team.

2. Basis of Presentation

Our accompanying unaudited condensed consolidated financial statements as of and for the three and nine months ended September 30, 2009 and 2008, have been prepared in accordance with United States generally accepted accounting principles (“U.S. GAAP”) and Regulation S-X of the U.S. Securities and Exchange Commission (“SEC”), consistently applied. The accompanying financial statements are condensed, because certain information and footnote disclosures normally included in annual financial statements have been condensed or omitted. In the opinion of management, the accompanying condensed consolidated financial statements contain all adjustments necessary to fairly present the financial position, results of operations, changes in shareholders’ equity and cash flows of the interim periods presented. All such adjustments are of a normal recurring nature. We have evaluated subsequent events through the date and time the financial statements were issued on November 12, 2009. The results of operations for any interim period are not necessarily indicative of results for the full financial year. The accompanying condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements for the year ended December 31, 2008. The accounting policies applied in preparing the accompanying condensed consolidated financial statements are consistent with those for the year ended December 31, 2008, except as discussed in Application of Accounting Policies to New Activity and Adoption of Accounting Standards below.

The preparation of the accompanying condensed consolidated financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and reported amounts of revenues and expenses during the reporting periods. Actual results could differ materially from those estimates.

Application of Accounting Policies to New Activity

During the nine months ended September 30, 2009, the Company increased sales of Pancrelipase (the Company’s currently marketed, low cost pancreatic enzyme replacement product). Pancrelipase is sold through the Company’s distributor, X-Gen Pharmaceuticals, Inc. (“X-Gen”). Pursuant to the agreement with X-Gen, under certain circumstances, customers have the right to return Pancrelipase to the Company and receive a refund.

As a result, unlike the treatment of the Company’s other products, revenue for Pancrelipase is not recognized when product is shipped to customers. Instead the Company recognizes revenue on product shipped when the Company considers that the product will not be returned and the Company defers revenue on shipments in excess of this. The Company has established reliable estimates of rates of returns for Pancrelipase using historical returns data from the product when it was marketed under a different brand name, through a different distributor in the same market, and from data of a similar pancreatic enzyme replacement product in the same market. In addition to historical rates of

EURAND N.V.
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(In thousands of euros, except share and per share data)

returns, the Company considers levels of inventory in the supply chain and levels of patient consumption, based on third party data. These are monitored in comparison to other pancreatic replacement products in the same market.

Adoption of New Accounting Standards

In June 2009, the Financial Accounting Standards Board ("FASB") issued authoritative guidance establishing two levels of U.S. GAAP – authoritative and nonauthoritative – and making the Accounting Standards Codification the source of authoritative, nongovernmental GAAP, except for rules and interpretive releases of the SEC. This guidance, which was incorporated into ASC Topic 105, "Generally Accepted Accounting Principles," was effective for financial statements issued for interim and annual periods ending after September 15, 2009. The adoption changed certain disclosure references to U.S. GAAP, but did not have any other impact on our consolidated financial statements.

In May 2009, the FASB issued authoritative guidance establishing general standards of accounting for and disclosure of events that occur after the balance sheet date but before financial statements are issued. This guidance, which was incorporated into ASC Topic 855, "Subsequent Events," was effective for interim or annual financial periods ending after June 15, 2009, and the adoption did not have any impact on our consolidated financial statements.

In April 2009, the FASB issued authoritative guidance requiring publicly traded companies to include certain fair value disclosures related to financial instruments in their interim financial statements. This guidance, which was incorporated into ASC Topic 825, "Financial Instruments," was effective for interim periods ending after June 15, 2009. We disclose the relevant fair value disclosures in our consolidated financial statements.

In December 2007, the FASB issued guidance which is now part of ASC 808-10, Collaborative Arrangements, (formerly EITF Issue 07-1, "Accounting for Collaborative Arrangements Related to the Development and Commercialization of Intellectual Property"). This new guidance defines collaborative arrangements and establishes presentation and disclosure requirements for transactions within a collaborative arrangement (both with third parties and between participants in the arrangement). The guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2008. The guidance requires retrospective application to all collaborative arrangements existing as of the effective date, unless retrospective application is impracticable. The impracticability evaluation and exception should be performed on an arrangement-by-arrangement basis. The adoption of this guidance had no impact on our financial position or results of operations, as there were no joint operating activity arrangements in which we, as an active party to the agreement, are exposed to significant risks and rewards dependent on the commercial success of the activity.

In December 2007, the FASB issued revised authoritative guidance related to business combinations, which provides for recognition and measurement of identifiable assets and goodwill acquired, liabilities assumed, and any noncontrolling interest in the acquiree at fair value. The guidance also established disclosure requirements to enable the evaluation of the nature and financial effects of a business combination. This guidance, which was incorporated into ASC Topic 805, "Business Combinations," was adopted by us as of January 1, 2009, and the adoption did not have a material impact on our consolidated financial statements.

In June 2008, the FASB issued FSP EITF 03-6-1, "Determining Whether Instruments Granted in Share-Based Payment Transactions Are Participating Securities", which is now part of ASC Topic 260, Earnings per Share. This new guidance addressed whether instruments granted in share-based payment transactions are participating securities prior to vesting and, therefore, need to be included in the earnings allocation in computing earnings per share (EPS) under the two-class method. This guidance was adopted by us as of January 1, 2009, and the adoption did not have a material impact on our consolidated financial statements.

EURAND N.V.
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(In thousands of euros, except share and per share data)

Recent Accounting Pronouncements

In October 2009, the FASB issued Accounting Standards Update (ASU) No. 2009-13, "Multiple-Deliverable Revenue Arrangements," which amends Accounting Standards Codification (ASC) Topic 605, "Revenue Recognition." ASU 2009-13 amends the ASC to eliminate the residual method of allocation for multiple-deliverable revenue arrangements, and requires that arrangement consideration be allocated at the inception of an arrangement to all deliverables using the relative selling price method. The ASU also establishes a selling price hierarchy for determining the selling price of a deliverable, which includes: (1) vendor-specific objective evidence if available, (2) third-party evidence if vendor-specific objective evidence is not available, and (3) estimated selling price if neither vendor-specific nor third-party evidence is available. Additionally, ASU 2009-13 expands the disclosure requirements related to a vendor's multiple-deliverable revenue arrangements. The changes to the ASC as a result of this update are effective prospectively for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010 (January 1, 2011 for us), and we are currently evaluating the potential impact, if any, of the adoption on our consolidated financial statements. The changes to the ASC as a result of this update also permit retrospective application for all periods presented.

In August 2009, the FASB issued ASU No. 2009-05, "Measuring Liabilities at Fair Value," which amends ASC Topic 820, "Fair Value Measurements and Disclosures." ASU 2009-05 provides clarification and guidance regarding how to value a liability when a quoted price in an active market is not available for that liability. The changes to the ASC as a result of this update are effective for the first reporting period (including interim periods) beginning after issuance (October 1, 2009 for us), and adoption is not expected to have a significant impact on our consolidated financial statements.

3. Fair value measurements

The carrying amounts of cash and cash equivalents, net accounts receivable, net accounts payable and short term borrowings approximate their fair value as of September 30, 2009 and December 31, 2008.

We hold marketable securities representing German government bonds classified as "held to maturity". Held to maturity investments are recorded at cost, adjusted for amortization of premiums and discounts.

	September 30, 2009		December 31, 2008	
	(unaudited)		(note 2)	
	Carrying value	Fair value measured at prices quoted in active markets for identical assets (Level 1)	Carrying value	Fair value measured at prices quoted in active markets for identical assets (Level 1)
Marketable securities	14,582	14,571	3,592	3,592

For marketable securities, pricing inputs are readily observable in the market, the valuation methodology used is widely accepted by market participants, and the valuation does not require significant management discretion. Level 1 inputs include quoted prices for identical instruments and are observable.

Marketable securities held as of September 30, 2009 and December 31, 2008 all had contractual maturities within one year of the reporting dates.

EURAND N.V.
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(In thousands of euros, except share and per share data)

4. Inventories, net

	September 30, 2009 (unaudited)	December 31, 2008 (note 2)
Raw materials	7,897	6,872
Work in progress	3,776	2,565
Finished goods	3,001	4,486
	<u>14,674</u>	<u>13,923</u>

Allowances for obsolescence of inventories were €1,701 and €1,336 as of September 30, 2009 and December 31, 2008, respectively.

5. Prepaid Expenses and Other Current Assets

	September 30, 2009 (unaudited)	December 31, 2008 (note 2)
Litigation settlement receivable – current portion	3,555	3,644
Prepayments	1,881	1,429
Recoverable amounts for income taxes	1,096	353
Recoverable amounts for other taxes	883	667
Deferred cost of goods sold	651	-
	<u>8,066</u>	<u>6,093</u>

6. Other Non Current Assets

	September 30, 2009 (unaudited)	December 31, 2008 (note 2)
Litigation settlement receivable – non-current portion	-	3,644
Other	23	23
	<u>23</u>	<u>3,667</u>

7. Income taxes

The major reconciling items between the income taxes computed at the Dutch statutory tax rate of 25.5% and the effective tax rate for the three and nine months ended September 30, 2009 are the increase in the valuation allowance recorded on net operating losses (“NOLs”) incurred by certain of our subsidiaries and the effect of Imposta Regionale sulle Attività Produttive (“IRAP tax”) in Italy.

The IRAP tax is an Italian regional tax on productive activities, and has a statutory rate of 3.9%. The IRAP tax base is similar to the corporate tax base, however deduction of interest and most labor costs is not permitted. The IRAP tax is not deductible for corporate tax purposes.

EURAND N.V.
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(In thousands of euros, except share and per share data)

The major reconciling items between the income taxes computed at the Dutch statutory tax rate of 25.5% and the effective tax rate for the three and nine months ended September 30, 2008 are the decrease in the valuation allowance recorded on NOLs incurred by certain of our subsidiaries and the effect of IRAP tax in Italy. Moreover, tax expense for the three and nine months ended September 30, 2008 included €1,363 of provision expense related to amounts required to be recorded for changes to our uncertain tax positions under Interpretation No. 48 (FIN 48), which is now a part of ASC Topic 740, "Income Taxes", including interest and penalties. The uncertain tax position related to a one time modification of a loan type financing arrangement between our U.S. and Italian subsidiaries in July 2008 which, although subject to interpretation of U.S. tax law, is more likely than not subject to a withholding tax which would not be recoverable by the Italian counterparty. Based on information available to date, other than incremental interest, the amount is not expected to change significantly in the next twelve months because no such modifications or similarly taxable actions are currently planned or expected. We are not able to determine when this tax position might be resolved with the relevant tax authorities.

8. Accrued Expenses and Other Current Liabilities

	September 30, 2009 (unaudited)	December 31, 2008 (note 2)
Accrued expenses	5,303	2,845
Accrued employee compensation	5,456	4,238
Social security and other contributions	857	1,711
Taxes, other than income taxes	681	1,186
Accrued product returns	813	22
Deferred payments for acquisition	1,024	1,078
Deferred revenues	2,474	526
	<u>16,608</u>	<u>11,606</u>

9. Shareholders' Equity

Share Capital

During the nine months ended September 30, 2009 and 2008, we issued 93,219 and 1,136,324 ordinary shares, respectively, in order to satisfy our obligations on the exercise of employee stock options.

Equity Based Compensation

Certain of our employees participate in the Eurand N.V. Equity Compensation Plan (the "Plan") for which a maximum of 9,735,224 ordinary shares have been authorized for grants of options and other share awards by us. The Plan, amended, restated and adopted on May 30, 2008 and amended on November 5, 2008 is an amendment and restatement of the Eurand N.V. Equity Compensation Plan amended, restated and adopted on August 29, 2007, which in turn was an amendment and restatement of the Eurand N.V. 1999 Stock Option Plan.

The criteria for measurement of option value, and consequently the commencement of the amortization of the expense, were met for 294,000 and 635,500 options, respectively, during the nine months ended September 30, 2009 and 2008.

10. Commitments and Contingencies

We are involved in legal proceedings arising in the normal course of business. Management believes that, based on advice of legal counsel, the outcome of these proceedings will not have a material adverse effect on our consolidated financial statements.

EURAND N.V.
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(In thousands of euros, except share and per share data)

11. Per Share Information

In accordance with ASC Topic 260, "Earnings per Share," we have reported both basic and diluted net profit (loss) per share, which were computed using the following data:

	For the three months ended September 30,		For the nine months ended September 30,	
	2009	2008	2009	2008
	(unaudited)	(unaudited)	(unaudited)	(unaudited)
EPS Numerator – Basic:				
Net income (loss)	<u>(394)</u>	<u>20,234</u>	<u>(1,970)</u>	<u>16,419</u>
EPS Denominator - Basic				
Weighted average number of ordinary shares outstanding	<u>45,775,720</u>	<u>45,062,378</u>	<u>45,761,056</u>	<u>44,689,409</u>
EPS Numerator – Diluted:				
Net income (loss)	<u>(394)</u>	<u>20,234</u>	<u>(1,970)</u>	<u>16,419</u>
EPS Denominator - Basic				
Weighted average number of ordinary shares outstanding	45,775,720	45,062,378	45,761,056	44,689,409
Ordinary share equivalents: stock options	<u>-</u>	<u>1,559,682</u>	<u>-</u>	<u>1,747,731</u>
Weighted average shares used to compute diluted net profit (loss) per share	<u>45,775,720</u>	<u>46,622,060</u>	<u>45,761,056</u>	<u>46,437,140</u>
Weighted average of stock options that had exercise prices adjusted for unrecognized compensation expense equal or higher than the average market price of our ordinary shares				
	<u>-</u>	<u>1,424,087</u>	<u>-</u>	<u>1,187,583</u>

The computation of diluted net loss per share for the three and nine months ended September 30, 2009 did not assume the effect of shares issuable upon the exercise of stock options as their effects are anti-dilutive.

EURAND N.V.
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(In thousands of euros, except share and per share data)

12. Geographic Revenues

Revenues based on the country in which the recipient of the product or service is resident, are as follows:

	For the three months ended		For the nine months ended	
	September 30,		September 30,	
	2009	2008	2009	2008
	(unaudited)	(unaudited)	(unaudited)	(unaudited)
U.S.A.	19,935	11,663	52,829	36,172
Germany	3,188	3,994	9,228	12,120
United Kingdom	2,545	2,279	7,372	6,698
Italy	792	1,501	3,478	4,408
Japan	937	1,239	3,464	3,437
Switzerland	224	545	2,486	1,715
Netherlands	1,246	543	2,326	1,295
Spain	388	601	1,847	1,142
France	343	253	1,804	1,184
Other	993	1,933	5,465	4,661
	<u>30,591</u>	<u>24,551</u>	<u>90,299</u>	<u>72,832</u>

13. Subsequent events

On October 27, 2009, the Company completed a public offering of 9,775,000 ordinary shares at the offering price of \$11.25. Of the total shares sold, 2,000,000 were newly issued by the Company, and the remaining 7,775,000 were previously issued and outstanding. Proceeds from the offering, before costs and expenses payable by the Company in connection with the offering, amounted to €14,391.

OPERATING AND FINANCIAL REVIEW AND PROSPECTS

You should read the following discussion and analysis in conjunction with our unaudited condensed consolidated financial statements and the related notes to our unaudited condensed consolidated financial statements and the other financial information appearing elsewhere in this report. Except for historical information contained herein, this discussion contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from the results discussed below. Accordingly, investors should not place undue reliance upon our forward-looking statements.

Forward Looking Statements

The forward-looking statements are contained primarily in the section entitled “Operating and Financial Review and Prospects”. All statements in this document that are not statements of historical fact are forward looking statements as defined in Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. In some cases, you can identify forward-looking statements by terms including “anticipates,” “believes,” “could,” “estimates,” “expects,” “intends,” “may,” “plans,” “potential,” “predicts,” “projects,” “should,” “will,” “would,” and similar expressions intended to identify forward-looking statements. These statements are based upon management’s current expectations and are subject to risks and uncertainties, known and unknown, which could cause actual results and developments to differ materially from those expressed or implied in such statements. In addition to the risks and uncertainties included in this Report on Form 6-K, other factors that could cause our actual results or actual outcomes to differ materially from those expressed in or implied by such forward-looking statements include, but are not limited to:

- our ability to market, commercialize and achieve market acceptance for ZENPEP™ or any of the products that we are developing, commercializing or may develop or commercialize in the future, including the growth, establishment or acquisition of specialty sales, marketing and distribution capabilities in the United States to commercialize products;
- the expected timing, costs, progress or success of any of our preclinical and clinical development programs, regulatory approvals, or commercialization efforts;
- delays in obtaining, or a failure to obtain and maintain, regulatory approval for our product candidates;
- the possibility the FDA may continue to extend the deadline for seeking or receiving a new drug application, or NDA, and/or not withdraw existing pancreatic enzyme products, or PEPs, from the U.S. market that do not receive approval for NDAs by the then applicable deadline;
- our ability to continue to successfully manufacture our existing products;
- the potential advantages of our products or product candidates over other existing or potential products;
- our ability to enter into any new co-development or licensing agreements or to maintain any existing co-development or licensing agreements with respect to our product candidates or products;
- our ability to effectively maintain existing licensing relationships and establish new licensing relationships;
- the expense, time and uncertainty involved in the development of our product candidates, some or all of which may never reach the regulatory approval stage;
- our reliance on collaboration partners and licensees, to obtain and maintain regulatory approval for certain of our products and product candidates, and to commercialize such products;
- our ability to compete in the pharmaceutical industry;

- our ability to protect our intellectual property and know-how and operate our business without infringing the intellectual property rights or regulatory exclusivity of others;
- the continuation of product sales by our collaborators and licensees;
- a loss of rights to develop and commercialize our products under our license and sublicense agreements;
- a loss of any of our key scientists or management personnel;
- our estimates of market sizes and anticipated uses of our products and product candidates;
- our estimates, and the estimates of others, including research analysts, of our future performance; and
- our estimates, and the estimates of others, including research analysts, regarding our anticipated future revenue, expenses, operating losses, capital requirements and our needs for additional financing.

In addition to the sections entitled “Forward Looking Statements” and “Risk Factors” in this report, see “Risks Related to Our Business” beginning on page 9 of our amended Form F-3, filed with the SEC on October 20, 2009, as well as the “Risk Factors” beginning on page 5 of our Annual Report on Form 20-F for the year ended December 31, 2008, filed on March 31, 2009 for a discussion of these risks and uncertainties.

Business Update

Product Development Pipeline Updates

EUR-1008 — ZENPEP™ (pancrelipase) Delayed-Release Capsules

As announced on August 28, 2009, the FDA approved ZENPEP (EUR-1008) for the treatment of exocrine pancreatic insufficiency due to cystic fibrosis or other conditions. ZENPEP is the only FDA-approved pancreatic enzyme product that has been evaluated in clinical studies in adults and children – including children from one to seven years old – and will offer four dosage strengths to meet the varied needs of infants, toddlers, adolescents and adults with EPI. ZENPEP is the sixth Eurand-developed product to be approved by the FDA since 2001 and the second this year following the May 8th approval of LAMICTAL® ODT™ (lamotrigine) Orally Disintegrating Tablets.

We recently announced the results of our Phase II/III clinical trial conducted with ZENPEP in patients with chronic pancreatitis. The data demonstrates that ZENPEP™ significantly improves fat absorption in patients with exocrine pancreatic insufficiency (EPI) due to chronic pancreatitis. In a patient population with mild-to-moderate EPI associated with chronic pancreatitis, a lower dose of 35,000 lipase units/day was found to significantly improve protein absorption and body weight compared to the baseline placebo period. In patients with more severe EPI, the higher dose of 140,000 lipase units/day was more effective than the lower dose.

EUR-1048 — Lamictal® ODT™ (lamotrigine) Orally Disintegrating Tablets

As announced on May 11, 2009, the FDA approved EUR-1048, LAMICTAL ODT for the treatment of Bipolar I disorder and seizures. Eurand’s partner, GlaxoSmithKline, launched LAMICTAL ODT in late June 2009. Co-developed by Eurand and GSK, LAMICTAL ODT uses Eurand’s AdvaTab® orally disintegrating tablet and Microcaps® taste-masking technologies. In addition to receiving an undisclosed milestone payment upon launch, Eurand earns revenue for manufacturing LAMICTAL ODT tablets for GSK, royalties on net sales of the product and milestone payments in connection with LAMICTAL ODT achieving predetermined sales levels in the U.S.

EUR-1025 — Once-Daily Formulation of Ondansetron

As previously disclosed, Eurand conducted two pivotal pharmacokinetic studies of EUR-1025, a proprietary once-a-day oral modified-release formulation of ondansetron versus an 8 mg dose of the anti-emetic drug Zofran®

(ondansetron). Based on the results of these studies, Eurand expects that EUR-1025 has a similar efficacy and safety profile as 8 mg Zofran dosed three times a day.

Presentation of Financial information

We prepared our financial statements included in this report in euros in accordance with U.S. GAAP. References to “U.S. dollars,” “dollars,” “U.S. \$” or “\$” in this report are to the currency of the United States and references to “euro”, “(euro)” or “€” are to the single currency of the European Union.

Exchange Rate Information

Fluctuations in the exchange rates between the euro and the dollar will affect the dollar amounts received by owners of our shares on payment of dividends, if any, paid in euros. Moreover, such fluctuations may also affect the dollar price of our shares on the NASDAQ Global Market.

The following table sets forth information regarding the exchange rates of U.S. dollar per euro for the periods indicated. Average rates are calculated by using the average of the closing noon buying rates on each day during the periods presented.

	<u>High</u>	<u>Low</u>	<u>Average</u>	<u>Period End</u>
Three months ended				
March 31, 2008	1.5805	1.4495	1.5007	1.5805
June 30, 2008	1.6010	1.5368	1.5625	1.5748
September 30, 2008	1.5923	1.3939	1.5030	1.4081
December 31, 2008	1.4358	1.2446	1.3202	1.3919
March 31, 2009	1.3946	1.2547	1.3035	1.3261
June 30, 2009	1.4270	1.2903	1.3619	1.4020
September 30, 2009	1.4795	1.3852	1.4311	1.4630
Nine months ended				
September 30,				
2008	1.6010	1.3939	1.5223	1.4081
2009	1.4795	1.2547	1.3653	1.4630
Month in 2009				
January	1.3946	1.2804	1.3244	1.2804
February	1.3064	1.2547	1.2797	1.2662
March	1.3730	1.2549	1.3050	1.3261
April	1.3458	1.2978	1.3214	1.3244
May	1.4126	1.3267	1.3646	1.4126
June	1.4270	1.3784	1.4014	1.4020
July	1.4279	1.3852	1.4092	1.4279
August	1.4416	1.4075	1.4266	1.4354
September	1.4795	1.4235	1.4575	1.4630
October	1.5029	1.4532	1.4821	1.4755

Results of Operations

This section discusses our operating results.

Nine months ended September 30, 2009, compared to the nine months ended September 30, 2008

The following table shows how revenues for the nine months ended September 30, 2009 changed compared to the same period in 2008.

	Nine Months ended September 30,			
	2009	2008	Increase (decrease) compared to previous period	
	(euros in thousands, except percentages)			
Product sales	73,151	60,675	12,476	21%
Royalty income	8,113	5,370	2,743	51%
Development fees	9,035	6,787	2,248	33%
Total revenues	<u>90,299</u>	<u>72,832</u>	<u>17,467</u>	<u>24%</u>

Revenues. Total revenues were €90.3 million for the nine months ended September 30, 2009, compared to €72.8 million for the same period in 2008, an increase of €17.5 million or 24%. The increase was primarily due to sales of pancreatic enzyme products in the U.S., both sales of our low cost Pancrelipase formulation and shipments of ULTRASE® to Axcan, as well as higher royalties from AMRIX® and higher development fees. Our growth was positively affected by changes in exchange rates, which increased the reported revenue figure by approximately €6.6 million for the nine months ended September 30, 2009. Excluding exchange rate effects the increase in revenues would have been approximately 15%.

Product sales were €73.2 million for the nine months ended September 30, 2009, an increase of €12.5 million or 21% compared to the same period in 2008. As mentioned above, this increase was primarily due to sales of our unbranded Pancrelipase formulation, which is not actively promoted in the U.S., and sales of ULTRASE® to our marketing partner, Axcan. The increase in product sales growth would have been €7.4 million or 12% if positive currency effects worth approximately €5.1 million were excluded.

Royalties were €8.1 million for the nine months ended September 30, 2009, an increase of €2.7 million or 51%, due mainly to increased royalties from AMRIX® and in part to positive foreign currency effects of approximately €788,000.

Development fees were €9.0 million for the nine months ended September 30, 2009 compared to €6.8 million for the same period in 2008, an increase of €2.2 million or 33%. The increase includes positive foreign exchange effects of approximately €90,000. Our development fees may fluctuate significantly from quarter to quarter depending on when certain milestone fees are earned.

Cost of Goods Sold. Cost of goods sold was €45.3 million for the nine months ended September 30, 2009 compared to €39.6 million for the same period in 2008, representing an increase of €5.7 million or 14%. If foreign exchange effects of approximately €2.5 million were excluded then the increase would have been €3.2 million or 8%, lower than the corresponding growth rate of product sales of 12% excluding the effects of foreign exchange. This lower growth rate of costs compared to sales was partly due to the increased proportion of higher margin products in our total product sales.

Total Research and Development Expenses. Research and development expenses were €18.2 million for the nine months ended September 30, 2009 compared to €13.2 million for the same period in 2008, representing an increase of €5.0 million or 38%. We allocate our research and development expenses into two categories, research and development expenses attributable to development fees and other research and development expenses.

Research and Development Expenses Attributable to Development Fees. For the nine months ended September 30, 2009, we were involved in a number of external projects for third parties, which we refer to in our consolidated statement of operations as research and development expenses attributable to development fees. For the nine months ended September 30, 2009, we incurred €4.8 million in research and development expenses attributable to development fees, representing 26% of our total research and development expenses. The largest component of these research and development expenses attributable to development fees was personnel costs. For the nine months ended September 30, 2009, €1.8 million of personnel costs were incurred, representing an increase of €0.2 million, or 9% compared to the same period in 2008. With more than 10 active external projects during the nine months ended September 30, 2009, no single project was individually significant.

Other Research and Development Expenses. For the nine months ended September 30, 2009, the only internal project that was individually significant with respect to our total research and development expenses was ZENPEP (EUR-1008). In our consolidated statement of operations, we refer to internal research and development expenses as other research and development expenses. Development costs for EUR-1008 increased by €0.7 million to €5.3 million, primarily due to our clinical trial of EUR-1008 in chronic pancreatitis, during the nine months ended September 30, 2009, representing a 16% increase compared to the same period of 2008. For the nine months ended September 30, 2009, the portion of our research and development expenses attributable to other internal development projects increased by €3.2 million to €3.1 million and was comprised of multiple projects, none of which was individually significant in relation to our total research and development expenses for the nine months ended September 30, 2009.

Selling, General and Administrative Expenses. Selling, general and administrative expenses were €4.5 million for the nine months ended September 30, 2009 compared to €3.3 million for the same period in 2008, representing an increase of €1.2 million or 5%, which is explained by foreign exchange effects of approximately €1.4 million.

Income Tax Expense. For the nine months ended September 30, 2009, we recorded income taxes of €3.2 million on pre-tax income of €1.2 million. In the nine months ended September 30, 2008, we recorded income taxes of €4.0 million on a pre-tax income of €0.5 million. In general, our taxes do not correlate directly with our profits and losses before tax because, primarily, we are subject to certain local income taxes in Italy for which labor and financial costs are non-deductible, and we have recorded valuation allowances to offset the benefits of tax loss carryforwards in certain operating subsidiaries that operated at a loss during the periods.

Tax expense for the nine months ended September 30, 2008 included €1.4 million of provision expense related to amounts required to be recorded for changes to our uncertain tax positions including interest and penalties. The uncertain tax position related to a one time modification of a loan type financing arrangement between our U.S. and Italian subsidiaries in July 2008 which, although subject to interpretation of U.S. tax law, is more likely than not subject to a withholding tax which would not be recoverable by the Italian counterparty. Based on information available to date, other than incremental interest, the amount is not expected to change significantly in the next twelve months because no such modifications or similarly taxable actions are currently planned or expected. We are not able to determine when this tax position might be resolved with the relevant tax authorities.

Three months ended September 30, 2009, compared the three months ended September 30, 2008

The following table shows how revenues for the three months ended September 30, 2009 changed compared to the same period in 2008.

	Three months ended September 30,			
	2009	2008	Increase (decrease) compared to previous period	
(euros in thousands, except percentages)				
Product sales	25,053	20,131	4,922	24%
Royalty income	2,815	2,013	802	40%
Development fees	2,723	2,407	316	13%
Total revenues	<u>30,591</u>	<u>24,551</u>	<u>6,040</u>	<u>25%</u>

Revenues. Total revenues were €30.6 million for the quarter ended September 30, 2009, an increase of €6.0 million or 25%. The increase was primarily due to sales of pancreatic enzyme products in the U.S., both our low cost Pancrelipase formulation and shipments of ULTRASE® to Axcan, as well as higher royalties from AMRIX®. This growth was positively affected by changes in exchange rates which increased the reported revenue figure by approximately €1.3 million for the quarter ended September 30, 2009. Excluding these effects, the increase in revenues would have been 19%.

Product sales were €25.1 million for the quarter ended September 30, 2009, an increase of €4.9 million or approximately 24% compared to the same period in 2008. The increase was mainly due to the higher sales of pancreatic enzyme products mentioned above and approximately €1.1 million of positive currency effects.

Royalties were €2.8 million for the quarter ended September 30, 2009, an increase of €802,000 or 40%, due primarily to increased royalties from AMRIX® and in part to positive foreign currency effects of approximately €120,000.

Development fees were €2.7 million for the quarter ended September 30, 2009 compared to €2.4 million for the same period in 2008. Our development fees fluctuate significantly from quarter to quarter depending on when milestone fees are earned.

Cost of Goods Sold. Cost of goods sold was €15.5 million for the quarter ended September 30, 2009, an increase of €1.4 million or 10%. If foreign exchange effects of approximately €37,000 were excluded then the increase would have been €1.1 million or 8%, lower than the corresponding growth rate of product sales of 19% excluding the effects of foreign exchange. This lower growth rate of costs compared to sales was partly due to the increased proportion of higher margin products in our total product sales.

Total Research and Development Expenses. Research and development expenses were €6.5 million for the three months ended September 30, 2009 compared to €4.7 million for the same period in 2008, representing an increase of €1.7 million or 36%. We allocate our research and development expenses into two categories, research and development expenses attributable to development fees and other research and development expenses.

Research and Development Expenses Attributable to Development Fees. For the three months ended September 30, 2009, we were involved in a number of external projects for third parties, which we refer to in our consolidated statement of operations as research and development expenses attributable to development fees. For the three months ended September 30, 2009, we incurred €1.0 million in research and development expenses attributable to development fees, representing 15% of our total research and development expenses. The largest component of these research and development expenses attributable to development fees was personnel costs. For the three months ended September 30, 2009, €0.5 million of personnel costs were incurred, representing a decrease of €0.1 million, or 16% compared to the same period in 2008. With more than 10 active external projects during the three months ended September 30, 2009, no single project was individually significant.

Other Research and Development Expenses. For the three months ended September 30, 2009, the only internal project that was individually significant with respect to our total research and development expenses was ZENPEP (EUR-1008). In our consolidated statement of operations, we refer to internal research and development expenses as other research and development expenses. Development costs for EUR-1008 increased by €0.4 million to €1.9 million, representing a 30% increase compared to the same period of 2008. For the three months ended September 30, 2009, the portion of our research and development expenses attributable to other internal development projects increased by €1.7 million to €3.6 million and was comprised of multiple projects, none of which was individually significant in relation to our total research and development expenses for the three months ended September 30, 2009.

Selling, General and Administrative Expenses. Selling, general and administrative expenses were €7.9 million for the quarter ended September 30, 2009 compared to €7.4 million for the same period in 2008, representing an increase of €430,000 or 6%, in part due to foreign exchange effects of approximately €200,000.

Income Tax Expense. For the quarter ended September 30, 2009, we recorded income taxes of €21,000 on pre-tax income of €27,000. In the quarter ended September 30, 2008, we recorded income taxes of €2.4 million on a pre-tax income of €22.6 million. In general, our taxes do not correlate directly with our profits and losses before tax because, primarily, we are subject to certain local income taxes in Italy for which labor and financial costs are non-deductible, and we have recorded valuation allowances to offset the benefits of tax loss carryforwards in certain operating subsidiaries that operated at a loss during the periods.

Tax expense for the three months ended September 30, 2008 included €1.4 million of provision expense related to amounts required to be recorded for changes to our uncertain tax positions including interest and penalties. The uncertain tax position related to a one time modification of a loan type financing arrangement between our U.S. and Italian subsidiaries in July 2008 which, although subject to interpretation of U.S. tax law, is more likely than not subject to a withholding tax which would not be recoverable by the Italian counterparty. Based on information available to date, other than incremental interest, the amount is not expected to change significantly in the next twelve months because no such modifications or similarly taxable actions are currently planned or expected. We are not able to determine when this tax position might be resolved with the relevant tax authorities.

Changes in Financial Position

We estimate our net proceeds from the recent public offering of 2,000,000 of our ordinary shares on October 27, 2009 to be €3.9 million after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

Cash and cash equivalents. Cash and cash equivalents were €6.7 million as of September 30, 2009 compared to €9.1 million as of December 31, 2008. Our cash and cash equivalents decreased due to net investments of €4.6 million, including investments in marketable securities of €0.8 million and investments in property, plant and equipment of €3.8 million, which more than offset cash provided by operating activities in the period of €2.3 million.

Marketable securities. Marketable securities were €4.6 million as of September 30, 2009 compared to €3.6 million as of December 31, 2009.

Total shareholders' equity. Shareholders' equity decreased from €02.1 million on December 31, 2008 to €01.1 million on September 30, 2009, primarily as a result of a net loss of €2.0 million, a stock option compensation of €1.8 million and a negative exchange translation adjustment of €1.1 million.

Chiesi Agreement

On April 2, 2008, we entered into a license agreement with Chiesi Farmaceutici S.p.A., or Chiesi, under which we received an exclusive, non-transferable license in the U.S. (including the U.S. Virgin Islands and Puerto Rico) and Canada to develop and commercialize a finished pharmaceutical product containing Beclomethasone dipropionate as the pharmaceutically active ingredient, in tablet form, for the treatment of inflammatory bowel diseases and

related complications. We also received a non-exclusive license to develop and then commercialize the product outside of the U.S. and Canada, but only for the subsequent export of the product in the U.S. and/or Canada for resale. Under the license agreement, we are required to take all commercially reasonable steps to obtain and maintain regulatory approval for any product developed and/or commercialized under the license agreement. From April 2, 2008 through September 30, 2009, we paid Chiesi \$500,000. If certain milestones are achieved, we will be obligated to pay Chiesi up to an aggregate of an additional \$4,000,000 in milestone payments if and when certain commercial sales targets are achieved. In addition to these milestone payments, we are required to make royalty payments to Chiesi based on a low to mid single digit percentage of our net sales of the product. The license agreement will remain in effect for ten years from the date any product is first commercialized, on a country-by-country basis, unless earlier terminated. The agreement contains a standard early termination provision which provides for early termination by either party in the event certain conditions have occurred, including, but not limited to, either party's breach of the agreement, either party's filing for bankruptcy or either party making an assignment for the benefit of its creditors.

Off Balance Sheet Arrangements

As of September 30, 2009, we did not have any off balance sheet arrangements.

QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Exchange Rate Risk

Our European operations use the euro as the functional currency, and our U.S. operations use the U.S. dollar as the functional currency. We express our consolidated financial statements in euros. Our European operations transact business in euros primarily with European customers, with the notable exception of Axcan, our largest customer. Our U.S. operations transact business in U.S. dollars primarily with U.S. customers. We recognize the cumulative effect of foreign currency translations as a separate component of shareholders' equity.

A hypothetical 10% appreciation in currency exchange rates against the U.S. dollar from the prevailing market rates would have decreased our pre-tax profit by approximately €1,042 for the nine months ended September 30, 2009. Conversely, a hypothetical 10% depreciation in currency exchange rates against the U.S. dollar from the prevailing market rates would have increased our pre-tax profit by approximately €1,274 for the nine months ended September 30, 2009.

Impact of Inflation

We do not believe that inflation has had a material effect on our business, results of operations or financial condition for any of the periods discussed or that inflation will affect us to a different extent than it affects the general economy.

PART II. OTHER INFORMATION

ITEM 1A. RISK FACTORS

Risks Related to Our Financial Condition

We have a history of net losses, and we might not achieve or maintain profitability.

Except for a net income in 2008 of €13.6 million due to the recognition of a gain on settlement of litigation of €4.4 million which is not expected to recur, we have incurred significant net losses since our formation in 1999, when we were established as a company independent of American Home Products, now Wyeth. As of September 30, 2009, we had an accumulated deficit of €40.4 million. Our net income (losses) were approximately €(5.0) million, €(6.7) million and €13.6 million in 2006, 2007 and 2008, respectively. Our net loss was approximately €2.0 million (or \$2.9 million) for the nine months ended September 30, 2009. In addition, we have made, and expect to continue to make, investments in our research and development programs. Our selling, general and administrative expenses have been and will continue to be a significant component of our cost structure. We expect to incur increased expenses for at least the next year as we continue our research activities, conduct development of or seek regulatory approvals for our product candidates, and establish or acquire a specialty sales and marketing organization in the United States to launch our recently approved product, ZENPEP™

The commercial launch of ZENPEP™ in the United States is planned for the fourth quarter of 2009, but we expect a several-month ramp-up period and expect that associated expenses will precede revenues generated by the increased spending. We do not expect to recognize substantial revenues until 2010. If our launch of ZENPEP™ is not successful, either because of competition from other PEPs, an inability to build market share, increased selling or other expenses, or other difficulties, we may not generate sufficient revenues from ZENPEP™ to reach profitability.

Even if developing and commercializing one or more of our product candidates is successful, we may not be able to achieve or maintain profitability. Whether we maintain our operating profitability and achieve profitability in the future will depend on our ability to generate revenues that exceed our expenses. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. If we are unable to achieve profitability, the market value of our ordinary shares may decline and you could lose all or part of your investment.

Risks Related to ZENPEP™

We currently have limited internal sales and marketing capabilities. If we are unable to develop our sales and marketing capabilities on our own, or through contract sales forces or acquisition, we will not be able to fully exploit the commercial potential for ZENPEP™ in the United States.

We have limited sales and marketing experience in the United States. We anticipate continuing to make significant expenditures to grow our sales force to sell ZENPEP™ in EPI and expand our marketing capabilities. In order to successfully exploit ZENPEP™'s commercial potential, we must successfully market and sell the product and establish or develop the needed third party contracts to market and distribute the product in the United States. Any failure or extended delay in the expansion of our sales and marketing capabilities or inability to effectively operate in the marketplace could adversely impact the commercialization of ZENPEP™ and there can be no assurance that our marketing efforts will generate significant revenues.

We currently do not intend to sell ZENPEP™ outside of the United States. Therefore, we must enter into arrangements with third parties to perform these services outside of the United States. We may not be able to effectuate these agreements.

Events or factors that may inhibit or hinder our ZENPEP™ commercialization efforts include:

- developing our own commercial team will be expensive and time-consuming, could delay product launch, or result in high cash burn or reduced profitability;
- failure to acquire sufficient or suitable personnel to establish, oversee, or implement an effective launch plan;
- failure to recruit, train, oversee and retain adequate numbers of effective sales and marketing personnel;
- failure to acquire sales personnel that can effectively obtain access to or persuade adequate numbers of physicians to prescribe our products
- unforeseen costs and expenses associated with creating or acquiring and sustaining an independent sales and marketing organization;
- incurrence of costs in advance of anticipated revenues and subsequent failure to generate sufficient revenue to offset additional costs; and
- failure to understand the nature or needs of the market.

PEPs are lifesaving drugs. The FDA may not remove existing unapproved PEPs from the market in April 2010 even if they have not been FDA-approved. This would increase the level of competition in the PEP market.

Existing products to treat exocrine pancreatic insufficiency have been marketed in the United States since before the passage of the Federal Food, Drug, and Cosmetic Act, or FDCA, in 1938 and, consequently, there are currently marketed PEPs that have not been approved by the FDA. In 1995, the FDA issued a final rule requiring that these PEPs be marketed by prescription only, and, in April 2004, the FDA mandated that all manufacturers of EPI drug products file an NDA and receive approval for their products by April 2008 or be subject to regulatory action. In October 2007, the FDA published a notice in the Federal Register extending the deadline within which to obtain marketing approval for exocrine pancreatic insufficiency drug products until April 28, 2010 for those companies who were (a) marketing unapproved pancreatic enzyme products as of April 28, 2004, (b) submitted NDAs on or before April 28, 2009 and (c) who continue diligent pursuit of regulatory approval.

Despite the FDA's announcement, its position is non-binding, and the agency may not pursue regulatory action against companies that fail to meet any applicable deadline. If the FDA does not enforce its stated positions by the applicable deadline, the level of competition that ZENPEP™ will face will be significantly greater than we anticipate. In addition, the FDA could change its position or suspend enforcement again as it did in October 2007.

Although we anticipate, based on the FDA's announced position, a reduction in the number of marketed products aimed at the treatment of exocrine pancreatic insufficiency, this decline in competition may not occur. The fact that PEPs are lifesaving drugs may influence the FDA's action for any of our competitors' product candidates, particularly if it would result in two or fewer products on the market for the treatment of exocrine pancreatic insufficiency.

The level of competition that ZENPEP™ will face from these products in the United States will depend on whether and how many manufacturers of these products maintain them on the market after the applicable date, when and whether the FDA requests the withdrawal of unapproved products or simply addresses the manufacture, and whether manufacturers obtain approval for their NDAs by the deadline set by the FDA and, if they are unable to do so, whether the FDA takes regulatory action against these manufacturers if they do not exit the market and the nature of any such action, as the FDA did in 2007.

ZENPEP™ will compete with currently marketed products for exocrine pancreatic insufficiency, to the extent such products are either approved or permitted to remain on the market, and our competitors may have more resources available to them than us.

ZENPEP™ will compete with currently marketed products for exocrine pancreatic insufficiency. This competition could affect the market acceptance of ZENPEP™ or require us to lower the price of ZENPEP™, which would negatively impact our margin and our ability to achieve profitability. Other companies with existing PEPs include Solvay Pharmaceuticals or Solvay; Axcan Pharmaceuticals, or Axcan, whose coated product, i.e. a product that has been coated to protect the enzymes from degradation resulting from acids in the stomach, has been licensed from us; and McNeil Consumer Specialty, a subsidiary of Johnson & Johnson. In addition, we understand that other commercial entities have or have had synthetic product candidates in clinical development that could compete with ZENPEP™. These and other companies may have greater resources available than we do to support their products.

Solvay announced approval in May 2009 for its reformulated PEP, Creon®. In December 2007, the FDA accepted and granted priority review for Axcan's Ultrase NDA. Axcan has not yet received approval for its Ultrase NDA and we are unable to predict when or whether Axcan will receive approval. The Ultrase product which is currently marketed and awaiting approval has been licensed to Axcan by us. We receive manufacturing fees and royalties based on a percentage of Axcan's annual net sales of the finished product. The Creon and Ultrase products compete with ZENPEP™.

If we or our collaboration partners outside of the United States are unable to commercialize ZENPEP™ or experience significant delays in doing so, our growth prospects will be materially harmed.

We have invested significant time and financial resources in the development of ZENPEP™. We currently intend to out-license commercial rights to ZENPEP™ outside the United States, including Europe and Asia. Our ability, or that of our collaboration partners, to successfully develop and commercialize ZENPEP™ will depend on numerous factors, including:

- our ability to find commercial partners with the appropriate resources to efficiently commercialize the product and enter into agreements on commercially reasonable or commercially viable terms and conditions;
- our ability to coordinate global regulatory approval for the product in a consistent and effective manner;
- successfully completing any trials and tests required by applicable regulatory authorities;
- receiving marketing approvals from applicable regulatory authorities;
- continued operation of our manufacturing facilities, and our raw material suppliers, in compliance with current good manufacturing practice regulations, or cGMP;
- establishing favorable pricing from regulatory authorities outside of the United States; and
- obtaining commercial acceptance of ZENPEP™ from the medical community and third-party payors.

Any of the foregoing factors would cause us or our licensees to be unable to commercialize ZENPEP™ in the timeframe anticipated or at all. Any such delay or failure would cause our product revenues to suffer.

Even though ZENPEP™ has received regulatory approval for marketing in the United States, and we have met significant milestones necessary to achieve marketing authorization in several venues, we may not succeed in obtaining regulatory approval for ZENPEP™ from other regulatory agencies. Without regulatory approval from other regulatory agencies, we will be unable to commercialize ZENPEP™ to its full potential and our growth prospects will be materially impaired.

ZENPEP™ is subject to extensive regulation by the U.S. Food and Drug Administration, or FDA, the European Medicines Evaluation Agency, or EMEA, and other applicable regulatory authorities relating to the testing, manufacture, safety, efficacy, record-keeping, labeling, packaging, storage, approval, advertising, marketing, promotion, sale and distribution of drugs. For example, to obtain regulatory approval for our lead product, ZENPEP™, a new porcine-derived proprietary enzyme replacement product for the treatment of exocrine pancreatic insufficiency, or EPI, clinical trials must demonstrate that our product is safe and effective for use in humans.

We evaluated ZENPEP™ in patients suffering from EPI secondary to Cystic Fibrosis in two Phase III clinical trials. Our pivotal Phase III clinical trial was completed in November 2006 and evaluated ZENPEP™ in patients over the age of seven. Our supportive Phase III clinical trial was completed in September 2006 and evaluated ZENPEP™ in patients between the ages of one and seven. At the FDA's request, we completed a bioavailability study, the results of which were included in the submission of our NDA for ZENPEP™.

With regard to our U.S. regulatory submissions, we completed the rolling submission of our NDA for ZENPEP™ in December 2007 and the NDA filing was accepted and granted priority review in February 2008. In June 2008 we received an approvable letter from the FDA. We and our raw material supplier, Nordmark Arzneimittel GmbH & Co., responded to the deficiencies identified in the letter in late 2008. We received a complete response letter in January 2009 and were issued a late second quarter 2009 PDUFA date. In June 2009, the FDA notified us that it had extended the June 2009 PDUFA date by three months. On August 27, 2009, the FDA approved ZENPEP™ for sale in the United States for the treatment of EPI.

With regard to our European regulatory submissions, we filed with the Pediatric Committee, or PDCO, our Pediatric Investigational Plan, or PIP, for ZENPEP™ in June 2008 and the PIP was validated in July 2008. In September 2008 we received the PDCO Summary Report with the Request for Modification. We responded to the Request for Modification in March 2009, and we met with EMEA in late 2009 to discuss our submission. Satisfaction of regulatory requirements is costly, time-consuming, uncertain and subject to unanticipated delays. Even though we have completed two Phase III clinical trials with respect to ZENPEP™, we may never succeed in obtaining approval from the EMEA or any other applicable regulatory authority. Furthermore, since we currently intend to market directly ZENPEP™ in the United States and to out-license commercial rights to ZENPEP™ in many jurisdictions outside the United States, we must obtain regulatory approval in each of such jurisdictions, in addition to the approval we already obtained in the United States, which vary in their approval procedures, requirements and review. ZENPEP™ may fail to receive and maintain regulatory approval in certain jurisdictions for many reasons, including:

- our failure to demonstrate to the satisfaction of the EMEA or any other applicable regulatory authority that ZENPEP™ is safe and effective for a particular indication;
- our failure to demonstrate to the satisfaction of the EMEA or any other applicable regulatory authority that ZENPEP™ is safe and effective for a particular indication;
- our inability to demonstrate that the benefits of ZENPEP™ outweigh its risks;
- disagreement of the EMEA or any other applicable regulatory authorities with the manner in which we interpret the results from clinical trials;
- failure of the EMEA or any other applicable regulatory authorities to approve our manufacturing processes or facilities; and

- a change in the approval policies or regulations of the EMEA or any other applicable regulatory authority, or a change in the laws governing the approval process.

If we are unable to obtain adequate reimbursement for ZENPEP™ from government health administration authorities, private health insurers and other organizations, ZENPEP™ may be too costly for regular use and our ability to generate revenues would be harmed.

ZENPEP™ was only recently approved by the FDA, and accordingly, we do not have established insurance coverage or third-party reimbursement policies for ZENPEP™. Our future revenues and profitability will be adversely affected if governmental, private third-party payors and other third-party payors, including Medicare and Medicaid, do not sufficiently defray the cost of ZENPEP™ to the consumer. If these entities do not provide coverage and reimbursement for ZENPEP™ or determine to provide an insufficient level of coverage and reimbursement, ZENPEP™ may be too costly for general use, and physicians may not prescribe it. Many third-party payors cover only selected drugs, making drugs that are not preferred by such payor more expensive for patients, and often require prior authorization or failure on another type of treatment before covering a particular drug.

In addition to potential restrictions on coverage, the amount of reimbursement for our products may adversely affect results of operations. In the United States and elsewhere, there have been, and we expect there will continue to be, actions and proposals to control and reduce healthcare costs. Government and other third-party payors are challenging the prices charged for healthcare products and increasingly limiting and attempting to limit both coverage and level of reimbursement for prescription drugs.

If adequate coverage and reimbursement by third-party payors is not available, our ability to successfully commercialize ZENPEP™ may be adversely impacted. Prior to establishing pricing and reimbursement arrangements, we intend to deploy marketing strategies designed to make ZENPEP™ affordable for patients. In the event we are not able to successfully deploy such strategies, the market share of ZENPEP™ and our revenue may suffer. Any limitation on the use of ZENPEP™ or any decrease in the price of ZENPEP™ will have a material adverse effect on our business.

Risks Related to Our Business

We depend on the success of our existing products. If we are unable to maintain our existing arrangements with our licensees or fail to establish new licensing arrangements, our business and growth prospects will suffer.

Product sales and royalties of our top ten products accounted for approximately 69%, 68% and 67% of our total revenue in 2006, 2007 and 2008, respectively, and 74% for the nine months ended September 30, 2009. We depend on our arrangements with licensees and marketing collaborators to sell the majority of our products. If our licensees or marketing collaborators discontinue sales of our products, seek alternative or additional suppliers for the same or similar products or fail to satisfy their obligations under their agreements with us, or we are unable to establish new licensee and marketing relationships, our growth prospects would be materially harmed. For example, in 2006, a large customer for one of our cardiovascular products brought in a second supplier of the product, reducing their purchases from us by approximately €2.0 million (or \$2.8 million). In addition, if our licensees and marketing collaborators do not manage their inventory levels successfully, it could negatively impact our business and increase the volatility of our operating results. For example, in 2004, one of our major customers built up inventory levels of a product we supply to them; accordingly, their purchases in 2005 were substantially less than anticipated.

In addition, we may develop a proprietary product that competes directly with products that we currently supply to our existing licensees. This may have an adverse effect on our relationship with our licensees. For example, ZENPEP™ competes directly with existing PEPs that we supply to Axcan in the United States. Alternatively, a licensee could merge with or be acquired by another company, or experience financial or other setbacks unrelated to our arrangement that could affect such licensee's ability to perform its obligations under their agreement with us. The loss of licensees could materially adversely affect our business and financial condition.

Disputes may arise involving the contractual obligations of our customers, licensees or marketing collaborators to purchase our products or pay royalties on the sale of our products, and such disputes, if not resolved in our favor, could result in decreased revenues and material harm to our business.

Disputes may arise between us and a customer, licensee or marketing collaborator and may involve the issue of the obligation of the customer, licensee or marketing collaborator to continue to purchase our products and pay royalties on the sale of our products. Such a dispute could result in expensive arbitration or litigation, which may not be resolved in our favor.

We have a few key suppliers and the loss of one of these suppliers could interrupt the manufacturing of one or more of our products. Some of such suppliers are our sole source for key materials.

The FDA, EMEA and other applicable regulatory agencies each require us to identify to them any supplier of materials used in our products. We currently have a non-exclusive supply agreement with Nordmark Arzneimittel GmbH & Co, or Nordmark, under which Nordmark manufactures and supplies us with the pancreatin used in our ZENPEP™ formulation. Nordmark is currently our sole source for the pancreatin used in ZENPEP™. We also rely on a sole source for two coating materials, Ethocel and Shellac, used in our Diffucaps and Microcaps technologies. We have short term contractual agreements with these sole source suppliers. In the event that we are unable to obtain these materials from our current suppliers on acceptable terms, and are required to replace these products with alternatives, if such exist, the FDA or the EMEA may require additional testing and prior review and approval before they permit us to use the new supplier. It would typically take one year to identify and approve a new supplier. The loss of one of our current suppliers or any significant decrease or interruption in supply could interrupt the manufacture of our products. Furthermore, the FDA or the EMEA could extend these delays in situations where it requires approval of an alternative supplier. The loss of one of these sole suppliers could have a material adverse effect on our business.

Any difficulties with, or interruptions of, our manufacturing could delay our output of products and harm our relationships with our collaborators. If we are unable to continue to manufacture our existing products, our results of operations and future prospects will suffer.

Any difficulties with or interruptions of our manufacturing could delay our output of products and harm our relationships with our collaborators. We manufacture most of our products at our facilities in Milan, Italy and Dayton, Ohio. Due to regulatory and technical requirements, we have limited ability to shift production among our facilities or to outsource any part of our manufacturing to third parties. Damage to any of our manufacturing facilities caused by human error, physical or electronic security breaches, power loss or other failures or circumstances beyond our control, including acts of God, fire, explosion, flood, war, insurrection or civil disorder, acts of, or authorized by, any government, terrorism, accident, labor trouble or shortage, or inability to obtain material, equipment or transportation, could interrupt or delay our manufacturing or other operations. Furthermore, all of our employees in Europe, except our Chief Executive Officer, are subject to collective bargaining agreements, and national labor disputes could result in a work stoppage or strike by employees that could delay or interrupt our output of products. Due to the nature of these collective bargaining agreements, we have no control over such work stoppages or strikes by our employees in Europe, and a strike may occur even if our employees do not have any grievances against us. Any interruption in manufacturing, whether due to limitations in manufacturing capacity or arising from factors outside our control, could result in delays in meeting contractual obligations and could have a material adverse effect on our relationships with our collaborators and on our revenues.

The FDA, the EMEA and other applicable authorities periodically inspect our facilities to ensure compliance with various regulations, including those relating to current good manufacturing practice, or cGMP. In addition, the U.S. Drug Enforcement Agency, or DEA, applicable E.U. authorities and other applicable regulatory authorities must approve our facilities and processes for handling controlled substances. Those agencies may monitor our use of controlled substances and we may be subject to inspections evaluating our compliance with the use and handling of controlled substances. Our failure to comply with such requirements and standards of these agencies could result in the suspension of our manufacturing or closure of our facilities, which could have a material adverse effect on our business.

Development of pharmaceutical products is expensive, time-consuming and subject to uncertainties, and we may not realize a return on our investment in product development for a significant period of time, if at all.

Developing pharmaceutical products is expensive, and there is typically a significant amount of time prior to realizing a return on an investment in product development, if a return is realized at all. In 2006, 2007 and 2008, our research and development expenses were €16.3 million or approximately 20% of our revenues, €17.1 million or approximately 20% of our revenues, and €20.3 million or approximately 21% of our revenues, respectively. For the nine months ended September 30, 2009, our research and development expenses were €18.2 million (or \$26.2 million), or approximately 20.2% of our revenues.

To obtain regulatory approval for the sale of any product candidates, extensive clinical trials must demonstrate that our products are safe and effective for use in humans. Clinical trial costs are included in our research and development expenses and may take years to complete. We cannot be sure that we or our collaboration partners will complete clinical testing within the time we anticipate or that we or they will be able to do so without requiring significant resources or expertise in excess of what we anticipate. Completion of clinical trials depends on various factors, including the indication and size of the patient population and its proximity to clinical sites, the nature of the clinical protocol, the eligibility of the criteria for trial, competition for trial patients, availability of sufficient quantities of a product candidate, the assistance of third parties, regulatory compliance and adequate financial resources.

Our future plans include significant investments in research and development, including clinical trials, and related product opportunities. We believe that we must continue to dedicate a significant amount of financial and operational resources to our research and development efforts to grow our business and maintain our competitive position. However, we do not expect to receive significant revenues from these investments for several years, if at all.

We rely on third parties to conduct, supervise and monitor our clinical trials, and those third parties may perform in an unsatisfactory manner, such as by failing to meet established deadlines for the completion of such trials.

We rely in large part on third parties such as contract research organizations, or CROs, medical institutions and clinical investigators to enroll qualified patients and conduct, supervise and monitor our clinical trials. For example, we used CROs to monitor, supervise and compile data on our two Phase III clinical trials for ZENPEP™. Our reliance on these third parties for clinical development activities reduces our control over these activities. Our reliance on these third parties, however, does not relieve us of our regulatory responsibilities, including ensuring that our clinical trials are conducted in accordance with good clinical practice regulations, or GCP, and the investigational plan and protocols contained in the relevant regulatory application, such as the investigational new drug application. In addition, they may not complete activities on schedule, or may not conduct our preclinical studies or clinical trials in accordance with regulatory requirements or our trial design. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, our efforts to obtain regulatory approvals for, and to commercialize, our product candidates may be delayed or prevented.

There is a high risk that our product candidates will not have successful clinical trial results and will not advance to the regulatory approval stage.

We will only receive regulatory approval to commercialize a product candidate if we can demonstrate to the satisfaction of the FDA, the EMEA, or other applicable regulatory authorities, in adequate, well-designed and properly conducted clinical trials, that the product candidate is safe and effective and otherwise meets the appropriate standards required for approval for a particular indication. Clinical trials are lengthy, complex and extremely expensive processes with uncertain results. A failure or delay of one or more of our or our collaborators' clinical trials may occur at any stage of testing. Historically, favorable results from preclinical studies and early clinical trials have often not been confirmed in later clinical trials. Many companies in the pharmaceutical industry have experienced significant setbacks in advanced clinical trials or during the regulatory approval process, despite promising results. The effects of our product candidates may be different than expected or may include undesirable side effects that delay, extend or preclude regulatory approval or limit their commercial use if approved.

A number of events or factors, including any of the following, could delay the completion of our and our collaborators' ongoing and planned clinical trials and negatively impact our ability to market and sell, a particular product or product candidate, including the recently approved ZENPEP™:

- conditions imposed on us or our collaborators by the FDA, the EMEA or other applicable regulatory authorities, regarding the scope or design of our clinical trials;
- the results of clinical trials may not meet the level of statistical significance required for approval by the FDA, the EMEA or other applicable regulatory authorities;
- the FDA, the EMEA or other applicable regulatory authorities may require additional or expanded trials;
- delays in obtaining, or the inability to obtain or maintain, required approvals from institutional review boards, or IRBs, or other reviewing entities at clinical sites selected for participation in our clinical trials;
- insufficient supply or deficient quality of our product candidates or other materials necessary to conduct our clinical trials;
- difficulties in manufacturing the product;
- difficulties enrolling subjects and high drop-out rates of subjects in our or our collaborators' clinical trials;
- negative or inconclusive results from clinical trials, or results that are inconsistent with earlier results, that necessitate additional clinical studies;
- serious or unexpected drug-related side effects experienced by subjects in clinical trials; or
- failure of our third-party contractors or our investigators to comply with regulatory requirements or otherwise meet their contractual obligations to us in a timely manner.

Our clinical trials may not begin as planned, may need to be redesigned, and may not be completed on schedule, if at all. Delays in our clinical trials may result in increased development costs for our product candidates, which would cause the market price of our shares to decline and limit our ability to obtain additional financing. In addition, if one or more of our clinical trials are delayed, our competitors may be able to bring products to market before we do, and the commercial viability of our product candidates could be significantly reduced.

Even if we complete our clinical trials, we may never succeed in obtaining regulatory approval for any of our product candidates. Without regulatory approval, we will be unable to commercialize our product candidates, and our growth prospects will be materially impaired.

All of our product candidates must successfully complete development and gain regulatory approval before we or our collaborators can market them. Of the large number of products in development, only a small percentage result in the submission of a new drug application, or NDA, to the FDA or EMEA, and even fewer are approved for commercialization.

If the safety and efficacy of our product candidates is not demonstrated, the required regulatory approvals to commercialize these product candidates will not be obtained. Any product candidate that we or our collaborators seek to commercialize is subject to extensive regulation by the FDA, EMEA and other applicable regulatory authorities relating to the testing, manufacture, safety, efficacy, record-keeping, labeling, packaging, storage, approval, advertising, marketing, promotion, sale and distribution of drugs. In the United States and in many other jurisdictions, rigorous preclinical studies and clinical trials and an extensive regulatory review process must be successfully completed before a new drug can be sold. Satisfaction of these and other regulatory requirements is costly, time-consuming, uncertain and subject to unanticipated delays.

The time required to obtain approval by the FDA, the EMEA or other applicable regulatory authorities is unpredictable but typically it takes many years following the commencement of clinical trials, depending upon numerous factors, including the complexity of the product candidate. Our product candidates may fail to receive regulatory approval for many reasons, including:

- the failure to demonstrate to the satisfaction of the FDA, the EMEA or other applicable regulatory authorities that a product candidate is safe and effective for a particular indication;
- the inability to demonstrate that a product candidate's benefits outweigh its risks;
- the inability to demonstrate that the product candidate presents an advantage over existing products;
- disagreement of the FDA, the EMEA or other applicable regulatory authorities with the manner in which the results from preclinical studies or clinical trials are interpreted;
- failure of the FDA, the EMEA or other applicable regulatory authorities to approve the manufacturing processes or facilities of third-party manufacturers with whom we contract for clinical and commercial supplies; and
- a change in the approval policies or regulations of the FDA, the EMEA or other applicable regulatory authorities, or a change in the laws governing the approval process.

The FDA, or the EMEA or other applicable regulatory authorities, might decide that our findings are insufficient for approval and thus might require additional clinical trials or other studies. It is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain the appropriate regulatory approvals necessary for us or our collaborators to begin selling them. Furthermore, since we intend for our products to be commercialized in many jurisdictions, regulatory approval in each such jurisdiction must be obtained. The approval procedures vary among countries and can involve additional and costly preclinical studies and clinical testing and review. The time required to obtain approval in various jurisdictions may differ from that required to obtain FDA or EMEA approval, and approval by one regulatory authority, such as the FDA or EMEA, does not ensure approval by regulatory authorities elsewhere. The failure to obtain these approvals could harm our business and result in decreased revenues from lost sales, milestone payments or royalties in our co-development agreements.

Regulatory approval of a product candidate is limited to specific uses identified in the approval. Certain material changes to an approved product, such as manufacturing changes or additional label claims, are subject to further regulatory review and approval. Approval of a product candidate could also be contingent on post-marketing studies. In addition, any marketed drug and its manufacturer continue to be subject to strict regulation after approval, and any governmental approval can be withdrawn. Any problems with an approved drug or any violation of regulations could result in restrictions on the drug, including withdrawal from the market. In particular, drug manufacturers are subject to strict requirements governing their manufacturing practices and regular inspections to assess compliance with these and other requirements. Failure to comply with governmental requirements could lead to sanctions.

Regulatory approval of a product candidate in any jurisdiction is unpredictable. Despite guidance from the FDA, EMEA or other applicable regulatory agencies, there is no guarantee of obtaining approval. In addition, standards enunciated by regulatory agencies are constantly subject to change as a result of factors outside of our control. Our growth prospects will be materially impaired as a result of any delay in, or failure to receive, required regulatory approval for some or all of our product candidates.

Failure to obtain regulatory approval for our products in our markets and to retain approvals already granted will prevent us from marketing or licensing our products in these markets.

Sales of our products outside the United States and any of our product candidates that are commercialized are subject to the regulatory requirements of each country in which the products are sold. Accordingly, the introduction

of our products and product candidates in markets outside the United States will be subject to regulatory clearances in those jurisdictions.

Approval and other regulatory requirements vary by jurisdiction and may differ from the U.S. requirements. We may be required to perform additional preclinical or clinical studies even if FDA approval has been obtained. In addition, failures in European preclinical or clinical studies could impact our filings in the United States. Many countries also impose product standards, packaging and labeling requirements and import restrictions on our products. The approval by government authorities outside of the United States is unpredictable and uncertain and can be expensive. Our ability to market our approved products could be substantially limited due to delays in receipt of, or failure to receive, the necessary approvals or clearances.

In addition, changes in regulatory requirements can affect the commercial success of our existing products. For example, we are currently the exclusive supplier of coated PEPs to Axcan and X-Gen Pharmaceuticals (our current distributor of the product formerly marketed as Lipram[®]) in the United States. In 2008, revenues from these products in the United States accounted for 24% of our total revenues. In April 2004, the FDA mandated that all manufacturers of EPI drug products file a NDA and receive approval for their products by April 2008 or be subject to regulatory action. In addition, the FDA has indicated that it will continue to exercise enforcement discretion with respect to unapproved pancreatic enzyme drug products until April 2010, if the manufacturers have INDs on active status on or before April 2008, and have submitted NDAs on or before April 2009. We are unable to predict whether Axcan will receive approval of a NDA for their products by the deadline set by the FDA. Axcan has filed a NDA with the FDA in respect of the PEP we supply to them and, if such product is approved for sale in the United States, we would supply such product to them. If Axcan is unable to meet the FDA's requirements by the applicable deadline, and the FDA enforces removal of unapproved PEPs from the U.S. market, we will no longer have PEP sales to these companies in the United States.

Even if our product candidates receive regulatory approval or do not require regulatory approval, they may not become commercially viable products.

Even if our product candidates are approved for commercialization, or our products do not require approval for commercialization, they may not become commercially viable products. For example, even if we or our collaborators receive regulatory approval to market a commercial product, any such approval may be subject to limitations on the indicated uses for which we or our collaborators may market the product. In addition, a new product may appear promising at an early stage of development or after clinical trials but never reach the market, or it may reach the market and not result in product sales. A product or product candidate may not result in commercial success for various reasons, including:

- difficulty in large-scale manufacturing;
- low market acceptance by physicians, healthcare payors, patients and the medical community as a result of lower demonstrated clinical safety or efficacy compared to other products, prevalence and severity of adverse side effects, or other potential disadvantages relative to alternative treatment methods;
- insufficient or unfavorable levels of coverage or reimbursement from government or third-party payors;
- infringement on proprietary rights of others for which we have not received licenses;
- incompatibility with other drugs;
- other potential advantages of alternative treatment methods;
- ineffective marketing and distribution support;
- lack of cost-effectiveness; and
- timing of market introduction of competitive products.

If we are unable to develop commercially viable products, our business, results of operations and financial condition will be adversely affected.

Our existing products and our product candidates, if they receive regulatory approval for marketing, remain subject to ongoing regulatory requirements and, if we fail to comply with these requirements, we could lose these approvals, and the sales of any approved commercial products could be suspended.

After receipt of initial regulatory approval, each of our products remains subject to extensive post-approval regulatory requirements, including requirements relating to manufacturing, labeling, packaging, adverse event reporting, storage, advertising, promotion, distribution and record-keeping. Furthermore, if we receive regulatory approval to market a particular product candidate, the product will also remain subject to the same extensive regulatory requirements. Even if regulatory approval of a product is granted, the approval may be subject to limitations on the uses for which the product may be marketed or the conditions of approval, or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product, which could reduce our revenues, increase our expenses and render the approved product candidate not commercially viable. In addition, as clinical experience with a drug expands after approval because it is typically used by a greater number and more diverse group of patients after approval than during clinical trials, side effects and other problems may be observed after approval that were not seen or anticipated during pre-approval clinical trials or other studies. Any adverse effects observed after the approval and marketing of a product candidate could result in limitations on the use of such approved product or its withdrawal from the marketplace. Absence of long-term safety data may also limit the approved uses of our products, if any. If we or our collaborators fail to comply with the regulatory requirements of the FDA, the EMEA and other applicable regulatory authorities, or if previously unknown problems with any approved commercial products, manufacturers or manufacturing processes are discovered, we could be subject to administrative or judicially imposed sanctions or other setbacks, including:

- restrictions on the products, manufacturers or manufacturing processes;
- warning letters and untitled letters;
- civil penalties and criminal prosecutions and penalties;
- fines;
- injunctions;
- product seizures or detentions;
- import or export bans or restrictions;
- voluntary or mandatory product recalls and related publicity requirements;
- suspension or withdrawal of regulatory approvals;
- total or partial suspension of production; and
- refusal to approve pending applications for marketing approval of new products or of supplements to approved applications.

If we or our collaborators are slow or unable to adapt to changes in existing regulatory requirements or the promulgation of new regulatory requirements or policies, we or our collaborators or licensees may lose marketing approval for our products, resulting in decreased revenue from milestone payments, product sales or royalties and may potentially impact our ability to conduct business in the future.

If we fail to comply with the laws governing the marketing and sale of our products, regulatory agencies may take action against us, which could significantly harm our business.

As a pharmaceutical company, we are subject to a large body of legal and regulatory requirements. In particular, there are many federal, state and local laws that we need to comply with now that we are engaged in the marketing, promoting, distribution and sale of pharmaceutical products. The FDA extensively regulates, among other things, promotions and advertising of prescription drugs. In addition, the marketing and sale of prescription drugs must comply with the Federal fraud and abuse laws, which are enforced by the Office of the Inspector General of the Division, or OIG, of the Department of Health and Human Services. These laws make it illegal for anyone to give or receive anything of value in exchange for a referral for a product or service that is paid for, in whole or in part, by any federal health program. The federal government can pursue fines and penalties under the Federal False Claims Act which makes it illegal to file, or induce or assist another person in filing, a fraudulent claim for payment to any governmental agency.

Because, as part of our commercialization efforts, we provide physicians with samples we must comply with the Prescription Drug Marketing Act, or PDMA, which governs the distribution of prescription drug samples to healthcare practitioners. Among other things, the PDMA prohibits the sale, purchase or trade of prescription drug samples. It also sets out record keeping and other requirements for distributing samples to licensed healthcare providers.

In addition, we must comply with the body of laws comprised of the Medicaid Rebate Program, the Veterans' Health Care Act of 1992 and the Deficit Reduction Act of 2005. This body of law governs product pricing for government reimbursement and sets forth detailed formulas for how we must calculate and report the pricing of our products so as to ensure that the federally funded programs will get the best price.

Moreover, many states have enacted laws dealing with fraud and abuse, false claims, the distribution of prescription drug, drug samples and gifts, and the calculation of best price. These laws typically mirror the federal laws but in some cases, the state laws are more stringent than the federal laws and often differ from state to state, making compliance more difficult. We expect more states to enact similar laws, thus increasing the number and complexity of requirements with which we would need to comply.

Compliance with this body of laws is complicated, time consuming and expensive. We are a relatively small company that only recently began directly commercializing pharmaceutical products. As such, we have very limited experience in developing and managing, and training our employees regarding, a comprehensive healthcare compliance program. We cannot assure you that we are or will be in compliance with all potentially applicable laws and regulations. Even minor, inadvertent irregularities can potentially give rise to claims that the law has been violated. Failure to comply with all potentially applicable laws and regulations could lead to penalties such as the imposition of significant fines, debarment from participating in drug development and marketing and the exclusion from government-funded healthcare programs. The imposition of one or more of these penalties could adversely affect our revenues and our ability to conduct our business as planned.

In addition, the Federal False Claims Act, which allows any person to bring suit alleging the submission or the causing of submission of false or fraudulent claims for payment under federal programs and other violations of the statute and to share in any amounts paid by the entity to the government in fines or settlement. Such suits, known as qui tam actions, have increased significantly in recent years and have increased the risk that companies like us may have to defend a false claim action. We could also become subject to similar false claims litigation under state statutes. If we are unsuccessful in defending any such action, such action may have a material adverse effect on our business, financial condition and results of operations.

Rapid technological change could make our products, product candidates or technologies obsolete.

Pharmaceutical technologies and products are subject to rapid and significant technological change. We expect our competitors will develop new technologies and products that may render our products and pharmaceutical technologies uncompetitive or obsolete. The products and technologies of our competitors may be more effective than the products, product candidates and technologies developed by us. As a result, our products and product candidates may become obsolete before we recover expenses incurred in connection with their development or

realize revenues from any commercialized product. We are aware of other pharmaceutical companies that are developing competing technologies, which could render ZENPEP™ obsolete. For example, other pharmaceutical companies, including Biovitrum, Meristem and Solvay, have or had been developing microbial or synthetic enzyme products for the treatment of EPI. Altus announced in a November 2006 press release that it planned to initiate a Phase III clinical trial for its PEP in the second quarter of 2007. In late 2008, Altus announced it was suspending development of its synthetic enzyme product for the treatment of EPI. In mid 2009 Alnara Pharmaceuticals Inc. announced that it had acquired the Altus synthetic enzyme product from the Cystic Fibrosis Foundation and was proceeding with additional clinical development. Biovitrum announced in its full year report for 2006 that its PEP was in Phase II. Meristem announced on its website that the Phase I safety study and two Phase II studies for its PEP were complete and that the product was currently undergoing formulation optimization testing. If successful, such competing products could limit the potential success of ZENPEP™, and our growth prospects will be materially impaired.

We depend on our senior management and other key personnel to manage the growth of our business, and if we fail to attract and retain additional key personnel, we may not be able to expand our business or manage our growth effectively.

Our success depends significantly upon the continued service and performance of our senior management and other key personnel. High demand exists for senior management and other key personnel in the pharmaceutical industry. The loss of any of these people may negatively impact our ability to manage our company effectively and to carry out our business plan. In particular, we rely on the contributions of our senior management team, which consists of Gearóid Faherty, our Chief Executive Officer and Chairman, Mario Crovetto, our Chief Financial Officer, John Fraher, our Chief Commercial Officer, and Manya S. Deehr, our Chief Legal Officer and Corporate Secretary, and their continued service is critical to our success. Our senior management team is responsible for the development and implementation of our business strategy. Other key personnel include Michael Walters, Executive Vice President, Ruth Thieroff-Ekerdt, M.D., Chief Medical Officer and Robert Becker, M.D., Chief Research Officer. The loss of service of any member of our senior management team or key personnel could delay or prevent the successful completion of our planned clinical trials or the commercialization of our product candidates. Of our senior management team, only Mr. Faherty and Mr. Walters have employment agreements. Notwithstanding his employment agreement, Mr. Faherty may resign at any time.

As we advance our product candidates through clinical trials to commercialization, we will need to expand our marketing and sales capabilities. Future growth will impose significant added responsibilities on members of management. Our future financial performance and our ability to commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to manage our development efforts and clinical trials effectively and hire, train and integrate additional management, administrative and sales and marketing personnel. We may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successfully growing our company.

In addition, our growth and success depend on our ability to attract and retain additional highly qualified scientific, technical, clinical, sales, managerial and finance personnel. Intense competition exists among other companies and research and academic institutions for qualified personnel. If we cannot attract and retain sufficiently qualified technical employees on acceptable terms, we may not be able to develop and commercialize competitive products.

The failure to maintain our existing co-development relationships on acceptable terms could adversely affect our ability to develop and commercialize our product candidates and our future growth prospects.

We frequently enter into co-development agreements to create relationships for the purpose of exploring development opportunities with collaboration partners. In 2008, we entered into six co-development agreements with various collaborators and we continue to negotiate additional co-development agreements. In general, our co-development agreements involve feasibility studies and early-stage development activities whereby we receive an hourly service fee for research and development and, in some instances, may receive additional milestone payments based on the achievement of certain development goals within specified timeframes. Accordingly, our receipt of revenue in a given period during the development phase is dictated in part by the speed at which development goals are met and the time and resources that a collaboration partner wishes to dedicate to development in such period. In some instances, we and our collaboration partner decide to negotiate and include provisions in a co-development

agreement that will govern our relationship from development through commercialization. In other instances, we and our collaboration partner elect to define our relationship for the development phases and, if development is promising, may elect to enter into a subsequent agreement that further defines our relationship for subsequent periods of a product's or product candidate's life. The likelihood of completing development or progressing past development is highly uncertain notwithstanding the inclusion of provisions that govern the relationship through commercialization. Thus, the existence of such provisions, which could provide for the payment of royalties and sales milestones based on the success of the product, is not indicative of the likelihood that we will receive such payments. We believe we are not substantially dependent on any of our co-development agreements individually; however, the maintenance of such relationships is important to our growth prospects because of the potential that a co-development relationship could evolve into a licensing and supply relationship that could generate significant revenue from licensing fees, product sales, sales milestone payments and/or royalties.

Our obligations under our co-development agreements can include performance of development activities, such as feasibility studies, formulation optimization, stability testing and scale-up of the manufacturing process, supply of the product to the collaborator for clinical testing, assistance in the preparation of regulatory filings by our collaborator and supply of the product for sale by our collaborator. If we fail to meet certain of these obligations, we may lose our rights to certain development fees and future royalty and milestone payments, and our collaboration partners may have the right to terminate the agreement. In addition, many of our agreements allow for the collaboration partner to terminate the agreement with limited notice and without penalty or in the event the collaborator reasonably determines that the product does not justify continued development or commercialization. We have completed work under some of these agreements without developing a commercial product and, based on past experience, it is likely that a number of these agreements will not progress to the stage where the product is actually commercialized. In addition, even if our collaborators choose not to terminate an agreement, the risk still remains that the collaborator could decide not to launch a particular product. The loss of a collaboration partner as a result of either our failure to meet our obligations or early termination by the collaboration partner could affect our results of operations and future growth prospects.

Furthermore, our success is in part based upon a reputation that we are an attractive collaborator for leading pharmaceutical companies seeking to enhance existing products or to develop new products. For example, two of our co-development products, EUR-1048 and EUR-1000, are being developed in collaboration with GlaxoSmithKline, or GSK (acquired Reliant Pharmaceuticals in December 2007), and Amrix is being commercialized in collaboration with Cephalon, Inc. (acquired Amrix from ECR Pharmaceuticals in August 2007). If we fail to meet our obligations under these and other existing co-development agreements, we may diminish our reputation and decrease our potential future co-development opportunities.

If we are not successful in establishing and maintaining additional co-development relationships, our growth prospects will be materially harmed.

An important element of our business strategy is to establish co-development relationships with third parties to co-develop particular products or to accelerate the development of some of our early-stage product candidates. The process of establishing new co-development relationships is difficult, time-consuming and involves significant uncertainty. We face, and will continue to face, significant competition in seeking appropriate collaboration partners. Moreover, if we do establish co-development relationships, our collaborators may fail to fulfill their responsibilities or may seek to renegotiate or terminate their relationships with us due to unsatisfactory clinical results, a change in business strategy, a change of control or other reasons. In many cases, our collaborators may terminate their relationships with us with limited notice and without penalty or in the event the collaborator reasonably determines that the product does not justify continued development or commercialization. If we are unable to establish and maintain co-development arrangements on acceptable terms, we may have to delay or discontinue further development of one or more of our product candidates, seek regulatory approval or undertake commercialization activities at our own expense or find alternative sources of funding, and our growth prospects will be materially harmed.

We rely on our collaboration partners and licensees to successfully commercialize products using certain of our technologies, and we cannot control the actions of such collaborators and licensees. If we, our collaboration partners or licensees are unable to commercialize our co-development product candidates or if we, our collaboration partners or licensees experience significant delays in such commercialization, our growth prospects will be materially harmed.

Our arrangements with collaboration partners and licensees are critical to our success in bringing certain of our products and product candidates to market. In particular, we have invested and expect to continue investing significant time and financial resources in the development of our co-development products. We depend on our collaboration partners to conduct preclinical studies and clinical trials, as may be necessary, and to provide funding for our development of these product candidates. Furthermore, in most instances we rely on collaborators to commercialize our co-development products. If we or a significant number of our collaborators are unable to commercialize our co-development products or experience significant delays in such commercialization, our growth prospects will be materially harmed. The successful commercialization of a product or product candidate will depend on numerous events or factors, including:

- successfully completing preclinical studies and clinical trials and any additional trials and tests required by the FDA, the EMEA or other applicable regulatory authorities;
- receiving marketing approvals, to the extent required, from the FDA, the EMEA or other applicable regulatory authorities; and
- obtaining commercial acceptance, if approved, from the medical community and third-party payors.

We cannot control our collaborators' or licensees' performance or the resources they devote to our projects, and some of our collaborators can terminate their agreements with us for no reason and on limited notice. If a collaborator fails to perform as expected, we may have to use funds, personnel, laboratories and other resources that we have not budgeted for, or we may not be able to continue the particular project affected.

We generally expect a number of the new co-development agreements we enter into to terminate without significant development activity. A collaboration partner may choose to use its own or one of our competitors' technologies to develop a way to reformulate its drug and thus withdraw its support of our product candidate. Alternatively, we may develop a proprietary product candidate that competes directly with products that we currently manufacture for a collaboration partner. In addition, a collaboration partner could merge with or be acquired by another company, or experience financial or other setbacks unrelated to our collaboration that could jeopardize the co-development project. The loss of collaborators or projects could materially adversely affect our business, growth prospects and financial condition.

In addition, we currently manufacture for commercial distribution a number of drugs that are the subject of NDAs that have been approved or other applicable regulatory approval held by our collaborators and licensees. We also manufacture products for distribution and sales by our collaborators and licensees that we believe are exempt from the requirements for FDA approval, generally because the FDA has determined that the product does not need such approval. We also use third-party suppliers to provide bulk active drugs used in our products. Because our customers and suppliers are also subject to FDA regulation, our continued development and manufacturing of these products depends not only on our own compliance with FDA requirements but also on the compliance of customers and suppliers over whom we have no control.

Acquisitions are part of our growth strategy, and we may fail to execute this aspect of our strategy or to successfully integrate any acquired business.

As part of our growth strategy, we evaluate and pursue acquisitions of other businesses, technologies or products. We may not identify appropriate acquisition candidates or successfully consummate any of these acquisitions. To consummate any acquisition, we may need to incur additional debt or issue additional equity securities that dilute your interest. Depending on market conditions, we may not be able to obtain necessary financing for any acquisitions on terms acceptable to us, or at all. In addition, we may be required to pay external costs such as legal

advisory, market research consultancy and due diligence fees related to our pursuit and evaluation of potential acquisitions, even if the acquisitions are never consummated. For example, in 2005 we recorded a charge of €73,000 (or \$1.4 million) for such external costs related to two potential acquisitions that were not consummated.

Even if we are successful in completing one or more acquisitions, the failure to adequately address the financial, operational or legal risks of these transactions could harm our business. Accounting for acquisitions can require impairment losses or restructuring charges, large write-offs of in-process research and development expenses and ongoing amortization expenses related to other intangible assets. We also may incur unexpected or contingent liabilities in connection with acquisitions. In addition, integrating acquisitions can be difficult, and could disrupt our business and divert management resources. If we are unable to manage the integration of any acquisitions successfully, our ability to develop new products and continue to expand our product pipeline may be impaired.

We are exposed to political, economic and other risks that arise from operating a multinational business.

We have operations in several different countries. For the years ended December 31, 2006, 2007 and 2008, approximately 60%, 60% and 52% of our revenues, respectively, and for the nine months ended September 30, 2009, approximately 41% of our revenues were derived from sources outside the United States. We are therefore exposed to risks inherent in international operations. These risks include, but are not limited to:

- changes in general economic, social and political conditions;
- adverse tax consequences;
- the difficulty of enforcing agreements and collecting receivables through certain legal systems;
- inadequate protection of intellectual property;
- required compliance with a variety of laws and regulations of jurisdictions outside of the United States, including labor and tax laws;
- customers outside of the United States may have longer payment cycles;
- changes in laws and regulations of jurisdictions outside of the United States; and
- terrorist acts and natural disasters.

Our business success depends in part on our ability to anticipate and effectively manage these and other regulatory, economic, social and political risks inherent in multinational business. We cannot assure you that we will be able to effectively manage these risks or that they will not have a material adverse effect on our multinational business or on our business as a whole.

Currency exchange rate fluctuations may have a negative effect on our financial condition.

We are exposed to fluctuations in currency from purchases of goods, services and equipment and investments in other countries and funding denominated in the currencies of other countries. In particular, we are exposed to the fluctuations in the exchange rate between the U.S. dollar and the euro. During 2008, approximately 45% of our revenues was denominated in euros, while the remainder is denominated in U.S. dollars. During the nine months ended September 30, 2009, approximately 30% of our revenues was denominated in euros, while the remainder is denominated in U.S. dollars. We anticipate that the majority of revenue from commercialization of our products and product candidates will be in U.S. dollars and euros. Fluctuations in currency exchange rates may affect our results of operations and the value of our assets and revenues, and increase our liabilities and costs, which in turn may adversely affect reported earnings and the comparability of period-to-period results of operations. For example, in 2008, we experienced a negative foreign exchange effect on revenues of approximately 5%. Changes in currency exchange rates may affect the relative prices at which we and our competitors sell products in the same market.

Changes in the value of the relevant currencies also may affect the cost of goods, services and equipment required in our operations.

In addition, due to the constantly changing currency exposures and the potential substantial volatility of currency exchange rates, we cannot predict the effect of exchange rate fluctuations on our future results and, because we do not currently hedge fully against all currency risks and fluctuations between the U.S. dollar and the euro, such fluctuations may result in currency exchange rate losses. Fluctuations in exchange rates could result in our realizing a lower profit margin on sales of our product candidates than we anticipate at the time of entering into commercial agreements. Adverse movements in exchange rates could have a material adverse effect on our financial condition and results of operations. See “Quantitative and Qualitative Disclosures about Market Risk — Exchange Rate Risk” included herein.

Our competitors may develop products that are less expensive, safer or more effective than, and may diminish or prevent the commercial success of, any product candidates that we may bring to market. In addition, our proprietary products may compete with products we develop and manufacture for our collaborators or with our collaborators’ other products.

We face intense competition from pharmaceutical and biotechnology companies, including other drug formulation companies, contract research organizations, academic institutions and government agencies. Some of these competitors are also our collaboration partners.

Our competitors may be able to use alternative technologies that do not infringe upon our patents to formulate the active materials in our product; for example, alternative orally disintegrating tablets, particle-coating or controlled-release drug formulation technologies. They may, therefore, bring to market products that are able to compete with ZENPEP™, EUR-1025, Amrix, co-development products, such as EUR-1047 or EUR-1000, or other products that we have developed or may in the future develop. For example, in 2007 Par Pharmaceuticals Companies, Inc. and Mylan Pharmaceuticals, Inc. each received approval from the FDA for a generic form of Inderal LA that would compete with EUR-1000. If successful, products derived from alternative technologies will compete against our products and product candidates. Competing technologies include the multiple-particle systems of Watson, Biovail and Elan; the controlled-release tablet technologies of Penwest and SkyePharma; and the solubility- enhancement technologies of Elan, SkyePharma and Soliqs, a division of Abbott. The products derived from these technologies may be safer or more efficacious than our products and product candidates.

Potential products being tested in the United States and Europe of which we are not currently aware may also compete with product candidates using our drug formulation systems. Our collaboration partners could choose a competing drug formulation system to use with their drugs instead of ours. In addition, our collaboration partners themselves face competition with other major pharmaceutical companies on products using our drug formulation technologies, which could adversely impact the potential for our technologies and co-development products, as well as our royalty revenues and business and financial condition.

Many of our competitors have greater capital resources, manufacturing and marketing experience, research and development resources and production facilities than we have. Many of them also have more experience than we do in preclinical studies and clinical trials of new drugs and in obtaining FDA, EMEA and other applicable regulatory approvals or, as with some competitors, are already established in the market. In addition, their success in obtaining patents may make it difficult or impossible for us to compete with them.

Major technological changes can happen quickly in the drug formulation and pharmaceutical industries. Our competitors’ development of technologically improved or different products may make our technologies and product candidates obsolete or noncompetitive.

In addition, our proprietary products may compete with products we develop and manufacture for our collaborators or with our collaborators’ other products. Some of these products may target the same diseases and conditions that are the focus of our drug development programs. For example, Axcan, whose coated PEP product has been licensed from us, has filed an NDA for the product with the FDA. If approved, Ultrase would compete with ZENPEP™.

Our revenue is currently dependent upon a small number of customers, the loss of any one of which could have a material adverse impact on our business, financial condition and results of operations.

Our revenue is currently dependent upon a small number of customers. Our top two customers together accounted for 24%, 27% and 29% of revenues in 2006, 2007 and 2008, respectively, and 13%, 11% and 16% of the accounts receivable balance as of December 31, 2006, 2007 and 2008, respectively. Our largest customer, Axcan, accounted for 18%, 17% and 23% of revenues in 2006, 2007 and 2008, respectively, and 12%, 8% and 7% of the accounts receivable balance as of December 31, 2006, 2007 and 2008, respectively. Our second largest customer in 2006, 2007 and 2008 was Eisai, GSK and Cephalon, respectively, and each accounted for 6%, 10% and 7% of our revenues, respectively. In the nine months ended September 30, 2009, our top two customers together accounted for 38% of our revenues. In the nine months ended September 30, 2009, our largest customer, Axcan, and our second largest customer, Cephalon, accounted for 30% and 8% of our revenues respectively. The loss of either of our top two customers could have a material adverse effect on our business, financial condition and results of operations. For example, we are currently the exclusive supplier of coated PEPs to Axcan in the United States. The FDA has indicated that it will require the removal from the U.S. market by April 2010 of PEPs that do not have approved NDAs under its recently published guidance. We are unable to predict whether Axcan will receive approval of a NDA for its product by the April 2010 deadline set by the FDA. If Axcan is unable to meet the FDA's requirements by April 2010, and the FDA enforces removal of unapproved PEPs from the U.S. market, we will no longer have PEP sales to this customer in the United States. Additionally, our recently approved product ZENPEP™, will compete with Axcan's product.

Approximately 75% of employees are represented by collective bargaining or other labor agreements or arrangements, and we could face labor disruptions that would interfere with our operations.

Approximately 75% of our employees are represented by collective bargaining or other labor agreements or arrangements that provide greater bargaining or other rights to employees than do the laws of the United States. Such employment rights require us to expend greater time and expense in making changes to employees' terms of employment or carrying out staff reductions. In addition, many of our employees are located in Italy and France, where national strikes occur, and our employees may strike even if they do not have a grievance against us. While we believe that our relations with our employees are satisfactory, worker disruption on a local or national level or a significant dispute with our employees could have a material adverse effect on our business, financial position, results of operations and cash flows.

Risks Related to Intellectual Property

Patent protection for our products is important and uncertain.

Our success will depend, in part, on our ability and the ability of our licensees and collaboration partners to obtain patent protection for our technologies and product candidates, maintain the confidentiality of our trade secrets and know how, operate without infringing on the proprietary rights of others and prevent others from infringing our proprietary rights.

We try to protect our proprietary position by, among other things, filing U.S., European and other patent applications related to our proprietary products, technologies, inventions and improvements that may be important to the continuing development of our technology portfolio. Currently, our patent portfolio consists of over 300 issued patents and over 250 pending applications, and it includes patents which protect our Diffucaps[®], Microcaps[®], Advatab[®], Biorise[®] bioavailability enhancement, and polymer conjugation technologies. In addition, we believe features of EUR-1025 and our co-development products and product candidates are specifically covered by certain patents or patent applications in our portfolio.

Because the patent position of biopharmaceutical companies involves complex legal and factual questions, we cannot predict the validity and enforceability of patents with certainty. Our issued patents and the issued patents of our licensees or collaboration partners may not provide us with any competitive advantages, or may be held invalid or unenforceable as a result of legal challenges by third parties. Thus, any patents that we own or license from others may not provide any protection against competitors. Our pending patent applications, those we may file in the future or those we may license from third parties may not result in patents being issued. If these patents are issued, they

may not provide us with proprietary protection or competitive advantages against competitors with similar technology. The degree of future protection to be afforded by our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage.

Patent rights are territorial; thus, the patent protection we do have will only extend to those countries in which we have issued patents. Even so, the laws of certain countries do not protect our intellectual property rights to the same extent as do the laws of the United States and various European countries. Competitors may successfully challenge our patents, produce similar drugs or products that do not infringe our patents, or produce drugs in countries where we have not applied for patent protection or that do not respect our patents. Additionally, the nature of claims contained in unpublished patent filings around the world is unknown to us and it is not possible to know which countries patent holders may choose for the extension of their filings under the Patent Cooperation Treaty, or other mechanisms. Furthermore, it is not possible to know the scope of claims that will be allowed in published applications and it is also not possible to know which claims of granted patents, if any, will be deemed enforceable in a court of law.

Although we have sought to supplement regulatory exclusivity with patent protection for ZENPEP™, we may not ultimately receive any issued patents or related patent rights, and in any event such patents and related patent rights will only be available after we begin to commercialize ZENPEP™ in the United States, which may expose ZENPEP™ to increased competition.

We have filed four patent applications in the United States as well as an international application under the Patent Cooperation Treaty, or PCT, and national patent applications in Argentina, Chile and Taiwan with claims related to ZENPEP™. The PCT will provide priority for any foreign applications that we may file for these inventions. The applications include claims intended to provide market exclusivity for certain commercial aspects of the product, including the formulation, the methods of making, the methods of using and the commercial packaging of the product. We also maintain as trade secrets or know-how certain of the technology used in developing or manufacturing ZENPEP™.

However, we may not ultimately receive any issued patents or related patent rights, and even if we do, such patent protection may not prevent our competitors from developing similar products using different processes that are not covered by such a patent or patents. The disclosure to, or independent development by, a competitor of certain trade secrets or know-how could materially adversely affect any competitive advantage we may have over any such competitor. Furthermore, we will receive any issued patents or related patent rights after we begin to commercialize ZENPEP™ in the United States. If the FDA decides to accept ANDA applications for generic PEPs or otherwise limit regulatory exclusivity for the product, the timing of any patent protection may expose ZENPEP™ to increased competition from alternative products.

If we are unable to protect the confidentiality of our trade secrets or know-how, such proprietary information may be used by others to compete against us.

We rely on a combination of patents, trade secrets, know-how, technology, trademarks and regulatory exclusivity to maintain our competitive position. For example, while we have filed for patent protection for commercial aspects of ZENPEP™ in the United States and abroad, we also currently maintain as trade secrets or know-how certain of the technology used in developing or manufacturing ZENPEP™. We generally try to protect trade secrets, know-how and technology by entering into confidentiality or non-disclosure agreements with parties that have access to it, such as our collaboration partners, licensees, employees and consultants. Any of these parties may breach the confidentiality agreements and willfully or unintentionally disclose our confidential information, or our competitors might learn of the information in some other way. The disclosure to, or independent development by, a competitor of any trade secret, know-how or other technology not protected by a patent could materially adversely affect any competitive advantage we may have over any such competitor.

Legal proceedings or third-party claims of intellectual property infringement may require us to spend substantial time and money and could prevent us from developing or commercializing products.

The manufacture, use, offer for sale, sale or importation of our product candidates might infringe on the claims of third-party patents. A party might file an infringement action against us. The cost to us of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation or defense of a patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Patent litigation and other proceedings may also absorb significant management time. Consequently, we are unable to guarantee that we will be able to manufacture, use, offer for sale, sell or import our product candidates in the event of an infringement action. At present, we are not aware of pending or threatened patent infringement actions against us.

As a result of patent infringement claims, or to avoid potential claims, we may choose or be required to seek a license from a third party and would most likely be required to pay license fees or royalties or both. These licenses may not be available on acceptable terms, or at all. Even if we were able to obtain a license, the rights may be non-exclusive, which could potentially limit our competitive advantage. Ultimately, we could be prevented from commercializing a product or be forced to cease some aspect of our business operations if, as a result of actual or threatened patent infringement claims, we are unable to enter into licenses on acceptable terms. This inability to enter into licenses could harm our business significantly. At present, we have not received any written demands from third parties that we take a license under their patents.

In addition, a number of our contracts with our collaboration partners contain indemnity provisions that purport to indemnify us against any losses that arise from third-party claims that are brought in connection with the use of our products. Similarly, a number of our contracts with our licensors also contain indemnity provisions. In some instances, such provisions may not provide sufficient protection from such claims, if at all.

We may be subject to other patent-related litigation or proceedings that could be costly to defend and uncertain in their outcome.

In addition to infringement claims against us, we have been and may in the future become a party to other patent litigation or proceedings, including interference or re-examination proceedings filed with the United States Patent and Trademark Office or opposition proceedings in the European Patent Office regarding intellectual property rights with respect to our products and technology, as well as other disputes regarding intellectual property rights with licensees, licensors or others with whom we have contractual or other business relationships.

We are involved in four patent infringement actions filed in response to four Paragraph IV Certification Notice Letters received in October and November 2008 and June 2009 regarding an Abbreviated New Drug Application (ANDA) submitted to the FDA by Mylan Pharmaceuticals, Inc., Barr Pharmaceuticals, IMPAX Pharmaceuticals, Inc. and Anchen Pharmaceuticals, Inc. requesting approval to market and sell a generic version of the 15 mg and 30 mg strengths of AMRIX[®] (Cyclobenzaprine Hydrochloride Extended-Release Capsules). Each of the companies alleged in their respective notice letters that the U.S. Patent Number 7,387,793, entitled “Modified Release Dosage Forms of Skeletal Muscle Relaxants,” issued to Eurand is invalid, unenforceable and/or will not be infringed by the respective company’s manufacture, use or sale of the product described in its ANDA submission. The Eurand patent covers extended-release formulations containing the muscle relaxant cyclobenzaprine and expires on February 26, 2025. In the event that Cephalon and Eurand are unable to maintain the patent against the four infringers, Cephalon has a three-year period of marketing exclusivity for AMRIX that extends until February 2010. However, thereafter, AMRIX[®] could be subject to generic competition which would significantly reduce the Company’s royalty stream from the product.

The following issued European patents are currently subject to opposition procedures before the European Patent Office:

- EP 1058538 for Fast Disintegrating Tablets;
- EP 0914818 for Intraorally Rapidly Disintegrable Tablet; and
- EP 01335706 for Process for the Production of Microspheres of Pancreatic Enzymes with High Stability.

Post-issuance oppositions are not uncommon and we or our collaborator are defending these opposition procedures as a matter of course. We believe our freedom to operate or our ability to commercialize any products will not be adversely affected if we or our collaborator are unsuccessful in any of the opposition procedures.

Risks Related to Our Industry

We must comply with the laws, regulations and rules of many jurisdictions relating to the healthcare business, and if we are unable to fully comply with such laws, regulations and other rules, we could face substantial penalties. In addition, there are substantial healthcare regulatory reform proposals under consideration in the United States which, if approved, could significantly affect our business.

We are or will be, directly or indirectly through our customers, subject to extensive regulation by the various jurisdictions in which we may conduct our business, including the United States and the European Union. The laws that directly or indirectly affect our ability to operate our business include the following:

- the anti-kickback laws that prohibit persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce either the referral of an individual, or the furnishing or arranging for a good or service, for which payment may be made under federal healthcare programs such as Medicare and Medicaid in the United States;
- other healthcare laws, including Medicare laws in the United States, regulations, rules, manual provisions and policies that prescribe the requirements for coverage and payment for services performed by our customers, including the amount of such payment;
- laws and regulations, including the U.S. False Claims Act, which impose civil and criminal liability on individuals and entities who submit, or cause to be submitted, false or fraudulent claims for payment to the government;
- laws and regulations, including the U.S. False Statements Act, which prohibit knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services; and
- state law equivalents and comparable laws in countries outside of the United States, including laws regarding pharmaceutical company marketing compliance, reporting and disclosure obligations.

If our operations are found to be in violation of any of the laws, regulations, rules or policies described above or any other law or governmental regulation to which we or our customers are or will be subject, or if the interpretation of such laws, regulations, rules or policies changes, we may be subject to civil and criminal penalties, damages, fines, disbarment, exclusion from the Medicare and Medicaid programs and curtailment or restructuring of our operations. Similarly, if our customers are found noncompliant with applicable laws, they may be subject to sanctions, which could negatively impact us. Any penalties, damages, fines, curtailment or restructuring of our operations would harm our ability to operate our business and our financial results. The risk of our being found in violation of these laws is increased by the fact that many such laws have not been fully interpreted by the regulatory authorities or the courts, and their provisions may be open to a variety of interpretations. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses, divert management resources from the operation of our business and damage our reputation.

If the government or third-party payors fail to provide coverage and adequate payment rates for our products, the products of our collaboration partners or our future products, if any, our revenues and our prospects for profitability will be harmed.

Third-party payors, which include governments and private health insurers, increasingly are challenging the prices charged for medical products and services. In their attempts to reduce health care costs, they have also limited their coverage and reimbursement levels for new pharmaceutical products. In some cases, they refuse to cover the costs of drugs that are not new but are being used for newly approved purposes. Patients who use a product that we may develop might not be reimbursed for its cost. If third-party payors do not provide adequate coverage and reimbursement for our products, or those of our collaboration partners, or for our future products, doctors may not prescribe these products or patients may not use them. In addition, many third-party payors have implemented other drug cost-containment efforts that include drug utilization review, or prior authorization, for drug formularies and comparative effectiveness studies as well as increases in patient out-of-pocket expenses for more expensive and non-preferred drugs, and such measures may potentially impact the commercial viability or delay the launch of one of our products.

In some countries, particularly those of the European Economic Area, or EEA, the pricing of prescription pharmaceuticals is subject to government control, often resulting in lower pricing or reimbursement rates than in the U.S. market. For the years ended December 31, 2006, 2007 and 2008 and nine months ended September 30, 2009, approximately 46%, 47%, 40% and 31% of our revenues were derived in EEA countries, respectively, and those derived in Germany represented 19%, 21%, 17% and 10% and the United Kingdom represented 16%, 12%, 10% and 8%, of our revenues, in the same periods, respectively. In these countries, pricing negotiations with governmental authorities can take considerable time and delay the placing of a product on the market. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares cost-effectiveness of our product candidate with other available products. If reimbursement of our product is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be adversely affected.

Government authorities in many of our target markets have, from time to time, proposed legislation that would permit re-importation of drugs into those markets, including from countries where the drugs are sold at lower prices. This and other regulatory changes of a similar nature could force us to lower the prices at which we sell our products and impair our ability to derive revenues from these products.

Government authorities in many of our target markets have, from time to time, proposed legislation that would permit more widespread re-importation of drugs into jurisdictions in which we sell our products. This could include re-importation from countries where the drugs are sold at lower prices than in jurisdictions in which we sell our products. Such legislation, or regulatory changes of a similar nature, could lead to a decrease in the price we receive for any approved products, which, in turn, could impair our ability to generate revenues. For example, in 2005, pseudoephedrine was reclassified as a controlled substance in the United States and as a result we experienced a decrease in sales of that product. Alternatively, in response to such legislation and to minimize the risk of re-importation, we might elect not to seek approval for or market our products in certain jurisdictions, which could also reduce the revenue we generate from our product sales. For example, the Medicare Prescription Drug legislation, which became law in December 2003, requires the Secretary of Health and Human Services to promulgate regulations for drug re-importation from Canada into the United States under some circumstances, including when the drugs are sold at a lower price than in the United States. The Secretary retains the discretion not to implement a drug re-importation plan if he finds that the benefits do not outweigh the cost. Proponents of drug re-importation may attempt to pass legislation that would directly allow re-importation under certain circumstances. If legislation or regulations were passed allowing for the re-importation of drugs, the existence of lower cost alternatives could affect the prices we receive for any products that we may develop, thereby affecting our anticipated revenues and prospects for profitability.

We may be exposed to product liability claims, which could result in financial loss.

The use of product candidates in clinical trials and the commercial sale of products may expose us to product liability claims. Our collaboration partners, parties selling the products or consumers may bring these claims, which could result in financial losses. These lawsuits may divert our management from pursuing our business strategy and may be costly to defend. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for our product candidates;
- injury to our reputation;
- withdrawal of clinical trial participants;
- significant litigation costs and substantial monetary awards to, or costly settlement with, patients;
- product recalls and loss of revenue; and
- the inability to commercialize our product candidates.

We currently carry liability insurance for claims arising from the use of our product candidates during clinical trials, as specifically endorsed, and the commercial sale of our products, but we cannot be certain that this coverage will be sufficient to satisfy any liabilities that may arise. The limit for our group product liability insurance is €20.0 million (or \$28.0 million), per occurrence or annual aggregate, with a deductible of €200,000 (or \$280,000). As our development activities progress, this coverage may be inadequate and we may be unable to get adequate coverage at an acceptable cost or at all. This could prevent or limit the commercialization of our product candidates.

In addition, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts or scope to protect us against losses. Any claims against us, regardless of their merit, could severely harm our financial condition, strain our management and other resources and adversely impact or eliminate the prospects for commercialization of a product candidate or sale of a product subject to any such claim. Off-label use of our product may occur. While we do not promote off-label use, off-label uses of products are common and the FDA does not regulate a physician's choice of treatment. Off-label use or misuse of our product may subject us to additional liability.

We deal with hazardous materials and must comply with environmental, health and safety laws and regulations, which can be expensive and restrict how we do business and/or give rise to significant liabilities.

We are subject to various environmental, health and safety laws and regulations, including those governing air emissions, water and wastewater discharges, noise emissions, the use, management and disposal of hazardous, radioactive and biological materials and wastes, and the cleanup of contaminated sites. The cost of compliance with these laws and regulations could be significant. In the event of a violation of these requirements, including from accidental contamination or injury, we could be held liable for damages exceeding our available financial resources. We could be subject to monetary fines, penalties or third-party damage claims as a result of violations of such laws and regulations or noncompliance with environmental permits required at our facilities. As an owner and operator of real property and a generator of hazardous materials and wastes, we also could be subject to environmental cleanup liability, in some cases without regard to fault or whether we were aware of the conditions giving rise to such liability. In addition, we may be subject to liability and may be required to comply with new or existing environmental laws regulating pharmaceuticals in the environment. Environmental laws or regulations (or their interpretation) may become more stringent in the future. If any such future revisions require significant changes in our operations, or if we engage in the development and manufacturing of new products or otherwise expand our operations requiring new or different environmental controls, we will have to dedicate additional management resources and incur additional expenses to comply with such laws and regulations.

In the event of an accident, applicable authorities may curtail our use of hazardous materials and interrupt our business operations. In addition, with respect to our manufacturing facilities, we may incur substantial costs to

comply with environmental regulations and may become subject to the risk of accidental contamination or injury from the use of hazardous materials in our manufacturing process.

We do not maintain a separate insurance policy for any of the foregoing types of risks. In the event of environmental discharge or contamination or an accident, we may be held liable for any resulting damages, and any liability could exceed our resources.

If we or others identify side effects after any of our products are on the market, we or our collaborators or licensees may be required to withdraw our products from the market, perform lengthy additional clinical trials or change the labeling of our products, any of which would hinder or preclude our ability to generate revenues.

If we or others identify adverse side effects after any of our products are on the market:

- regulatory authorities may withdraw their approvals;
- we or our collaborators or licensees may be required to reformulate our products, conduct additional clinical trials, change the labeling of our products, implement MSR evaluation and mitigation programs, or implement changes to manufacturers' facilities to obtain new approvals;
- we or our collaborators or licensees may have to recall the affected products from the market;
- we or our collaborators or licensees may experience a significant drop in sales of the affected products;
- our reputation in the marketplace may suffer;
- we may become the target of lawsuits, including class action suits; and
- we or our collaborators or licensees may be required to withdraw our products from the market and may not be able to reintroduce them into the market.

Any of these events could harm or prevent sales of the affected products or could substantially increase the costs and expenses of commercializing or marketing these products.

If the FDA, EMEA or other applicable regulatory agencies approve generic products that compete with any of our branded products, sales of those products may be adversely affected.

The FDCA, FDA regulations and other applicable regulations and policies provide incentives to manufacturers to create modified, non-infringing versions of a drug to facilitate the approval of an ANDA or other application for generic substitutes. These manufacturers might only be required to conduct a relatively inexpensive study to show that its product has the same active ingredient(s), dosage form, strength, route of administration, and conditions of use, or labeling, as our product and that the generic product is bioequivalent to ours, meaning it is absorbed in the body at the same rate and to the same extent as our product. These generic equivalents, which must meet the same quality standards as branded pharmaceuticals, would be significantly less costly than ours to bring to market and companies that produce generic equivalents are generally able to offer their products at lower prices. Thus, after the introduction of a generic competitor, a significant percentage of the sales of a branded product is typically lost to the generic product. Accordingly, competition from generic equivalents could materially adversely impact our revenues, profitability and cash flows and substantially limit our ability to obtain a return on the investments we have made in those products.

Our development of formulations with generic drugs may expose us to litigation.

There has been substantial litigation in the pharmaceutical, biomedical and biotechnology industries with respect to the manufacture, use and sale of new products that are the subject of patent rights. Under the Drug Price Competition and Patent Restoration Act of 1984, when a drug developer files an ANDA for a generic drug, it must certify to the FDA that it believes its product will not infringe on any unexpired patent that a patent holder has listed

with the FDA as covering that brand-name product, or that any such patent is invalid or unenforceable. The drug developer must also provide such certification to the patent holder, who may challenge the developer's certification of non-infringement, invalidity or unenforceability by filing a suit for patent infringement. Such a patent challenge within the first 45 days of notice of the ANDA certification can result in a 30 month stay of approval by FDA of the ANDA. Certain of our collaboration partners may have or develop generic versions of existing or then existing drugs. Our development of any such generic versions of drugs will be subject to this process. Should a patent holder commence a lawsuit against us with respect to alleged patent infringement, the uncertainties inherent in patent litigation make the outcome of such litigation difficult to predict. Litigation over patents could result in delays in obtaining FDA approval to market our product candidates and diversion of management resources and the costs resulting therefrom. Similar risks of the delay in obtaining approvals in other applicable jurisdictions could result from patent related litigation.

We are currently unable to accurately predict what our short-term and long-term effective tax rates will be in the future.

We are subject to income taxes in both the United States and the various other jurisdictions in which we operate. Significant judgment is required in determining our worldwide provision for income taxes and, in the ordinary course of business, there are many transactions and calculations where the ultimate tax determination is uncertain. Our effective tax rates could be adversely affected by changes in the mix of earnings in countries with differing statutory tax rates, changes in the valuation of deferred tax assets and liabilities or changes in tax laws, as well as other factors. Our judgments may be subject to audits or reviews by local tax authorities in each of these jurisdictions, which could adversely affect our income tax provisions. Furthermore, we have had a limited historical profitability upon which to base our estimate of future short-term and long-term effective tax rates.

Risks Related to Our Ordinary Shares

We are a "controlled company" under the NASDAQ Stock Market rules, and as such we are entitled to exemption from certain NASDAQ corporate governance standards, and you may not have the same protections afforded to shareholders of companies that are subject to all of the NASDAQ corporate governance requirements.

We are a "controlled company" within the meaning of the NASDAQ Stock Market corporate governance standards. Under the NASDAQ Stock Market rules, a company of which more than 50% of the voting power is held by an individual, another company or a group is a "controlled company" and may elect not to comply with certain NASDAQ Stock Market corporate governance requirements, including (1) the requirement that a majority of the board of directors consist of independent directors, (2) the requirement that the nominating committee be composed entirely of independent directors and have a written charter addressing the committee's purpose and responsibilities and (3) the requirement that the compensation committee be composed entirely of independent directors and have a written charter addressing the committee's purpose and responsibilities. We may utilize these exemptions. Accordingly, you may not have the same protections afforded to shareholders of companies that are subject to all of the NASDAQ Stock Market corporate governance requirements.

Our ordinary share price could be highly volatile.

The realization of any of the risks described in these "Risk Factors" or other unforeseen risks could have a dramatic and adverse effect on the market price of our ordinary shares. In particular, and in addition to circumstances described elsewhere in these "Risk Factors," the following events or factors can adversely affect the market price of our ordinary shares:

- announcements of technological innovations or new products by us or others;
- public concern as to the safety of products we or others develop;
- general market conditions;

- success of research and development projects;
- changes in government regulations or patent decisions;
- the estimates of others, including research analysts, regarding our future performance, anticipated future revenues, expenses, operating losses, capital requirements and our need for additional financing;
- actions by our competitors; and
- developments by our collaboration partners.

Additionally, market prices for securities of biotechnology and pharmaceutical companies historically have been very volatile. The market for these securities has from time to time experienced significant price and volume fluctuations for reasons unrelated to the operating performance of any one company. The trading price of our ordinary shares has been, and could continue to be, subject to fluctuations in response to these factors, including the sale or attempted sale of a large amount of our ordinary shares into the market. From May 16, 2007, when our ordinary shares began trading on The NASDAQ Global Market, through September 30, 2009, the high and low sales prices of our ordinary shares ranged from \$6.17 to \$19.60. Broad market fluctuations may also adversely affect the market price of our ordinary shares. As a result of this volatility, investors may not be able to sell their shares at or above the price paid for them. In the past, following periods of market volatility, shareholders have often instituted securities class action litigation. If we were involved in securities litigation, it could have a substantial cost and divert resources and attention of management from our business.

Sales of substantial amounts of our ordinary shares in the public market could depress our share price.

Warburg, Pincus Equity Partners, L.P., Warburg, Pincus Ventures International, L.P. and their affiliates, or Warburg Pincus, in the aggregate, beneficially own approximately 54.8% of our outstanding ordinary shares. Any sales of substantial amounts of our ordinary shares in the public market, including sales or distributions of shares by Warburg Pincus, or the perception that such sales might occur, could harm the market price of our ordinary shares and could impair our ability to raise capital through the sale of additional equity securities.

Raising additional capital by issuing securities may cause dilution to existing shares.

We may need to raise substantial future capital to continue to complete clinical development and commercialize our products and product candidates and to conduct the research and development and clinical and regulatory activities necessary to bring our product candidates to market. Our future capital requirements will depend on many factors, including:

- the failure to achieve commercial success of ZENPEP™ or costs incurred to launch ZENPEP™ in the United States;
- the failure to obtain regulatory approval of ZENPEP™ in markets outside of the United States;
- our success in establishing new collaboration partnerships;
- the success of our collaboration partners in selling products utilizing our technologies;
- the results of our preclinical studies and clinical trials for our earlier stage product candidates, and any decisions to initiate clinical trials if supported by the preclinical results;
- the costs, timing and outcome of regulatory review of any of our product candidates that progress to clinical trials;

- the costs of establishing or acquiring specialty sales, marketing and distribution capabilities, if any of our product candidates are approved;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our issued patents and defending intellectual property-related claims;
- the costs of financing unanticipated working capital requirements and responding to competitive pressures
- the extent to which we acquire or invest in businesses, products or technologies and other strategic relationships; and

Additional financing may not be available on terms favorable to us, or at all. If adequate funds are not available or are not available on acceptable terms, our ability to fund our expansion, take advantage of unanticipated opportunities, develop or enhance technology or services, or otherwise respond to competitive pressures would be significantly limited. In addition, we may be required to terminate or delay preclinical studies, clinical trials or other development activities for one or more of our product candidates, or delay our establishment of sales and marketing capabilities or other activities that may be necessary to commercialize our products or product candidates.

If we raise additional funds through co-development and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or product candidates, or grant licenses on terms that are not favorable to us. If we raise additional funds by issuing equity or convertible debt securities, we will reduce the percentage ownership of our then-existing shareholders, and these securities may have rights, preferences or privileges senior to those of our existing shareholders. Further, shareholders' ownership will be diluted if we raise additional capital by issuing equity securities.

Warburg, Pincus Equity Partners, L.P., Warburg, Pincus Ventures International, L.P. and their affiliates, our major shareholders, control approximately 54.8% of our ordinary shares, and this concentration of ownership may deter a change in control or other transaction that is favorable to our shareholders.

Warburg, Pincus Equity Partners, L.P., Warburg, Pincus Ventures International, L.P. and their affiliates, or Warburg Pincus, in the aggregate, beneficially own approximately 54.8% of our outstanding ordinary shares. These shareholders could effectively control all matters requiring our shareholders' approval, including the election of directors. This concentration of ownership may also cause, delay, deter or prevent a change in control, and may make some transactions more difficult or impossible to complete without the support of these shareholders, regardless of the impact of this transaction on our other shareholders.

We are a Netherlands public limited liability company (naamloze vennootschap) and it may be difficult for you to obtain or enforce judgments against us or our executive officers, some of our directors and some of our named experts in the United States.

We were formed under the laws of The Netherlands and, as such, the rights of holders of our ordinary shares and the civil liability of our directors will be governed by the laws of The Netherlands and our articles of association. The rights of shareholders under the laws of The Netherlands may differ from the rights of shareholders of companies incorporated in other jurisdictions. Most of our directors and our executive officers and most of our assets and the assets of our directors are located outside the United States. In addition, under our articles of association, all lawsuits against us and our directors and executive officers shall be governed by the laws of The Netherlands and must be brought exclusively before the Courts of Amsterdam, The Netherlands. As a result, you may not be able to serve process on us or on such persons in the United States or obtain or enforce judgments from U.S. courts against them or us based on the civil liability provisions of the securities laws of the United States. There is doubt as to whether Netherlands courts would enforce certain civil liabilities under U.S. securities laws in original actions and/or enforce claims for punitive damages. See "Service of Process and Enforceability of Civil Liabilities."

Under our articles of association, we indemnify and hold our directors harmless against all claims and suits brought against them, subject to limited exceptions. Under our articles of association, to the extent allowed by law, the rights and obligations among or between us, any of our current or former directors, officers and employees and any current

or former shareholder shall be governed exclusively by the laws of The Netherlands and subject to the jurisdiction of The Netherlands courts, unless such rights or obligations do not relate to or arise out of their capacities listed above. Although there is doubt as to whether U.S. courts would enforce such provision in an action brought in the United States under U.S. securities laws, such provision could make enforcing judgments obtained outside of The Netherlands more difficult to enforce against our assets in The Netherlands or jurisdictions that would apply Netherlands law.

We do not anticipate paying dividends on our ordinary shares, which could reduce the return on your investment.

We have not paid cash dividends on our ordinary shares and do not expect to do so in the foreseeable future. We currently intend to retain our future earnings, if any, to fund the development and growth of our business. In addition, terms of any existing or future debt agreements may preclude us from paying dividends. Accordingly, any return on your investment must come from appreciation of our ordinary shares.

Your rights as a holder of ordinary shares will be governed by Dutch law and will differ from the rights of shareholders under U.S. law.

We are a limited liability company incorporated under the laws of The Netherlands. The rights of holders of ordinary shares are governed by Dutch law and our articles of association. These rights differ from the typical rights of shareholders in U.S. corporations. For example, Dutch law significantly limits the circumstances under which shareholders of Dutch companies may bring an action on behalf of a company.

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

As a public company, we incur significant legal, accounting and other expenses. In addition, the Sarbanes-Oxley Act, as well as rules subsequently implemented by the Securities and Exchange Commission, or SEC, and the NASDAQ Global Market, have imposed requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Our management and other personnel devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations have resulted in substantial legal and financial compliance costs and make some activities more time-consuming and costly.

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

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

Recent adverse changes in U.S., global, or regional economic conditions could have a continuing adverse effect on the profitability of some or all of our businesses.

Recent turmoil in the financial markets has adversely affected economic activity in the United States and other regions of the world in which we do business. Although we believe that based on our current cash, cash equivalents and short term investments balances and expected operating cash flows, the current lack of liquidity in the credit markets will not have a material impact on our liquidity, cash flow, or financial flexibility, continued deterioration of the credit and capital markets could cause additional impairments to our investment portfolio, which could negatively impact our financial condition and reported earnings. The continued decline in economic activity could adversely affect demand for our products, thus reducing our revenue and earnings as well as have an adverse impact on our customers, distributors, collaboration partners, suppliers, service providers and ability to develop outlicensing relationships.

SIGNATURES

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

Date: November 12, 2009

EURAND N.V.
(Registrant)

By: /s/ Manya S. Deehr
Manya S. Deehr
Chief Legal Officer & Secretary