ZOGENIX, INC.
Form 10-Q
November 10, 2011

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

September 30, 2011 For the quarterly period ended September 30, 2011

OR

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

For the transition period from to

Commission file number: 001-34962

Zogenix, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**20-5300780**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**
12671 High Bluff Drive, Suite 200	
San Diego, California	**92130**
(Address of Principal Executive Offices)	**(Zip Code)**

858-259-1165

(Registrant s Telephone Number, Including Area Code)

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No ¨

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

Large accelerated filer ¨	Accelerated filer ¨
Non-accelerated filer x (Do not check if a smaller reporting company)	Smaller reporting company ¨

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

The number of outstanding shares of the registrant s common stock, par value $0.001 per share, as of November 1, 2011 was 65,184,844.

ZOGENIX, INC.

FORM 10-Q

For the Quarterly Period Ended September 30, 2011

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PART I FINANCIAL INFORMATION

Item 1. Financial Statements

Zogenix, Inc.

Consolidated Balance Sheets

(In Thousands)

	September 30, 2011 (Unaudited)	December 31, 2010
Assets		
Current assets:		
Cash and cash equivalents	$ 70,847	$ 49,172
Trade accounts receivable	5,947	4,474
Inventory, net	17,204	18,293
Prepaid expenses and other current assets	2,422	2,251
Total current assets	96,420	74,190
Property and equipment, net	14,668	15,434
Other assets	5,795	4,644
Total assets	$ 116,883	$ 94,268
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	$ 4,415	$ 5,580
Accrued expenses	10,529	9,439
Accrued compensation	3,428	3,604
Revolving credit facility	4,503	3,449
Long-term debt, current portion	6,640	3,519
Deferred revenue, current portion	6,251	9,973
Total current liabilities	35,766	35,564
Long-term debt, less current portion	44,870	19,934
Deferred rent	316	360
Deferred revenue, less current portion	4,688	9,376
Other long-term liabilities	1,077	300
Commitments and contingencies		
Stockholders equity:		
Common stock	64	34
Additional paid-in capital	288,403	226,802
Accumulated deficit	(258,301)	(198,102)
Total stockholders equity	30,166	28,734
Total liabilities and stockholders equity	$ 116,883	$ 94,268

See accompanying notes.

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Zogenix, Inc.

Consolidated Statements of Operations

(In Thousands, except Per Share Amounts)

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Revenue:				
Net product revenue	$ 8,835	$ 5,710	$ 24,986	$ 11,828
Contract revenue	1,563	1,348	4,688	2,810
Total revenue	10,398	7,058	29,674	14,638
Operating expenses:				
Cost of sales	5,482	2,932	14,333	8,233
Royalty expense	343	216	972	598
Research and development	10,134	8,004	27,540	19,394
Selling, general and administrative	14,701	12,540	42,642	37,962
Total operating expenses	30,660	23,692	85,487	66,187
Loss from operations	(20,262)	(16,634)	(55,813)	(51,549)
Other income (expense):				
Interest income	2	1	21	4
Interest expense	(2,470)	(5,426)	(4,984)	(6,938)
Change in fair value of warrant liability	546	187	546	(12,833)
Change in fair value of embedded derivatives	137	0	137	0
Other income (expense)	16	(253)	(86)	(113)
Total other income (expense)	(1,769)	(5,491)	(4,366)	(19,880)
Net loss before income taxes	(22,031)	(22,125)	(60,179)	(71,429)
Provision for income taxes	(7)	0	(20)	0
Net loss	$ (22,038)	$ (22,125)	$ (60,199)	$ (71,429)
Net loss per share, basic and diluted	$ (0.59)	$ (16.00)	$ (1.71)	$ (53.31)
Weighted average shares outstanding, basic and diluted	37,320	1,383	35,127	1,340

See accompanying notes.

Zogenix, Inc.

Consolidated Statements of Cash Flows

(In Thousands)

(Unaudited)

	Nine Months Ended September 30,	
	2011	**2010**
Operating activities:		
Net loss	$ (60,199)	$ (71,429)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	3,502	1,712
Depreciation and amortization	1,192	1,046
Amortization of debt issuance costs and non-cash interest	1,289	3,763
Change in fair value of warrant liability	(546)	12,833
Change in fair value of embedded derivatives	(137)	0
Loss on disposal and impairment of property and equipment	0	3
Changes in operating assets and liabilities:		
Trade accounts receivable	(1,473)	(2,165)
Inventory, net	1,089	(4,438)
Prepaid expenses and other current assets	(181)	(125)
Other assets	213	(5,506)
Accounts payable and accrued expenses	(529)	4,847
Deferred rent	(44)	(26)
Deferred revenue	(8,411)	993
Net cash used in operating activities	(64,235)	(58,492)
Investing activities:		
Purchases of property and equipment	(426)	(2,084)
Net cash used in investing activities	(426)	(2,084)
Financing activities:		
Net proceeds from borrowing of debt and revolving credit facility	34,353	42,702
Payments on borrowings of debt and revolving credit facility	(6,094)	(15,367)
Proceeds from exercise of common stock options	92	3
Proceeds from issuance of common stock, net of issuance costs	57,985	0
Net cash provided by financing activities	86,336	27,338
Net increase (decrease) in cash and cash equivalents	21,675	(33,238)
Cash and cash equivalents at beginning of period	49,172	44,911
Cash and cash equivalents at end of period	$ 70,847	$ 11,673

See accompanying notes.

Zogenix, Inc.

Notes to Consolidated Financial Statements

1. Organization and Basis of Presentation

Zogenix, Inc. (the Company) is a pharmaceutical company commercializing and developing products for the treatment of central nervous system disorders and pain. The Company s first commercial product, Sumavel® DosePro® (*sumatriptan* injection) Needle-free Delivery System, offers fast-acting, easy-to-use, needle-free subcutaneous delivery of *sumatriptan* for the acute treatment of migraine and cluster headache in a pre-filled, single-use delivery system. Sumavel DosePro was approved by the U.S. Food and Drug Administration (FDA) on July 15, 2009 and was launched in the United States in January 2010.

The Company was incorporated in the state of Delaware on May 11, 2006 as SJ2 Therapeutics, Inc. and commenced operations on August 25, 2006. On August 28, 2006, the Company changed its name to Zogenix, Inc.

The Company has incurred significant net losses since inception and has relied on its ability to fund its operations through equity financings, debt financings, revenues from the sale of its product Sumavel DosePro and proceeds from business collaborations. As the Company continues to incur losses, successful transition to profitability is dependent upon achieving a level of revenues adequate to support the Company s cost structure. This may not occur and, unless and until it does, the Company will continue to need to raise additional cash. The Company expects its cash resources will be sufficient to fund its operations through December 31, 2011.

On June 30, 2011, the Company amended certain terms of its loan agreement with Oxford Finance LLC, as successor in interest to Oxford Finance Corporation (Oxford), and Silicon Valley Bank (SVB) including the deferral of principal repayment to commence on February 1, 2012 (see note 5). Concurrent to the amendment of the Oxford and SVB loan agreement, the Company entered into equity and royalty financing agreements with Cowen Healthcare Royalty Partners II, L.P. (Cowen Royalty) pursuant to which the Company committed to borrow $30,000,000 from Cowen Royalty and to sell $1,500,000 of its common stock for $29,484,000 in net proceeds. The Cowen equity and royalty financing closed on July 18, 2011 (see note 5).

On September 21, 2011, the Company completed a public offering (Offering) of common stock pursuant to a Registration Statement that was declared effective on September 15, 2011. As a result of the Offering, the Company sold 30,000,000 shares of its common stock, at a price of $2.00 per share. The underwriters were granted an option to purchase up to 4,500,000 additional shares of common stock at $2.00 per share, of which 711,566 shares were sold on October 4, 2011. As a result of the Offering, the Company raised a total of $57,919,000 in net proceeds (including the underwriters October purchase) after deducting underwriting discounts and commissions of $2,586,000 and offering expenses of $918,000. Costs directly associated with the Company s Offering were capitalized and recorded as deferred offering costs prior to the closing of the Offering. These costs have been recorded as a reduction of the proceeds received in arriving at the amount recorded in additional paid-in capital.

Management expects operating losses and negative cash flows to continue for at least the next several years as the Company continues to incur costs related to the continued development of its product candidates and commercialization of its approved product. Management may pursue additional equity or debt financings if required to help support its planned operations beyond December 31, 2011. There can be no assurance that the Company will be able to obtain any source of financing on acceptable terms, or at all.

2. Summary of Significant Accounting Policies

Financial Statement Preparation and Use of Estimates

The unaudited consolidated financial statements have been prepared by Zogenix, Inc. according to the rules and regulations of the Securities and Exchange Commission (SEC) and, therefore, certain information and disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States have (GAAP) been omitted.

In the opinion of management, the accompanying unaudited consolidated financial statements for the periods presented reflect all adjustments, which are normal and recurring, necessary to fairly state the financial position, results of operations and cash flows. These unaudited consolidated financial statements should be read in conjunction with the audited financial statements included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2010 filed with the SEC on March 4, 2011.

The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Actual results may differ from those estimates.

Principles of Consolidation

The unaudited interim consolidated financial statements include the accounts of Zogenix, Inc. and its wholly owned subsidiary Zogenix Europe Limited, which was incorporated under the laws of England and Wales in June 2010. All intercompany transactions and investments have been eliminated in consolidation. Zogenix Europe Limited s functional currency is the U.S. dollar, the reporting currency of its parent.

Cash and Cash Equivalents

The Company considers cash equivalents to be only those investments which are highly liquid, readily convertible to cash and have an original maturity of three months or less when purchased.

Restricted Cash

In December 2009, the Company issued a letter of credit for $200,000 in connection with an operating lease. The letter of credit is collateralized by a certificate of deposit in the same amount. Restricted cash of $200,000 at September 30, 2011 and December 31, 2010 is included in other assets on the consolidated balance sheet.

Accounts Receivable

The Company evaluates the collectability of its accounts receivable based on a variety of factors including the length of time the receivables are past due, the financial health of the customer and historical experience. Based upon the review of these factors, the Company did not record an allowance for doubtful accounts at September 30, 2011 and December 31, 2010. The need for bad debt allowance is evaluated each reporting period.

Fair Value Measurements

The carrying amount of financial instruments consisting of cash, trade accounts receivable, prepaid expenses and other current assets, accounts payable, accrued expenses excluding warrant liability, accrued compensation, borrowings under the revolving credit facility and current portion of long-term debt included in the Company s consolidated financial statements are reasonable estimates of fair value due to their short maturities. Based on the borrowing rates currently available to the Company for loans with similar terms, management believes the fair value of long-term debt approximates its carrying value.

Authoritative guidance establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level 1: Observable inputs such as quoted prices in active markets;

Level 2: Inputs, other than the quoted prices in active markets, that are observable either directly or indirectly; and

Level 3: Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions.

Assets and liabilities measured at fair value on a recurring basis as of September 30, 2011 and December 31, 2010 are as follows (in thousands):

	Fair Value Measurements at Reporting Date Using			
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
At September 30, 2011				
Assets				
Money market fund shares(1)	$ 65,536	0	0	$ 65,536
Liabilities				
Common stock warrant liability(2)	$ 0	0	244	$ 244
Embedded derivative liabilities(3)	$ 0	0	468	$ 468
At December 31, 2010				
Assets				
Money market fund shares(1)	$ 42,615	0	0	$ 42,615

(1) Money market fund shares are included as a component of cash and cash equivalents on the consolidated balance sheet.

(2) Common stock warrants measured at fair value using the Black-Scholes option pricing valuation model are included as a component of accrued expenses on the consolidated balance sheet. The assumptions used in the Black-Scholes option pricing valuation model were: (a) a risk-free interest rate based on the rates for U.S. Treasury zero-coupon bonds with maturities similar to those of the remaining contractual term of the warrants; (b) an assumed dividend yield of zero based on the Company s expectation to not pay dividends in the foreseeable future; (c) an expected term based on the remaining contractual term of the

warrants; and (d) given the Company s lack of relevant historical data due to the Company s limited historical experience, an expected volatility based upon the historical volatility of comparable companies whose share prices have been publicly available for a sufficient period of time.

(3) Embedded derivative liabilities measured at fair value using various discounted cash flow valuation models are included as a component of other long-term liabilities on the consolidated balance sheet. The assumptions used in the discounted cash flow valuation models include: (a) management s revenue projections and a revenue sensitivity analysis based on possible future outcomes; (b) probability weighted net cash flows based on the likelihood of Cowen Royalty receiving revenue interest payments over the term of the agreement or a change in control payout, and probability that the Astellas co-promotion agreement would terminate; (c) probability of bankruptcy; and (d) weighted average cost of capital that included the addition of a company specific risk premium to account for uncertainty associated with the Company achieving future cash flows. Further, the assumptions used in the discounted cash flow valuation models also included: (a) the probability of a change in control occurring during the term of the Cowen Royalty financing agreement; and (b) the probability of an exercise of the embedded derivative instruments.

The following table provides a reconciliation of liabilities measured at fair value using significant observable inputs (Level 3) for the three and nine months ended September 30, 2011 (in thousands):

	Common Stock Warrant Liability	Embedded Derivative Liabilities
Balance at December 31, 2010	0	0
Issuance	790	605
Changes in fair value	(546)	(137)
Balance at September 30, 2011 (unaudited)	$ 244	$ 468

Changes in fair value of the liabilities shown in the table above are recorded through a change in fair value of warrant liability and change in fair value of embedded derivatives in other income (expense) in the consolidated statements of operations.

Concentration of Credit Risk, Sources of Supply and Significant Customers

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash and cash equivalents and trade accounts receivable. The Company maintains accounts in federally insured financial institutions in excess of federally insured limits. The Company also maintains investments in money market funds that are not federally insured. However, management believes the Company is not exposed to significant credit risk due to the financial position of the depository institutions in which these deposits are held and of the money market funds and other entities in which these investments are made. Additionally, the Company has established guidelines regarding the diversification of its investments and their maturities, which are designed to maintain safety and liquidity.

The Company sells its products primarily to established wholesale distributors in the pharmaceutical industry. Credit is extended based on an evaluation of the customer s financial condition, and collateral is not required. Approximately 96.1% of the trade accounts receivable balance as of September 30, 2011 represents amounts due from three wholesale distributors. The Company evaluates the collectability of its accounts receivable based on a variety of factors including the length of time the receivables are past due, the financial health of the customer and historical experience. Based upon the review of these factors, the Company did not record an allowance for doubtful accounts at September 30, 2011.

The Company relies on third-party manufacturers for the production of Sumavel DosePro and single source third-party suppliers to manufacture several key components of Sumavel DosePro. If the Company s third-party manufacturers are unable to continue manufacturing Sumavel DosePro, or if the Company lost one or more of its single source suppliers used in the manufacturing process, the Company may not be able to meet market demand for its product.

Astellas Pharma US, Inc. (Astellas) provides a significant amount of funding for the advertising and promotional costs for Sumavel DosePro and co-promotes the product in the United States.

Inventory

Inventory is stated at the lower of cost or market. Cost, which includes amounts related to materials, labor and overhead, is determined in a manner which approximates the first-in, first-out (FIFO) method. The Company capitalizes inventory produced in preparation for product launches upon FDA approval when costs are expected to be recoverable through the commercialization of the product. The Company provides

reserves for potentially excess, dated or obsolete inventories based on an analysis of inventory on hand and on firm purchase commitments compared to forecasts of future sales.

Property and Equipment, Net

Property and equipment is recorded at cost, net of accumulated depreciation and amortization. Depreciation is calculated on a straight-line basis over the estimated useful lives of the respective assets, as follows:

Computer equipment and software	3 years
Furniture and fixtures	3-7 years
Manufacturing equipment and tooling	3-15 years
Leasehold improvements	Shorter of estimated useful life or lease term

Impairment of Long-Lived Assets

The Company reviews its long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable.

Revenue Recognition

The Company recognizes revenue from the sale of Sumavel DosePro and from license fees and milestones earned on collaborative arrangements. Revenue is recognized when (i) persuasive evidence of an arrangement exists, (ii) delivery has occurred and title has passed, (iii) the price is fixed or determinable and (iv) collectability is reasonably assured. Revenue from sales transactions where the buyer has the right to return the product is recognized at the time of sale only if (i) the Company s price to the buyer is substantially fixed or determinable at the date of sale, (ii) the buyer has paid the Company, or the buyer is obligated to pay the Company and the obligation is not contingent on resale of the product, (iii) the buyer s obligation to the Company would not be changed in the event of theft or physical destruction or damage of the product, (iv) the buyer acquiring the product for resale has economic substance apart from that provided by the Company, (v) the Company does not have significant obligations for future performance to directly bring about resale of the product by the buyer, and (vi) the amount of future returns can be reasonably estimated.

Product Revenue

The Company sells Sumavel DosePro product in the United States to wholesale pharmaceutical distributors, and on a limited basis to retail pharmacies, or collectively the Company s customers, subject to rights of return within a period beginning six months prior to, and ending 12 months following, product expiration. Prior to the third quarter of 2011, Sumavel DosePro had a limited sales history, and the Company could not reliably estimate expected returns of the product at the time of shipment. Accordingly, the Company deferred recognition of revenue on product shipments of Sumavel DosePro until the right of return no longer existed, which occurred at the earlier of the time Sumavel DosePro units were dispensed through patient prescriptions or expiration of the right of return. Units dispensed are generally not subject to return, except in the rare cases where the product malfunctions or the product is damaged in transit. The Company estimates patient prescriptions dispensed using an analysis of third-party information, including third-party market research data, information obtained from certain wholesalers with respect to inventory levels at wholesalers and inventory movement and retail pharmacy re-stocking activity.

During the third quarter of 2011, the Company began to recognize net product sales upon the shipment of product to wholesale pharmaceutical distributors and retail pharmacies to provide a more accurate estimate of product sales activity, and because the Company had developed sufficient historical experience and data to reasonably estimate future returns of Sumavel DosePro. As a result, the Company is no longer deferring the recognition of product revenues and related cost of goods for products shipped to its customers. In order to develop a methodology to reliably estimate product returns and provide a basis for recognizing revenue on sales to customers at the time of product shipment, the Company analyzed many factors, including, without limitation; (i) retail pharmacy re-order activity, (ii) actual Sumavel DosePro product return history, taking into account product expiration dating at the time of shipment and product launch stocking activities, (iii) levels of inventory in the wholesale and retail channel and prescription units dispensed, and (iv) industry data regarding product return rates. Based on the data gathered, the Company believes it has the information needed to reasonably estimate product returns.

In connection with the Company being able to reliably estimate product returns and the resulting change in the timing of recognition of product sales, previously reported deferred product revenues and deferred cost of sales as of June 30, 2011 have been recognized as product revenue and cost of sales during the period. In addition the Company recorded an estimated cost for future returns based on product that remained in the distribution channel at September 30, 2011 and the Company recorded the cost of actual return experience for the three months ended September 30, 2011. In the third quarter of 2011, the Company received product returns from the initial stocking at the time of launch of some retail pharmacy stores which resulted in a higher rate of returns than what may be experienced with an established product. As a result of the establishment of a return reserve and the recognition of deferred product revenues, net product sales for the quarter ended September 30, 2011 were reduced by $995,000.

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The Company recognized $8,835,000 and $5,710,000 in Sumavel DosePro product revenue for the three months ended September 30, 2011 and 2010, and $24,986,000 and $11,828,000 in Sumavel DosePro product revenue for the nine months ended September 30, 2011 and 2010, respectively, which was net of estimated wholesaler and retail pharmacy discounts, stocking allowances, prompt pay discounts, chargebacks, rebates, patient discount programs and product returns, as applicable. The Company had a deferred product revenue balance of $0 and $3,722,000 at September 30, 2011 and December 31, 2010, respectively, for Sumavel DosePro product shipments, which was net of estimated wholesaler and retail pharmacy discounts, stocking allowances, prompt pay discounts, chargebacks, rebates and patient discount programs.

The Company permits certain wholesale pharmaceutical distributors to purchase limited quantities of product after the announcement of an increase to the wholesale acquisition cost (WAC) of the Company s product and prior to the effectiveness of the increase. In turn, WAC price increases can result in accelerated purchases by wholesalers relative to anticipated retail and prescription demand. The timing of purchases made by wholesale distributors and retail pharmacies are subject to fluctuations for these reasons among others. Absent accelerated purchasing by wholesalers or other periodic changes in buying patterns, the wholesale channel has historically contained two to three weeks of product on hand. As of September 30, 2011, wholesale distributors reported approximately four weeks of the Company s product on hand.

Sumavel DosePro is also sold to third parties that license the rights to market and sell the product in territories outside of the United States. Under these arrangements, Sumavel DosePro is sold at a specified transfer price with the right of return available for damaged goods upon receipt or in the event of a recall. All risk for retail and wholesale fees and discounts, collectability of customer receivables, customer returns and expiration of the product remain with the licensee. As such, the Company recognizes revenues for product sales under license arrangements upon acceptance of the product (generally at point of shipment). The Company also receives royalties on net sales of Sumavel DosePro at a predetermined rate as a pass through of royalties payable to Aradigm. The Company did not recognize any product revenues for the nine months ended September 30, 2011 and 2010, respectively, in sales under license arrangements.

Product Sales Allowances

The Company recognizes product sales allowances as a reduction of product sales in the same period the related revenue is recognized. Product sales allowances are based on amounts owed or to be claimed on the related sales. These estimates take into consideration the terms of the Company s agreements with customers and third-party payors and the levels of inventory within the distribution channels that may result in future rebates or discounts taken. In certain cases, such as patient support programs, the Company recognizes the cost of patient discounts as a reduction of revenue based on estimated utilization. If actual future results vary, the Company may need to adjust these estimates, which could have an effect on product revenue in the period of adjustment. The Company s product sales allowances include:

Wholesaler and Retail Pharmacy Discounts. The Company offers discounts to certain wholesale distributors and retail pharmacies based on contractually determined rates. The Company accrues the discount on shipment to the respective wholesale distributors and retail pharmacies and recognizes the discount as a reduction of revenue in the same period the related revenue is recognized.

Prompt Pay Discounts. The Company offers cash discounts to its customers, generally 2% of the sales price, as an incentive for prompt payment. The Company accounts for cash discounts by reducing accounts receivable by the prompt pay discount amount and recognizes the discount as a reduction of revenue in the same period the related revenue is recognized.

Chargebacks. The Company provides discounts primarily to authorized users of the Federal Supply Schedule (FSS) of the General Services Administration under an FSS contract negotiated by the Department of Veterans Affairs and various organizations under Medicaid contracts and regulations. These entities purchase products from the wholesale distributors at a discounted price, and the wholesale distributors then charge back to the Company the difference between the current retail price and the price the entity paid for the product. The Company estimates and accrues chargebacks based on estimated wholesaler inventory levels, current contract prices and historical chargeback activity. Chargebacks are recognized as a reduction of revenue in the same period the related revenue is recognized.

Rebates. The Company participates in certain rebate programs, which provide discounted prescriptions to qualified insured patients. Under these rebate programs, the Company pays a rebate to the third-party administrator of the program, generally two to three months after the quarter in which prescriptions subject to the rebate are filled. The Company estimates and accrues for these rebates based on current contract prices, historical and estimated future percentages of product sold to qualified patients and estimated levels of inventory in the distribution channel. Rebates are recognized as a reduction of revenue in the same period the related revenue is recognized.

Patient Discount Programs. The Company offers discount card programs to patients for Sumavel DosePro in which patients receive discounts on their prescriptions that are reimbursed by the Company. The Company estimates the total amount that will be redeemed based on levels of inventory in the distribution and retail channels and recognizes the discount as a reduction of revenue in the same period the related revenue is recognized.

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Stocking Allowances. The Company may offer discounts and extended payment terms, generally in the month of the initial commercial launch of a new product, on the first order made by certain wholesale distributors and retail pharmacies based on contractually determined rates. The Company accrues the discount on shipment to the respective wholesale distributors and retail pharmacies and recognizes the discount as a reduction of revenue in the same period the related revenue is recognized.

Product Returns

The Company s product returns allowance is primarily based on estimates of future product returns over the period during which wholesale pharmaceutical distributors and retail pharmacies have a right of return, which in turn is based in part on estimates of the remaining shelf life of the Company s product. Sumavel DosePro currently has a shelf life of 24 months from the date of manufacture. The Company allows wholesale pharmaceutical distributors and retail pharmacies to return unused product that are within six months before and up to one year after its expiration date for a credit at the then-current WAC, reduced by a nominal fee for processing the return. At the time of sale, the Company estimates the quantity and value of product that may ultimately be returned pursuant to these rights.

The Company utilizes a channel analysis which considers historical product shipments to its customers less historical returns and estimated historical prescriptions written to estimate the number of units of product that remain with its customers (product not yet dispensed to patients or otherwise known as product in the distribution channel). Based on that analysis, the Company develops an estimate of the quantity of product in the distribution channel which may be subject to return exposure. The Company establishes an estimate for its product return exposure taking actual return experience and qualitative factors into account, such as: (i) contractual terms with its customers, (ii) estimated remaining shelf life of the product in the distribution channel, (iii) estimated prescription demand for the product, (iv) communications with its customers and (v) retail pharmacy re-order patterns and re-order activity. The Company s actual experience and the qualitative factors that it uses to determine the necessary reserve for product returns are subject to change based on unforeseen events and uncertainties. The Company assesses the trends that could affect its estimates and may make changes to the allowance each reporting period. The Company s allowance for product returns was $1,264,000 as of September 30, 2011.

The Company s estimates of product returns and product allowances require management s most subjective and complex judgment due to the need to make estimates about matters that are inherently uncertain. If actual future payments for return and product allowances and other discounts exceed the estimates the Company made at the time of sale, its financial position, results of operations and cash flows would be negatively impacted.

Contract Revenue

The Company recognizes revenues related to license fees and milestone payments received under its Co-Promotion Agreement with Astellas entered into in July 2009 (Co-Promotion Agreement). Revenue arrangements with multiple deliverables are divided into separate units of accounting if certain criteria are met, including whether the deliverable has stand-alone value to the customer, the customer has a general right of return relative to the delivered item and delivery or performance of the undelivered item is probable and substantially within the vendor s control. Arrangement consideration is allocated at the inception of the arrangement to all deliverables on the basis of their relative selling price. The selling price for each deliverable is determined using: (i) vendor-specific objective evidence of selling price (VSOE), if it exists, (ii) third-party evidence of selling price (TPE) if VSOE does not exist, and (iii) the Company s best estimate of the selling price if neither VSOE nor TPE exists. For transactions entered into prior to January 1, 2011, revenue is recognized for each deliverable based upon the applicable revenue recognition criteria discussed above and upon acceptance of goods or performance of service. Effective January 1, 2011, for new or significantly modified transactions, the Company allocates revenue consideration, excluding contingent consideration, based on the relative selling prices of the separate units of accounting contained within an arrangement containing multiple deliverables.

Collaborative Arrangements

The Company records certain transactions between collaborators in the consolidated statement of operations on either a gross or net basis within revenues or operating expenses, depending on the characteristics of the collaboration relationship, and provides for enhanced disclosure of collaborative relationships. The Company evaluates its collaborative agreements for proper classification of shared expenses, license fees, milestone payments and any reimbursed costs within the consolidated statement of operations based on the nature of the underlying activity. If payments to and from collaborative partners are not within the scope of other authoritative accounting literature, the statement of operations classification for the payments is based on a reasonable, rational analogy to authoritative accounting literature that is applied in a consistent manner. For collaborations relating to commercialized products, if the Company acts as the principal in the sale of goods or services, the Company records revenue and the corresponding operating costs in its respective line items within the consolidated statement of operations based on the nature of the shared expenses. Per authoritative accounting guidance, the principal is the party who is responsible for delivering the product to the customer, has latitude with establishing price and has the risks and rewards of providing product to the customer, including inventory and credit risk. Effective January 1, 2011, for collaborations relating to research or development arrangements, the Company will recognize revenue for a payment that is contingent upon the achievement of a substantive milestone in its entirety in the period in which the milestone is achieved.

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Research and Development Expenses

All costs of research and development are expensed in the period incurred. Research and development costs primarily consist of salaries and related expenses for personnel, stock-based compensation expense, outside service providers, facilities costs, fees paid to consultants, professional services, travel costs, dues and subscriptions, depreciation and materials used in clinical trials and research and development. The Company expenses costs relating to the purchase and production of pre-approval inventories as research and development expense in the period incurred until FDA approval. The Company received FDA approval for Sumavel DosePro in July 2009, after which it began capitalizing costs as inventory related to the production of Sumavel DosePro, including the cost of materials, third-party manufacturing costs, freight and indirect personnel and other overhead costs.

The Company reviews and accrues expenses related to clinical trials based on work performed, which relies on estimates of total costs incurred based on completion of patient studies and other events. The Company follows this method since reasonably dependable estimates of the costs applicable to various stages of a research agreement or clinical trial can be made. Accrued clinical development costs are subject to revisions as trials progress to completion. Revisions are charged to expense in the period in which the facts that give rise to the revision become known.

Advertising Expense

The Company records the cost of its advertising efforts when services are performed or goods are delivered. The Company incurred approximately $1,813,000 and $621,000 in advertising costs for the three months ended September 30, 2011 and 2010 and $4,193,000 and $3,506,000 in advertising costs for the nine months ended September 30, 2011 and 2010, respectively. At September 30, 2011 and December 31, 2010, the Company capitalized advertising costs of $9,000, and $93,000, respectively, in prepaid and other current assets.

Income Taxes

Deferred tax assets and liabilities are determined based on the differences between the financial reporting and tax basis of assets and liabilities using enacted tax rates which will be in effect when the differences reverse. The Company provides a valuation allowance against net deferred tax assets unless, based upon the available evidence, it is more likely than not that the deferred tax asset will be realized. The Company recognizes the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained on examination by the taxing authorities based on the technical merits of the position.

Foreign Currency Transactions

Gains or losses resulting from transactions denominated in foreign currencies are included in other income (expense) in the consolidated statements of operations. The Company recorded gains and losses from foreign currency transactions in other income (expense) of $16,000 and ($253,000) for the three months ended September 30, 2011 and 2010 and ($86,000) and ($113,000) for the nine months ended September 30, 2011 and 2010, respectively.

Stock-Based Compensation

Stock-based compensation cost is measured at the grant date, based on the estimated fair value of the award, and is recognized as expense over the employee s requisite service period on a straight-line basis. As of September 30, 2011, there were no outstanding equity awards with market or performance conditions. Equity awards issued to non-employees are recorded at their fair value on the measurement date and are re-measured at each reporting date as the underlying awards vest unless the instruments are fully vested, immediately exercisable and nonforfeitable on the date of grant.

Net Loss per Share

Basic net loss per share is calculated by dividing the net loss by the weighted average number of common shares outstanding for the period reduced by weighted average shares subject to repurchase, without consideration for common stock equivalents. Diluted net loss per share is computed by dividing the net loss by the weighted average number of common share equivalents outstanding for the period determined using the treasury-stock method and as-if converted method, as applicable. For purposes of this calculation, stock options and warrants are considered to be common stock equivalents and are only included in the calculation of diluted net loss per share when their effect is dilutive.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Numerator				
Net loss	$ (22,038)	$ (22,125)	$ (60,199)	$ (71,429)
Denominator				
Weighted average common shares outstanding	37,320	1,448	35,132	1,446
Weighted average shares subject to repurchase	0	(65)	(5)	(106)
Weighted average shares outstanding, basic and diluted	37,320	1,383	35,127	1,340
Basic and diluted net loss per share	$ (0.59)	$ (16.00)	$ (1.71)	$ (53.31)

Potentially dilutive securities not included in the calculation of diluted net loss per share because to do so would be anti-dilutive are as follows (in thousands, of common equivalent shares):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Convertible preferred stock	0	14,240	0	14,240
Common stock warrants	508	1,548	508	1,548
Common stock subject to repurchase	0	24	0	24
Common stock options and restricted stock units	3,441	1,483	3,441	1,483
	3,949	17,295	3,949	17,295

Segment Reporting

Management has determined that the Company operates in one business segment, which is the commercialization and development of pharmaceutical products.

Recent Accounting Pronouncements

In October 2009, the Financial Accounting Standards Board (the FASB) issued an Accounting Standard Update which replaced the concept of allocating revenue consideration amongst deliverables in a multiple-element revenue arrangement according to fair value with an allocation based on selling price. The amended guidance also establishes a hierarchy for determining the selling price of revenue deliverables sold in multiple element revenue arrangements. The selling price used for each deliverable will be based on vendor-specific objective evidence (VSOE) if available, third-party evidence if VSOE is not available, or management s estimate of an element s stand-alone selling price if neither VSOE nor third-party evidence is available. The amendments in this update also require an allocation of selling price amongst deliverables be performed based upon each deliverable s relative selling price to total revenue consideration, rather than on the residual method previously permitted. The updated guidance is effective for the first annual reporting period beginning on or after June 15, 2010, and may be applied retrospectively for all periods presented or prospectively to arrangements entered into or materially modified after the adoption date. The Company prospectively adopted the updated guidance on January 1, 2011 and will apply the amended guidance to revenue arrangements containing multiple deliverables that are entered into or significantly modified on or after January 1, 2011. As the Company did not enter into any new collaborations or materially modify any existing collaborations in 2011, adoption of this guidance did not have a material impact on the Company s results of operations.

In March 2010, the FASB Emerging Issues Task Force (EITF) ratified a new accounting standard which amends guidance on the milestone method of revenue recognition. The EITF concluded that the milestone method is a valid application of the proportional performance model when applied to research or development arrangements. Milestones, as defined per the revised guidance, are (1) events that can only be achieved in whole or in part on either the entity s performance or on the occurrence of a specific outcome resulting in the entity s performance (2) for which there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved and (3) that would result in additional payments being due to the Company. The Company evaluates events under this guidance at the inception of an arrangement to determine the existence of milestones and if they are substantive. This standard allows an entity to make an accounting policy election to

recognize a payment that is contingent upon the achievement of a substantive milestone in its entirety in the period in which the milestone is achieved. This standard is effective for fiscal years beginning on or after June 15, 2010 with early adoption permitted. The guidance may be applied prospectively for milestones achieved after the adoption date or retrospectively for all periods presented. The Company adopted this guidance on January 1, 2011 on a prospective basis. Adoption of this guidance did not have a material impact on the Company s results of operations.

In May 2011, the FASB issued accounting guidance related to fair value measurements and disclosures to achieve common fair value measurements and disclosures between GAAP and International Financial Reporting Standards. This guidance clarifies the

application of certain existing fair value measurement guidance and expands the disclosures for fair value measurements that are estimated using significant unobservable (Level 3) inputs. This guidance is effective on a prospective basis for annual and interim reporting periods beginning on or after December 15, 2011. The adoption of this updated standard is not expected to have a material effect on the Company s results of operations.

In June 2011, the FASB issued an Accounting Standards Update which requires entities to present reclassification adjustments included in other comprehensive income on the face of the financial statements and allows entities to present the total of comprehensive income, the components of net income and the components of other comprehensive income either in a single continuous statement of comprehensive income or in two separate consecutive statements. It also eliminates the option for entities to present components of other comprehensive income as part of the statement of changes to stockholders equity. The updated guidance is effective for fiscal and interim periods beginning after December 15, 2011, with early adoption permitted. The adoption of this updated standard is not expected to have a material effect on the Company s results of operations.

3. License Agreement

Durect Development and License Agreement

On July 11, 2011, the Company entered into a development and license agreement with Durect Corporation (the License Agreement). Under the License Agreement, the Company will be responsible for the clinical development and commercialization of Relday, a proprietary, long-acting injectable formulation of risperidone using Durect s SABER controlled-release formulation technology in combination with the Company s DosePro® needle-free, subcutaneous drug delivery system. Durect will be responsible for non-clinical, formulation and Chemistry, Manufacturing and Controls development responsibilities. Durect will be reimbursed by the Company for its research and development efforts on the product.

The Company paid a non-refundable upfront fee to Durect of $2,250,000, which was recorded as research and development expenses in the consolidated statement of operations during the three months ended September 30, 2011. The Company is obligated to pay Durect up to $103,000,000 in total future milestone payments with respect to the product subject to and upon the achievement of various development, regulatory and sales milestones. The Company is also required to pay a mid single-digit to low double-digit percentage patent royalty on annual net sales of the product determined on a jurisdiction-by-jurisdiction basis. The patent royalty term is equal to the later of the expiration of all Durect technology patents or joint patent rights in a particular jurisdiction, the expiration of marketing exclusivity rights in such jurisdiction, or 15 years from first commercial sale in such jurisdiction. After the patent royalty term, the Company will continue to pay royalties on annual net sales of the product at a reduced rate for so long as the Company continues to sell the product in the jurisdiction. The Company is also required to pay to Durect a tiered percentage of fees received in connection with any sublicense of the licensed rights.

Durect granted to the Company an exclusive worldwide license, with sub-license rights, to Durect intellectual property rights related to Durect s proprietary polymeric and non-polymeric controlled-release formulation technology to make and have made, use, offer for sale, sell and import risperidone products, where risperidone is the sole active agent, for administration by injection in the treatment of schizophrenia, bipolar disorder or other psychiatric related disorders in humans. Durect retains the right to supply the Company s Phase 3 clinical trial and commercial product requirements on the terms set forth in the License Agreement.

Durect retains the right to terminate the License Agreement with respect to specific countries if the Company fails to advance the development of the product in such country, either directly or through a sublicensee. In addition, either party may terminate the License Agreement upon insolvency or bankruptcy of the other party, upon written notice of a material uncured breach or if the other party takes any act impairing such other party s relevant intellectual property rights. The Company may terminate the License Agreement upon written notice if during the development or commercialization of the product, the product becomes subject to one or more serious adverse drug experiences or if either party receives notice from a regulatory authority, independent review committee, data safety monitory board or other similar body alleging significant concern regarding a patient safety issue. The Company may also terminate the License Agreement with or without cause, at any time upon prior written notice.

4. Consolidated Balance Sheet Details

Inventory, net (in thousands)

	September 30, 2011	December 31, 2010
Raw materials	$ 5,331	$ 5,727
Work in process	9,497	6,454
Finished goods	2,376	4,861
Deferred costs	0	1,251
	$ 17,204	$ 18,293

Deferred costs represent the costs of product shipped for which recognition of revenue has been deferred.

Accrued Expenses (in thousands)

	September 30, 2011	December 31, 2010
Accrued clinical expense	$ 2,736	$ 3,629
Accrued co-promotion service fee	1,480	1,190
Accrued discounts and allowances	1,266	813
Accrued sales and marketing expenses	1,013	263
Accrued interest expenses	993	265
Accrued product returns	1,264	0
Accrued royalty expenses	324	319
Warrant liability	244	0
Value added tax payable	0	989
Other accrued expenses	1,209	1,971
	$ 10,529	$ 9,439

5. Term Debt

In June 2008, the Company entered into and borrowed $18,000,000 under the Loan and Security Agreement with Oxford and CIT Healthcare LLC (the Oxford Agreement). The obligations under the Oxford Agreement were collateralized by personal property excluding certain intellectual property and all equipment pledged to secure the equipment financing described below. In July and October 2010, the Company amended and restated the Oxford Agreement, and Oxford and SVB became party to the amended agreement. In June 2011, the Company again amended and restated the amended Oxford/SVB agreement (the Amended Oxford/SVB Agreement), which provided among other things, the addition of intellectual property to the collateral securing the Oxford/SVB loan and the deferral of principal repayment to commence on February 1, 2012. The Amended Oxford/SVB Agreement consists of a $25,000,000 term loan and a $10,000,000 revolving credit facility. The obligations under the Amended Oxford/SVB Agreement are collateralized by the Company s intellectual property and personal property (including, among other things, accounts receivable, equipment, inventory, contract rights, rights to payment of money, license agreements, general intangibles and cash) but excluding, among other things, copyrights, patents, patent applications, trademarks, service marks, and trade secret rights.

The Amended Oxford/SVB Agreement includes financial covenants requiring that the Company achieve, as of the last day of each month measured on a trailing three-month basis, actual revenue of at least a specified percentage of the Company s projected revenue as provided to Oxford and SVB in the event the Company fails to maintain a liquidity ratio (defined, in general, as the ratio of (a) cash and cash equivalents deposited with SVB plus unused borrowing capacity under that agreement to (b) all debt, capital lease obligations and contingent obligations owed to the lenders) of 1.25 to 1.00. The Amended Oxford/SVB Agreement also includes a covenant that the audit report accompanying the Company s year-end consolidated financial statements for fiscal year 2010 and thereafter not include a going concern qualification. In March 2011, the Company obtained a waiver from Oxford and SVB for the breach caused by the receipt of the 2010 audit report from our independent registered public accounting firm, which includes a modification of their standard report for the going concern uncertainty. In addition, the

Amended Oxford/SVB Agreement prohibits the Company from (1) incurring any debt other than, among other things, debt under the Amended Oxford/SVB Agreement, (2) entering into mergers with, or acquisitions of all or substantially all the assets of, another entity with a value in excess of $100,000, and also prohibits the occurrence of a change in control of the Company, as defined in the Amended Oxford/SVB Agreement. The Amended Oxford/SVB Agreement provides that an event of default will occur if, among other customary events of default, (1) there is a material adverse change in the Company s business, operations or condition (financial or otherwise) or material impairment in the prospects of the Company repaying any portion of its obligations under the agreement, (2) there is a material impairment in the value of the collateral pledged to secure its obligations under the agreement, (3) the Company defaults in the payment of any amount payable under the agreement when due, or (4) breaches any covenant in the agreement (subject to a grace period in some cases).

The $25,000,000 term loan bears an interest rate of 12.06% per annum. The monthly repayment schedule includes interest only payments through January 2012 followed by principal and interest payments for the subsequent 24 months. The term loan requires a final payment of $1,200,000, in addition to principal repayments, at the loan maturity date, which is January 1, 2014. The Company has the option to prepay the outstanding balance of the term loan in full, subject to the $1,200,000 final payment and a prepayment fee of either 2% or 3% of the principal amount prepaid depending upon when the prepayment occurs. The outstanding principal balance of the term loan as of September 30, 2011and December 31, 2010 is $25,000,000.

Under the terms of the revolving credit facility, the Company may borrow up to $10,000,000 based on eligible accounts receivable and inventory balances, as defined within the Amended Oxford/SVB Agreement. Amounts outstanding under the revolving credit facility accrue interest, payable monthly, at a floating rate per annum equal to the greater of 3.29% above SVB s prime rate or 7.29%. In addition, the Company pays a monthly fee equal to 0.5% per annum of the average unused portion of the revolving credit facility. The revolving credit facility requires a final payment of $100,000, in addition to principal and interest repayments, at the loan maturity date. The Company has the option to terminate the revolving credit facility prior to the loan maturity date and repay the outstanding balance in full, subject to a termination fee between $100,000 and $300,000 depending upon when the termination occurs.

As of September 30, 2011 and December 31, 2010, the Company had $4,588,000 and $3,585,000, respectively, of outstanding principal under the revolving credit facility, and $5,412,000 and $6,415,000, respectively, was available for future borrowings to the extent of available borrowing base. As of September 30, 2011 and December 31, 2010, $4,503,000 and $3,449,000, respectively, is reflected on the consolidated balance sheet net of debt discounts related to the fees and warrants issued in connection with the Amended Oxford/SVB Agreement.

Equipment Financing

In March 2007, the Company entered into a $10,000,000 master loan and security agreement (GE Agreement) with GE Capital Corporation (GE Capital) for the purpose of financing capital equipment purchases. Each borrowing is under a promissory note repayable in 48 monthly installments based upon a monthly repayment schedule bearing interest at an annual rate determined on the date of borrowing. The first promissory note was executed in March 2007 for $3,500,000 with an interest rate of 10.08%. A second promissory note was executed in December 2007 for $1,000,000 with an interest rate of 9.91%. The Company s ability to make further borrowing under the GE Agreement expired on December 21, 2007.

The Company had the option to prepay the outstanding balance of the promissory notes in full, subject to a prepayment fee as defined in the GE Agreement. The outstanding principal balance of the GE Agreement as of December 31, 2010 was $675,000 and was repaid in full on June 30, 2011.

Cowen Royalty Financing Agreement

On July 18, 2011, the Company closed the royalty financing agreement (the Financing Agreement) with Cowen Royalty. Under the terms of the Financing Agreement, the Company borrowed $30,000,000 from Cowen Royalty (the Borrowed Amount) and the Company agreed to repay such Borrowed Amount together with a return to Cowen Royalty, as described below, out of the Company s direct product sales, co-promotion revenues and out-license revenues (collectively, Revenue Interest) that the Company may record or receive as a result of worldwide commercialization of the Company s products including Sumavel DosePro, Zohydro (formerly ZX002) and other future products.

In addition, upon the closing of and in connection with the Financing Agreement, the Company issued and sold to Cowen Royalty $1,500,000 of the Company s common stock, or 388,601 shares, at a price of $3.86 per share. The Company also issued to Cowen Royalty a warrant exercisable into 225,000 shares of the Company s common stock. The warrant is exercisable at $9.00 per share and has a term of 10 years. As the warrant contains covenants where compliance with such covenants may be outside the control of the Company, the warrant was recorded as a current liability and marked to market at each reporting date using the Black-Scholes option pricing valuation model (see note 2).

Under the Financing Agreement, the Company is obligated to pay to Cowen Royalty:

- 5% of the first $75,000,000 of Revenue Interest recorded (in the case of net product sales) or received (in the case of co-promotion revenues and license fees) by the Company in a calendar year (or 5.75% if the co-promotion agreement with Astellas is terminated prior to June 30, 2013, with a reversion back to 5% possible if certain net sales of Sumavel DosePro are achieved or if Zohydro is commercialized in the four calendar quarters immediately following the effective date of termination);

2.5% of the next $75,000,000 of Revenue Interest recorded (in the case of net product sales) or received (in the case of co-promotion revenues and license fees) by the Company in a calendar year; and

0.5% of Revenue Interest over and above $150,000,000 recorded (in the case of net product sales) or received (in the case of co-promotion revenues and license fees) by the Company in a calendar year.

Net sales of Sumavel DosePro outside the United States are only included in the Revenue Interest if such net sales exceed $10,000,000. Once the aggregate payments, including the fixed payments described below, made by the Company to Cowen Royalty equal $75,000,000, the percentage of Revenue Interest owed to Cowen Royalty is reduced to 0.5% for the remainder of the term of the Financing Agreement, with only Sumavel DosePro and Zohydro subject to the Revenue Interest payments thereafter. The Company is also obligated to make three fixed payments of $10,000,000 on (or before at the option of the Company) each of January 31, 2015, January 31, 2016 and January 31, 2017. Prepayment requires the consent of the lenders under the Amended Oxford/SVB Agreement while balances remain outstanding under that facility. Unless terminated as discussed below, the Financing Agreement terminates on March 31, 2018.

The obligation of the Company to make the Revenue Interest payments during the term of the Financing Agreement are secured under a security agreement by a second priority security interest (junior to the security interest of Oxford and SVB under the Amended Oxford /SVB Agreement) in all assets of the Company, including intellectual property and other rights of the Company to the extent necessary or used to commercialize the Company products. The security interest will be extinguished at the end of the term or once the aggregate payments made by the Company to Cowen Royalty equal $75,000,000, whichever is sooner. Cowen Royalty, Oxford and SVB entered into an intercreditor agreement which governs their respective rights as secured creditors. The Company has agreed to specified positive and negative covenants in connection with the Financing Agreement.

The Company has the option to terminate the Financing Agreement at the Company s election in connection with a change of control of the Company, upon the payment of a base amount of $52,500,000, or, if higher, an amount that generates a 19% internal rate of return on the Borrowed Amount as of the date of prepayment, in each case reduced by the Revenue Interest and principal payments received by Cowen Royalty up to the date of prepayment.

Cowen Royalty has the option to terminate the Financing Agreement at its election in connection with a change of control of the Company (which includes the sale, transfer, assignment or licensing of the Company s rights in the United States to either Sumavel DosePro or Zohydro), a bankruptcy event with respect to the Company or an event of default under the financing agreement. Upon such a termination by Cowen Royalty, the Company is obligated to make a payment of a base amount of $45,000,000, or, if higher, an amount that generates a 17% internal rate of return on the Borrowed Amount as of the date of prepayment, in each case reduced by the Revenue Interest and principal payments received by Cowen Royalty up to the date of prepayment.

In addition to the Company s and Cowen Royalty s option to terminate the Financing Agreement, the initial Revenue Interest percentage payable to Cowen Royalty is subject to an incremental increase in the event of an early termination of the Company s co-promotion arrangement with Astellas. The rights of the Company and Cowen Royalty to early terminate the Financing Agreement, as well the potential change in the Revenue Interest rate in connection with the early termination of the Astellas co-promotion agreement, meet the definition of an embedded derivative. As a result, the Company carved out these embedded derivatives from the Financing Agreement and determined the fair value of each derivative using various discounted cash flow valuation models taking into account the probability of these events occurring and various scenarios surrounding the potential Revenue Interest payments that would be made if these events occurred (see note 2). The aggregate fair value of the embedded derivatives was $605,000 at issuance and was included in other long-term liabilities.

The Company received aggregate net proceeds of $29,484,000 from the Financing Agreement (including the purchase of common stock). The $30,000,000 borrowed is reflected as long-term debt at September 30, 2011, net of $1,805,000 in discounts. The discounts, which are being amortized using the effective interest method over the term of the arrangement within interest expense, include the fair value of the common stock warrants issued to Cowen Royalty of $790,000, fees payable to Cowen Royalty in connection with the execution of the arrangement of $476,000 and the fair value of embedded derivatives of $605,000. The Company has recognized other income in relation to the change in the fair value of the common stock warrant and embedded derivatives of $546,000 and $137,000, respectively, for the three and nine months ended September 30, 2011 in the statement of operations.

The following is a summary of all debt obligations recorded in current and long-term debt on the balance sheet at September 30, 2011 (in thousands):

	Revolver	Oxford /SVB	Cowen Royalty
Long-term debt, current portion	$ 4,588	$ 7,676	$ 0
Debt discount	(85)	(1,036)	0
Total long-term debt, current portion	$ 4,503	$ 6,640	$ 0
Long-term debt, less current portion	$ 0	$ 17,324	$ 30,000
Debt discount	0	(649)	(1,805)

Total long-term debt, less current portion	$ 0	$ 16,675	$ 28,195

6. Common Stock Warrants

In June 2011, and in connection with entering into the Amended Oxford/SVB Agreement (see note 5), the Company issued to Oxford and SVB warrants exercisable into an aggregate of 26,455 shares of common stock. The warrants are exercisable at $3.78 per share of common stock and have a term of 7 years. The value of the warrants of approximately $76,000 was recorded as debt discount and additional paid in capital in the consolidated balance sheet as of September 30, 2011.

In July 2011, upon the closing of and in connection with the Financing Agreement (see note 5), the Company issued to Cowen Royalty a warrant exercisable into 225,000 shares of common stock. The warrant is exercisable at $9.00 per share of common stock and has a term of 10 years. As the warrant contains covenants where compliance with such covenants may be outside of the Company s control, the warrant was recorded as a current liability and is marked to market at each reporting date. The fair value of the warrant was approximately $244,000 as of September 30, 2011.

7. Employee Stock Purchase Plan

During 2010, the Company adopted the 2010 Employee Stock Purchase Plan (the Purchase Plan), which allows employees to purchase shares of the Company s common stock during a specified offering period. The purchase price is 85% of the lower of the closing price of the stock on the first day of the offering period or the closing price of the stock on the date of purchase. Eligible employees may elect to withhold up to 20% of their compensation during any offering period for the purchase of stock up to a maximum of 20,000 shares per purchase period. A total of 750,000 shares of common stock are reserved for issuance under the Purchase Plan. The first offering period under the Purchase Plan is from June 1, 2011 through May 31, 2012 with two purchase periods of six months each.

8. Stock-Based Compensation

The Company uses the Black-Scholes option-pricing model for determining the estimated fair value and stock-based compensation for stock-based awards to employees and the board of directors. The assumptions used in the Black-Scholes option-pricing model for the three and nine months ended September 30, 2011 are as follows:

	Three Months Ended September 30, 2011	Nine Months Ended September 30, 2011
Stock Options		
Risk free interest rate	1.6%	1.6 % to 2.6%
Expected term	6.1 years	5.0 to 6.1 years
Expected volatility	80.91%	72.3% to 89.7%
Expected dividend yield	0.0%	0.0%
Fair value of underlying stock	$3.65 to $5.06	$3.65 to $5.06
Employee Stock Purchase Plan		
Risk free interest rate	0.1%	0.1%
Expected term	0.5 years	0.5 years
Expected volatility	75.2%	75.2%
Expected dividend yield	0.0%	0.0%
Fair value of underlying stock	$4.15	$4.15

The risk-free interest rate assumption was based on the rates for U.S. Treasury zero-coupon bonds with maturities similar to those of the expected term of the award being valued. The assumed dividend yield was based on the Company s expectation of not paying dividends in the foreseeable future. The weighted average expected term of options was calculated using the simplified method as prescribed by accounting guidance for stock-based compensation. This decision was based on the lack of relevant historical data due to the Company s limited historical experience. In addition, due to the Company s limited historical data, the estimated volatility was calculated based upon the historical volatility of comparable companies whose share prices have been publicly available for a sufficient period of time.

The Company recognized stock-based compensation expense related to stock options and employee stock purchase plan rights as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Cost of sales	$ 42	$ 32	$ 105	$ 73
Research and development	209	121	540	262
Selling, general and administrative	1,066	721	2,857	1,377
Total	$ 1,317	$ 874	$ 3,502	$ 1,712

As of September 30, 2011, there was approximately $11,283,000 and $175,000 of total unrecognized compensation costs related to outstanding options and employee stock purchase plan rights, which is expected to be recognized over weighted average periods of 3.08 years and 0.42 years, respectively.

In accordance with accounting guidance for stock-based compensation, the Company re-measured the fair value of stock option grants to non-employees at each reporting date and recognized the related income or expense during their vesting period. Expense recognized for stock options to consultants was immaterial for the three and nine months ended September 30, 2011 and 2010.

Information with respect to the number and weighted average exercise price of stock options and restricted stock units are summarized as follows (number of shares in thousands):

	Shares	Weighted Average Exercise Price
Outstanding at December 31, 2010	1,479	$ 3.35
Granted	2,090	4.50
Exercised	(67)	1.37
Canceled/Forfeited	(61)	4.14
Outstanding at September 30, 2011	3,441	$ 4.09

9. Subsequent Event

In connection with the Company s Offering on September 21, 2011, the Company granted the underwriters an option to purchase up to 4,500,000 additional shares of common stock, at a price of $2.00 per share. On October 4, 2011, the Company sold 711,566 shares of common stock to the underwriters in connection with this purchase option for net proceeds of $1,338,000.

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

Forward-Looking Statements

This Quarterly Report on Form 10-Q and the information incorporated herein by reference contain forward-looking statements that involve substantial risks and uncertainties, including statements regarding the future sales potential for Sumavel DosePro, the progress and timing of clinical trials, the safety and efficacy of our product candidates, the goals of our development activities, estimates of the potential markets for our product candidates, estimates of the capacity of manufacturing and other facilities to support our products, projected cash needs and our expected future revenues, operations and expenditures. The forward-looking statements are contained principally in the sections entitled Risk Factors, Management s Discussion and Analysis of Financial Condition and Results of Operations and Business. In some cases, you can identify forward-looking statements by the following words: may, will, could, would, should, expect, intend, plan, anticipate, believe, project, potential, continue, ongoing or the negative of these terms or other comparable terminology, although not all forward-looking statemen contain these words. These statements relate to future events or our future financial performance or condition and involve known and unknown risks, uncertainties and other factors that could cause our actual results, levels of activity, performance or achievement to differ materially from those expressed or implied by these forward-looking statements. We discuss many of these risks, uncertainties and other factors in this Quarterly Report on Form 10-Q in greater detail under the heading Item 1A Risk Factors.

Given these risks, uncertainties and other factors, we urge you not to place undue reliance on these forward-looking statements, which speak only as of the date of this report. You should read this Quarterly Report on Form 10-Q completely and with the understanding that our actual future results may be materially different from what we expect. For all forward-looking statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995. We undertake no obligation to revise or update publicly any forward-looking statements, whether as a result of new information, future events or otherwise, unless required by law.

Sumavel®, DosePro®, Zohydro , Relday , Intrajet® and Zogenix are our trademarks. All other trademarks, trade names and service marks appearing in this Quarterly Report on Form 10-Q are the property of their respective owners.

Unless the context requires otherwise, references in this Quarterly Report on Form 10-Q to Zogenix, we, us and our refer to Zogenix, Inc., including, as of June 7, 2010, its consolidated subsidiary.

The interim financial statements and this Management s Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the financial statements and notes thereto for the year ended December 31, 2010 and the related Management s Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our Annual Report on Form 10-K for the year ended December 31, 2010.

Overview

Background

We are a pharmaceutical company commercializing and developing products for the treatment of central nervous system disorders and pain. Our first commercial product, Sumavel DosePro (*sumatriptan* injection) Needle-free Delivery System, offers fast-acting, easy-to-use, needle-free subcutaneous administration of *sumatriptan* for the acute treatment of migraine and cluster headache in a pre-filled, single-use delivery system. We launched the commercial sale of Sumavel DosePro in the United States in January 2010 with our co-promotion partner, Astellas Pharma US, Inc., or Astellas. Our sales and marketing organization is comprised of approximately 105 professionals. Our field sales force of approximately 94 representatives is promoting Sumavel DosePro primarily to neurologists and other prescribers of migraine medications, including headache clinics and headache specialists. Our promotional efforts are complemented by our collaboration with Astellas and approximately 400 of its sales representatives, who are promoting Sumavel DosePro primarily to primary care physicians, OB/GYNs, emergency medicine physicians and urologists in the United States, or the Astellas Segment. Our lead product candidate, Zohydro (formerly ZX002), is a novel, oral, single-entity extended-release formulation of *hydrocodone* currently in Phase 3 development for the treatment of moderate to severe chronic pain in patients requiring around-the-clock opioid therapy. We reported top-line results from our pivotal Phase 3 efficacy trial for Zohydro in August 2011 and expect to submit a New Drug Application, or NDA, with the U.S. Food and Drug Administration, or FDA, by early 2012. We in-licensed exclusive U.S. rights to Zohydro from Alkermes, plc (formerly Elan Pharma International Limited), or Alkermes, in 2007.

In July 2011, we entered into a development and license agreement with Durect Corporation, or the Relday license agreement, pursuant to which we will be responsible for the clinical development and commercialization of Relday, a proprietary, long-acting injectable formulation of risperidone using Durect s SABER controlled-release formulation technology in combination with our DosePro® needle-free, subcutaneous drug delivery system. Risperidone is used to treat the symptoms of schizophrenia and bipolar disorder in adults and teenagers 13 years of age and older. Relday will be developed to address unmet clinical needs in this patient population and is being developed to be a once-monthly, subcutaneous antipsychotic product. We expect to initiate clinical studies for this new product candidate in patients with schizophrenia in early 2012 following filing of an investigational new drug application.

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We have experienced net losses and negative cash flow from operating activities since inception, and as of September 30, 2011, had an accumulated deficit of $258.3 million. We expect to continue to incur net losses and negative cash flow from operating activities for at least the next several years primarily as a result of the development expenses in connection with clinical trials and pre-clinical studies for Zohydro, the costs of clinical development of Relday and the cost of the sales and marketing expenses associated with Sumavel DosePro. As of September 30, 2011, we had cash and cash equivalents of $70.8 million. On June 30, 2011, we amended certain terms of our loan agreement with Oxford Finance Corporation, or Oxford, and Silicon Valley Bank, or SVB, including the deferral of principal repayment to commence on February 1, 2012. In July 2011, we entered into an equity and royalty financing agreement with Cowen Healthcare Royalty Partners II, L.P., or Cowen Royalty, resulting in net proceeds of $29.5 million to us. Although it is difficult to predict future liquidity requirements, we believe that our cash and cash equivalents as of September 30, 2011, together with future product revenue and borrowings available under our $10.0 million revolving credit facility, will be sufficient to fund our operations into the second quarter of 2013. We will need to obtain additional capital to finance our operations beyond that point. We intend to raise additional capital through debt or equity financings or through collaborations or partnerships with other companies. If we are not able to raise additional capital on terms acceptable to us, or at all, as and when needed, we may be required to reduce or curtail our operations and costs, and we may be unable to continue as a going concern. In its report on our consolidated financial statements for the year ended December 31, 2010, our independent registered public accounting firm included an explanatory paragraph expressing substantial doubt regarding our ability to continue as a going concern.

Co-Promotion Agreement

Under our co-promotion agreement with Astellas that we entered into in July 2009, or the co-promotion agreement, Astellas primarily promotes Sumavel DosePro to the Astellas Segment in the United States. Our sales force promotes Sumavel DosePro primarily to neurologists and other prescribers of migraine medications, including headache clinics and headache specialists in the United States. We jointly share in the cost of advertising, marketing and other promotional activities related to the Sumavel DosePro brand and are required to provide minimum levels of sales effort to promote Sumavel DosePro. Under the co-promotion agreement, we are responsible for the manufacture, supply and distribution of all Sumavel DosePro commercial product and are principally responsible for entering into any contracts and other arrangements with third parties regarding the sale of Sumavel DosePro.

At the inception of the co-promotion agreement and in exchange for the right to promote Sumavel DosePro, Astellas made a non-refundable up-front payment of $2.0 million to us and agreed to make an additional $18.0 million of payments to us upon the achievement of a series of milestones. As of September 30, 2011, we had received a total of $20.0 million from Astellas. These proceeds are reflected as deferred revenues on our consolidated balance sheets at September 30, 2011 and December 31, 2010. Beginning with the launch of Sumavel DosePro in January 2010, we began recognizing these proceeds as contract revenues on a ratable basis over the remaining term of the agreement, which remains in effect through June 30, 2013, subject to extension by one year at Astellas option, contingent upon payment of a predetermined option fee.

In consideration for Astellas performance of its commercial efforts, we are required to pay Astellas a service fee on a quarterly basis that represents a fixed percentage of between 45% and 55% of Sumavel DosePro net sales to the Astellas Segment. In addition, upon completion of the co-promotion term, Astellas generally will be eligible to receive two additional annual tail payments calculated as decreasing fixed percentages (ranging from a mid-twenties down to a mid-teen percentage) of net sales in the Astellas Segment in the last 12 months of its active promotion. Astellas pays us the lesser of our direct out-of-pocket costs or a fixed fee for all sample units they order for distribution to their sales force. Amounts received from Astellas for shared marketing costs and sample product are reflected as a reduction of selling, general and administrative expenses, and amounts payable to Astellas for shared marketing expenses and service fees are reflected as selling, general and administrative expenses. For the three months ended September 30, 2011 and 2010, we incurred $1.7 million and $1.1 million, respectively, and for the nine months ended September 30, 2011 and 2010, we incurred $4.9 million and $2.2 million, respectively, in service fee expenses. For the three months ended September 30, 2011 and 2010, we recognized $0.4 million and $1.0 million, respectively, and for the nine months ended September 30, 2011 and 2010, we recognized $1.5 million and $3.5 million, respectively, in shared marketing expense.

We record the revenues related to all products sales, including sales generated by the Astellas sales force. Consequently, we record cost of sales for all product sales.

We rely on Astellas and its sales force to promote Sumavel DosePro to the Astellas Segment and any inability of its sales force to effectively sell the product or any termination, amendment or restructuring of the co-promotion agreement could adversely affect our consolidated results of operations and financial condition. For the three and nine months ended September 30, 2011, the Astellas Segment represented approximately 37% and 39%, respectively, of our product demand before consideration of the cost of the service fee payable to Astellas for its sales efforts as described above.

Under the terms of the co-promotion agreement, Astellas could terminate the agreement for any or no reason upon 180-days written notice. The co-promotion agreement may also be terminated by Astellas or us for a number of other specified reasons, some of which are beyond our control. In the event Astellas terminates the agreement for specified reasons or a material uncured breach by us of our minimum sales effort obligations, we would be required to pay Astellas only the first of the two annual tail payments described above.

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In addition, either party may terminate the agreement based upon a failure of the Sumavel DosePro brand to achieve certain minimum sales levels in 2011, as defined in the co-promotion agreement. Based on our net product revenue through September 30, 2011, we do not expect to meet these 2011 minimum sales levels for Sumavel DosePro, and therefore expect that both we and Astellas will have the right to terminate the agreement on this basis. If either party were to exercise this termination right, it must provide 90 days written notice to the other party after the actual net sales of Sumavel DosePro through December 31, 2011 have been ascertained. In the event of such a termination relating to sales levels of Sumavel DosePro, we would be required to make the two annual tail payments described above.

In the event of a termination by us or Astellas, we would expect to either expand our sales force to promote Sumavel DosePro to certain physicians within the Astellas Segment, and/or seek another co-promotion partner in order to support the future sales and marketing of Sumavel DosePro.

Durect License Agreement

In July 2011, we paid a non-refundable upfront fee to Durect of $2.25 million under the Relday license agreement. We are obligated to pay Durect up to $103.0 million in total future milestone payments with respect to Relday subject to and upon the achievement of various development, regulatory and sales milestones. We are also required to pay a mid single-digit to low double-digit percentage patent royalty on annual net sales of the product determined on a jurisdiction-by-jurisdiction basis. The patent royalty term is equal to the later of the expiration of all Durect technology patents or joint patent rights in a particular jurisdiction, the expiration of marketing exclusivity rights in such jurisdiction, or 15 years from first commercial sale in such jurisdiction. After the patent royalty term, we will continue to pay royalties on annual net sales of the product at a reduced rate for so long as we continue to sell the product in the jurisdiction. We are also required to pay to Durect a tiered percentage of fees received in connection with any sublicense of the licensed rights.

Revenues

During the year ended December 31, 2010, we began recognizing product revenues from sales of Sumavel DosePro made by us and Astellas under our co-promotion agreement and through sales by us to Desitin Arzneimittel GmbH, or Desitin, under our licensing and distribution agreement. During this same period, we began recognizing contract revenues from license and milestone payments received under the Astellas co-promotion agreement. For the three months ended September 30, 2011 and 2010 we recognized $8.8 million and $5.7 million, respectively, and for the nine months ended September 30, 2011 and 2010 we recognized $25.0 million and $11.8 million, respectively, in net product revenues. For the three months ended September 30, 2011 and 2010 we recognized $1.6 million and $1.3 million, respectively, and for the nine months ended September 30, 2011 and 2010 we recognized $4.7 million and $2.8 million, respectively, in contract revenues associated with license and milestone payments made to us by Astellas under the co-promotion agreement. We sell Sumavel DosePro product in a package of six pre-filled, single-dose units to wholesale pharmaceutical distributors, and on a limited basis to retail pharmacies, or, collectively, our customers, at a wholesale acquisition cost, or WAC, or gross sales price, of $522 per package as of September 30, 2011 and $538 per package effective October 1, 2011. Sales to our customers are subject to specified rights of return. Prior to the third quarter of 2011, there was limited return history of Sumavel DosePro, and we could not reliably estimate expected returns of the product at the time of shipment. Accordingly, we deferred the recognition of revenue on product shipments of Sumavel DosePro to our customers until the right of return no longer existed, which occurred at the earlier of the time Sumavel DosePro units were dispensed through patient prescriptions or expiration of the right of return.

During the third quarter of 2011, we began to recognize net product sales upon the shipment of product to wholesale pharmaceutical distributors and retail pharmacies to provide a more accurate estimate of product sales activity, and because we had developed sufficient historical experience and data to reasonably estimate future returns of Sumavel DosePro. As a result, we are no longer deferring the recognition of product revenues and related cost of goods for products shipped to our customers. In order to develop a methodology to reliably estimate product returns and provide a basis for recognizing revenue on sales to customers at the time of product shipment, we analyzed many factors, including, without limitation: (i) retail pharmacy re-order activity, (ii) actual Sumavel DosePro product return history, taking into account product expiration dating at the time of shipment and product launch stocking activities, (iii) levels of inventory in the wholesale and retail channel and prescription units dispensed, and (iv) industry data regarding product return rates. Based on the data gathered, we believe we have the information needed to reasonably estimate product returns.

In connection with us being able to reliably estimate product returns and the resulting change in the timing of recognition of product sales, previously reported deferred product revenues and deferred cost of sales as of June 30, 2011 have been recognized as product revenue and cost of sales during the period. In addition, we recorded an estimated cost for future returns based on product that remained in the distribution channel at September 30, 2011 and we recorded the cost of actual return experience for the three months ended September 30, 2011. In the third quarter of 2011, we received product returns from the initial stocking at the time of launch of some retail pharmacy stores which resulted in a higher rate of returns than

what may be experienced with an established product. As a result of the establishment of a return reserve and the recognition of deferred product revenues, net product sales for the quarter ended September 30, 2011 were reduced by $1.0 million.

We permit certain wholesale pharmaceutical distributors to purchase limited quantities of product after the announcement of an increase to the wholesale acquisition cost (WAC) of our product and prior to the effectiveness of the increase. In turn, WAC price increases can result in accelerated purchases by wholesalers relative to anticipated retail and prescription demand. The timing of purchases made by wholesale distributors and retail pharmacies are subject to fluctuations for these reasons among others. Absent accelerated purchasing by wholesalers or other periodic changes in buying patterns, the wholesale channel has historically contained two to three weeks of product on hand. As of September 30, 2011, wholesale distributors reported approximately four weeks of our product on hand.

In November 2010, Desitin received regulatory approval to market Sumavel DosePro in Denmark and subsequently received approvals in Germany, Sweden, Norway and the United Kingdom. As a result, we started to sell Sumavel DosePro to Desitin under our licensing and distribution agreement in December 2010. We sell our product to Desitin at a specified transfer price with the right of return available for damaged goods upon receipt by Desitin or in the event of a recall. Desitin maintains all risk for retail and wholesaler fees and discounts, collectability of customer receivables, customer returns and expiration of the product. We will also receive a low single-digit royalty from Desitin on net sales of Sumavel DosePro in Europe and other licensed territories, as a pass through of royalties payable to Aradigm. As such, we recognize revenues for product sales to Desitin upon acceptance of product by Desitin (generally at point of shipment). For the nine months ended September 30, 2011 and 2010 we recognized no revenue for sales to Desitin. We recognized an immaterial amount of royalty revenues related to the Desitin agreement for the nine months ended September 30, 2011.

Cost of Sales

Cost of sales consist primarily of materials, third-party manufacturing costs, freight and indirect personnel and other overhead costs associated with sales of Sumavel DosePro based on units dispensed through patient prescriptions, as well as reserves for excess, dated or obsolete commercial inventories and production manufacturing variances. Our cost of sales for the three months ended September 30, 2011 and 2010, was $5.5 million and $2.9 million, respectively and for the nine months ended September 30, 2011 and 2010, our cost of sales was $14.3 million and $8.2 million, respectively. Our product gross margin for the three months ended September 30, 2011 and 2010 was 38% and 49%, respectively and for the nine months ended September 30, 2011 and 2010, our product gross margin was 43% and 30%, respectively. Prior to the change in timing of our revenue recognition in the third quarter of 2011, the cost of sales associated with the deferred product revenues were recorded as deferred costs, which were included in inventory, until such time the deferred revenue was recognized. Deferred cost of sales totaled $0 and $1.1 million at September 30, 2011 and December 31, 2010, respectively.

Royalty Expense

Royalty expense consists of the amortization of the $4.0 million milestone payment paid by us to Aradigm Corporation upon the first commercial sale of Sumavel DosePro in the United States (which occurred in January 2010) and royalties payable to Aradigm based on net sales of Sumavel DosePro by us or one of our licensees. We are not required to make any further milestone payments to Aradigm. Our ongoing royalty obligation payable to Aradigm is set forth in the asset purchase agreement we entered into with Aradigm in August 2006 pursuant to which we acquired the rights to the DosePro technology. We incurred $0.3 million and $0.2 million in royalty expense to Aradigm during the three months ended September 30, 2011 and 2010, respectively, and during the nine months ended September 30, 2011 and 2010, we incurred $1.0 million and $0.6 million, respectively, in royalty expense to Aradigm.

Research and Development Expenses

Our research and development expenses consist of expenses incurred in developing, testing and seeking marketing approval of our product candidates, including:

- payments made to third-party contract research organizations, or CROs, and investigational sites, which conduct our trials on our behalf, and consultants;
- expenses associated with regulatory submissions, preclinical development and clinical trials;
- payments to third-party manufacturers, which produce our active pharmaceutical ingredient and finished product;

payments made to third-party CROs, laboratories and consultants in connection with preclinical studies;

personnel related expenses, such as salaries, benefits, travel and other related expenses, including stock-based compensation; and

facility, maintenance, depreciation and other related expenses.

We expense all research and development costs as incurred.

In March 2010, we initiated our Phase 3 clinical development program for Zohydro. We utilize CROs, contract laboratories and independent contractors for the conduct of pre-clinical studies and clinical trials. In 2010, we began tracking third party costs by type of study being conducted. We recognize the expenses associated with the services provided by CROs based on the percentage of each study completed at the end of each reporting period. We coordinate clinical trials through a number of contracted investigational sites and recognize the associated expense based on a number of factors, including actual and estimated subject enrollment and visits, direct pass-through costs and other clinical site fees. For the three and nine months ended September 30, 2011, we incurred $4.9 million and $17.8 million, respectively, in third party research and development costs related to Zohydro.

We use our employee and infrastructure resources across our product and product candidate development programs. Therefore, we have not tracked salaries, other personnel related expenses, facilities or other related costs to our product development activities on a program-by-program basis. However, we estimate that the majority of our research and development expenses incurred to date are attributable to our Zohydro program.

We expect our research and development costs for 2011 to increase over amounts incurred in 2010 as we progress through the Phase 3 clinical program of Zohydro and with the addition of our Relday program. We expect third party research and development costs for Zohydro remaining through NDA filing to range from $10 million to $12 million. These expenditures are subject to numerous uncertainties regarding timing and cost to completion. Completion of our Phase 3 clinical trials may take longer than currently estimated. The cost of clinical trials may vary significantly over the life of a project as a result of differences arising during clinical development, including, among others:

- the number of sites included in the trials;
- the length of time required to enroll suitable subjects;
- the duration of subject follow-ups;
- the length of time required to collect, analyze and report trial results;
- the cost, timing and outcome of regulatory review; and
- potential changes by the FDA in clinical trial and NDA filing requirements for a specific therapeutic area.

In addition, in August 2011 we paid Alkermes, from whom we in-licensed exclusive rights to Zohydro in November 2007, a milestone payment in the amount of $0.8 million in connection with the completion of the treatment phase of our pivotal efficacy Phase 3 clinical trial, Study 801. We may be obligated to pay Alkermes up to $3.75 million in total future milestone payments with respect to Zohydro depending upon the achievement of various development and regulatory events. If Zohydro is approved, we are also required to pay a mid single-digit percentage royalty on its net sales for a specified period of time and continue to pay royalties on net sales of the product thereafter at a reduced low single-digit percentage rate in accordance with the terms of the license agreement.

If our Phase 3 clinical trials are successful, we expect to submit an NDA for Zohydro with the FDA by early 2012. However, the successful development and commercialization of Zohydro is highly uncertain. We also expect to incur customary regulatory costs associated with the NDA, if and when submitted, which will be significant. If Zohydro is approved, we also expect to incur significant expenses related to manufacturing and marketing activities. However, at this time, we cannot reasonably estimate or know the nature, specific timing and estimated costs of the efforts that will be necessary to complete the remainder of the development of Zohydro after submission of our NDA filing, if or when Zohydro will receive regulatory approval and, if approved, if and when material net cash inflows may commence from Zohydro or the amount of any such inflows. This is due to the numerous risks and uncertainties associated with developing and commercializing drugs, including the uncertainty of:

the costs, timing and outcome of our clinical trials and pre-clinical studies of Zohydro;

the costs, timing and outcome of regulatory review of Zohydro;

the costs of commercialization activities, including product marketing, sales and distribution;

the potential for future collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development and commercialization plans and capital requirements;

the costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending intellectual property-related claims;

the emergence of competing technologies and products and other adverse marketing developments;

the effect on our product development activities of actions taken by the FDA or other regulatory authorities; and

our degree of success in commercializing Zohydro, if approved.

A change in the outcome of any of these variables with respect to the development of Zohydro could mean a significant change in the costs and timing associated with these efforts.

We also expect to incur costs associated with pre-clinical studies and formulation work for our early-stage product candidates. However, at this time, due to the inherently unpredictable nature of pre-clinical development and given the early stage of such product candidates, we are unable to estimate with any certainty the costs we will incur for such pre-clinical work.

Selling, General and Administrative Expenses

Our selling expenses, which include sales and marketing costs, consisted primarily of salaries, benefits, consulting fees, costs of obtaining prescription and market data and market research studies related to Sumavel DosePro and Zohydro, including shared marketing and advertising costs under our co-promotion agreement with Astellas, service fees to Astellas and sample costs.

Our general and administrative expenses consist primarily of salaries and related costs for personnel in executive, finance, accounting, business development and internal support functions. In addition, general and administrative expenses include facility costs and professional fees for legal, consulting and accounting services. We expect general and administrative expense to increase as a result of the costs we incur operating as a public company. These increases likely will include salaries and related expenses, legal and consultant fees, accounting fees, director fees, increased directors and officers insurance premiums, fees for investor relations services and enhanced business and accounting systems.

Interest Income

Interest income consists of interest earned on our cash and cash equivalents.

Interest Expense

Interest expense consists of interest or royalty payments incurred in connection with the $4.5 million borrowed under our loan and security agreement with General Electric Capital Corporation, or GE Capital, our $25.0 million loan and security agreement and revolving credit facility with Oxford and SVB, our $30.0 million financing agreement with Cowen Royalty, and non-cash interest expense associated with amortization of debt discount and debt issuance costs and the estimated cost of royalty payments calculated under the effective interest method.

As a result of additional borrowings under the amended Oxford loan agreement, the deferral of principal payments resulting from the amended Oxford/SVB loan agreement in June 2011 and the $30.0 million Cowen Royalty financing entered into in July 2011, interest expense related to debt service will increase over 2010 levels.

Change in Fair Value of Warrant Liability

Change in fair value of warrant liability for the three and nine months ended September 30, 2010 represents non-cash (expense) income associated with changes in the fair value of the warrants to purchase preferred stock.

In connection with our initial public offering in November 2010, the liability reflected on our consolidated balance sheet for convertible preferred stock warrants was reclassified to stockholders equity (deficit) and we will no longer recognize the change in fair value of these warrants in the consolidated statement of operations.

Change in fair value of warrant liability for the three and nine months ended September 30, 2011 represents non-cash income associated with the changes in the fair value of the warrants to purchase common stock issued in connection with our Cowen Royalty financing agreement (see note 5).

Change in Fair Value of Embedded Derivatives

Change in fair value of embedded derivatives for the three and nine months ended September 30, 2011 represents non-cash income from changes in the fair value of the embedded derivatives associated with the Cowen Royalty financing agreement (see note 5).

Other Income (Expense)

Other income (expense) consists of foreign currency transaction gains and losses. All of our revenues are currently generated in U.S. dollars while a majority of our manufacturing expenses are payable in foreign currencies, primarily U.K. pounds sterling and the Euro.

Provision for Income Taxes

We incurred $20,000 and $0 in income tax expense for the three and nine months ended September 30, 2011 and 2010, respectively, related to taxable income generated by our wholly-owned subsidiary, Zogenix Europe Limited.

Internal Control Over Financial Reporting

Assessing our staffing and training procedures to improve our internal control over financial reporting is an ongoing process. We are not currently required to comply with Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, and are therefore not required to make an assessment of the effectiveness of our internal control over financial reporting. Further, our independent registered public accounting firm has not been engaged to express, nor have they expressed, an opinion on the effectiveness of our internal control over financial reporting.

For the year ending December 31, 2011, pursuant to Section 404 of the Sarbanes-Oxley Act, management will be required to deliver a report that assesses the effectiveness of our internal control over financial reporting. Pursuant to Section 404(c) of the Sarbanes-Oxley Act, our independent registered public accounting firm will not be required to deliver an attestation report on the effectiveness of our internal control over financial reporting for the year ending December 31, 2011.

Critical Accounting Policies and Estimates

There have been no significant changes in critical accounting policies during the nine months ended September 30, 2011, as compared to the critical accounting policies described in *Item 7-Management s Discussion and Analysis of Financial Condition and Results of Operations Critical Accounting Policies and Significant Judgments and Estimates* in our Annual Report on Form 10-K for the year ended December 31, 2010, except for the following critical accounting policies and estimates:

Revenue Recognition

We recognize revenue from the sale of Sumavel DosePro and from license fees and milestones earned on collaborative arrangements. Revenue is recognized when: (i) persuasive evidence of an arrangement exists, (ii) delivery has occurred and title has passed, (iii) the price is fixed or determinable and (iv) collectability is reasonably assured. Revenue from sales transactions where the buyer has the right to return the product is recognized at the time of sale only if (i) our price to the buyer is substantially fixed or determinable at the date of sale, (ii) the buyer has paid us, or the buyer is obligated to pay us and the obligation is not contingent on resale of the product, (iii) the buyer s obligation to us would not be changed in the event of theft or physical destruction or damage of the product, (iv) the buyer acquiring the product for resale has economic substance apart from that provided by us, (v) we do not have significant obligations for future performance to directly bring about resale of the product by the buyer, and (vi) the amount of future returns can be reasonably estimated.

Product Revenue

We sell Sumavel DosePro product in the United States to wholesale pharmaceutical distributors, and on a limited basis to retail pharmacies, or collectively our customers, subject to rights of return within a period beginning six months prior to, and ending 12 months following, product expiration. Prior to the third quarter of 2011, Sumavel DosePro had a limited sales history, and we could not reliably estimate expected returns of the product at the time of shipment. Accordingly, we deferred recognition of revenue on product shipments of Sumavel DosePro until the right of return no longer existed, which occurred at the earlier of the time Sumavel DosePro units were dispensed through patient prescriptions or expiration of the right of return. Units dispensed are generally not subject to return, except in the rare cases where the product malfunctions or the product is damaged in transit. We estimate patient prescriptions dispensed using an analysis of third-party information, including third-party market research data.

During the third quarter of 2011, we began to recognize net product sales upon the shipment of product to wholesale pharmaceutical distributors and retail pharmacies to provide a more accurate estimate of product sales activity, and because we had developed sufficient historical experience and data to reasonably estimate future returns of Sumavel DosePro. As a result, we no longer defer the recognition of product revenues and related cost of goods for products shipped to its customers. In order to develop a methodology to reliably estimate product returns and provide a basis for recognizing revenue on sales to customers at the time of product shipment, we analyzed many factors, including, without limitation: (i) retail pharmacy re-order activity, (ii) actual Sumavel Dosepro product return history, taking into account product expiration dating at the time of shipment and product launch stocking activities, (iii) levels of inventory in the wholesale and retail channel and prescription units dispensed, and (iv) industry data regarding product return rates. Based on the data gathered, we believe we have the information needed to reasonably estimate product returns.

In connection with us being able to reliably estimate product returns and the resulting change in the timing of recognition of product sales, previously reported deferred product revenues and deferred cost of sales as of June 30, 2011 have been recognized as product revenue and cost of sales during the period. In addition, we recorded an estimated cost for future returns based on product that remained in the distribution channel at September 30, 2011 and we recorded the cost of actual return experience for the three months ended September 30, 2011. In the third quarter of 2011, we received product returns from the initial stocking at the time of launch of some retail pharmacy stores which resulted in a higher rate of returns than what may be experienced with an established product.

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As a result of the establishment of a return reserve and the recognition of deferred product revenues, net product sales for the quarter ended September 30, 2011 were reduced by $1.0 million.

We permit certain wholesale pharmaceutical distributors to purchase limited quantities of product after the announcement of an increase to the wholesale acquisition cost (WAC) of our product and prior to the effectiveness of the increase. In turn, WAC price increases can result in accelerated purchases by wholesalers relative to anticipated retail and prescription demand. The timing of purchases made by wholesale distributors and retail pharmacies are subject to fluctuations for these reasons among others. Absent accelerated purchasing by wholesalers or other periodic changes in buying patterns, the wholesale channel has historically contained two to three weeks of product on hand. As of September 30, 2011, wholesale distributors reported approximatley four weeks of our product on hand.

Sumavel DosePro is also sold to third parties that license the rights to market and sell the product in territories outside of the United States. Under these arrangements, Sumavel DosePro is sold at a specified transfer price with the right of return available for damaged goods upon receipt or in the event of a recall. All risk for retail and wholesaler fees and discounts, collectability of customer receivables, customer returns and expiration of the product remain with the licensee. As such, we recognize revenues for product sales under license arrangements upon acceptance of the product (generally at point of shipment). The Company also receives royalties on net sales of Sumavel DosePro at a predetermined rate as a pass through of royalties payable to Aradigm.

Product Returns

Our product returns allowance is primarily based on estimates of future product returns over the period during which wholesale pharmaceutical distributors and retail pharmacies have a right of return, which in turn is based in part on estimates of the remaining shelf life of our product. Sumavel DosePro currently has a shelf life of 24 months from the date of manufacture. We allow wholesale pharmaceutical distributors and retail pharmacies to return unused product that are within six months before and up to one year after its expiration date for a credit at the then-current WAC, reduced by a nominal fee for processing the return. At the time of sale, we estimate the quantity and value of product that may ultimately be returned pursuant to these rights.

We utilize a channel analysis which considers historical product shipments to its customers less historical returns and estimated historical prescriptions written to estimate the number of units of product that remains with our customers (product not yet dispensed to patients or otherwise known as product in the distribution channel). Based on that analysis, we develop an estimate of the quantity of product in the distribution channel which may be subject to return exposure. We establish an estimate for its product return exposure taking actual return experience and qualitative factors into account, such as: (i) contractual terms with our customers, (ii) estimated remaining shelf life of the product in the distribution channel, (iii) estimated prescription demand for the product, (iv) communications with our customers, and (v) retail pharmacy re-order patterns and re-order activity. Our actual experience and the qualitative factors that we use to determine the necessary reserve for product returns are subject to change based on unforeseen events and uncertainties. We assess the trends that could affect our estimates and may make changes to the allowance each reporting period.

Our estimates of product returns and product allowances require management s most subjective and complex judgment due to the need to make estimates about matters that are inherently uncertain. If actual future payments for return and product allowances and other discounts exceed the estimates we made at the time of sale, our financial position, results of operations and cash flows would be negatively impacted.

Results of Operations

Comparison of the three months ended September 30, 2011 and 2010

Revenue. Revenue for the three months ended September 30, 2011 was $10.4 million and $7.1 million for the three months ended September 30, 2010. Product revenue for the three months ended September 30, 2011 and 2010 consists of $8.8 million and $5.7 million, respectively. During the third quarter of 2011, we began to recognize net product sales upon the shipment of product to wholesale pharmaceutical distributors and retail pharmacies because we had developed sufficient historical experience and data to reasonably estimate future returns of Sumavel DosePro. Prior to the third quarter of 2011, we recognized product revenue based on product dispensed to patients as estimated by independent third party data providers, which amounts were recorded net of estimated wholesaler and retail pharmacy discounts, stocking allowances, prompt pay discounts, chargebacks, rebates and patient discount programs, as applicable. Product revenue for the three months ended September 30, 2011 represents Sumavel DosePro shipped to wholesale distributors and retail pharmacies, which is net of estimated wholesaler and retail pharmacy discounts, stocking allowances, prompt pay discounts, chargebacks, rebates, patient discount programs and product returns, as applicable. The aggregate $3.1 million increase in product revenue is primarily due to an increase in prescription demand from the initial launch of Sumavel DosePro in late January 2010. However, in connection with the establishment of an estimate for returned product and the recognition of previously reported deferred product revenues as of June 30, 2011 net product sales for the quarter ended

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September 30, 2011 were reduced by $1.0 million.

Contract revenue for the three months ended September 30, 2011 and 2010 consists of $1.6 million and $1.3 million, respectively. Contract revenue represents amortization of license fee payments and milestone payments we received in connection with the co-promotion agreement we entered into with Astellas in July 2009 and which we began recognizing upon the commencement of sales of Sumavel DosePro in January 2010. The contract revenue in the third quarter of 2010 reflects a pro-rata amount of amortization of license fees and milestones as compared to the contract revenues in the third quarter of 2011, which reflects the full amortization of all license fees and milestone payments.

Cost of Sales. Cost of sales for the three months ended September 30, 2011 was $5.5 million and $2.9 million for the three months ended September 30, 2010. Product gross margin was 38% for the three months ended September 30, 2011 compared to 49% for the three months ended September 30, 2010. Cost of sales, for the three months ended September 30, 2011 and 2010 represents the cost of Sumavel DosePro units shipped to wholesale distributors and retail pharmacies and the impact of underutilized production capacity and other manufacturing variances. We developed production capacity to support higher levels of Sumavel DosePro production than initial sample and prescription demand was required to ensure adequate safety stock levels and to maintain the ability to support increased demand, as necessary. Until our prescription and sample demands are at a level where we can fully utilize the capacity committed to our contract manufacturing facilities, we will continue to experience underutilization of our production capacity. In addition, as we adjust production levels in certain periods to manage our inventory levels, we may incur additional charges for excess capacity which will negatively impact our gross margins.

Royalty Expense. Royalty expense for the three months ended September 30, 2011 and 2010 was $0.3 million and $0.2 million, respectively. Royalty expense represents the amortization of a $4.0 million milestone payment we made in connection with the asset purchase agreement with Aradigm payable on the first commercial sale of Sumavel DosePro, which occurred in January 2010, as well as royalties payable to Aradigm from net sales of Sumavel DosePro during the period.

Research and Development Expenses. Research and development expenses increased to $10.1 million for the three months ended September 30, 2011 compared to $8.0 million for the three months ended September 30, 2010. This increase of $2.1 million primarily was due to:

- an increase of $2.3 million as a result of the onetime non-refundable upfront fee paid to Durect in July 2011 upon execution of the Relday license agreement; and

- an increase of $0.8 million as a result of the milestone payment to Alkermes in connection with the completion of Study 801 of the Zohydro Phase 3 clinical trials; offset by

- a decrease of $1.0 million in research and development costs primarily related to the completion of Study 801 of the Zohydro Phase 3 clinical trials.

Selling, General and Administrative Expenses. Selling, general and administrative expenses increased to $14.7 million for the three months ended September 30, 2011 compared to $12.5 million for the three months ended September 30, 2010. Selling expenses were $11.5 million for the three months ended September 30, 2011 compared to $10.2 million for the three months ended September 30, 2010. General and administrative expenses were $3.2 million for the three months ended September 30, 2011 compared to $2.3 million for the three months ended September 30, 2010. The increase of $2.2 million in selling, general and administrative expenses primarily was due to:

- an increase of $1.3 million in sales and marketing expense primarily as a result of increased advertising and promotion activities related to Sumavel DosePro, an increase in services fees payable to our co-promotion partner from higher product revenues over the prior quarter and increased spending in marketing activities related to Zohydro, offset by a decrease in sample costs related to Sumavel DosePro; and

- an increase of $0.9 million of general and administrative expenses as a result of the costs we incurred for operating as a public company. These costs include salaries and related expenses, stock-based compensation charges, legal and consultant fees, accounting fees, director fees, increased directors and officers insurance premiums and fees for investor relations services.

Interest Income. Interest income increased to $2,000 for the three months ended September 30, 2011 compared to $1,000 for the three months ended September 30, 2010. This increase of $1,000 was due primarily to the increase in average cash and cash equivalent balances.

Interest Expense. Interest expense decreased to $2.5 million for the three months ended September 30, 2011 compared to $5.4 million for the three months ended September 30, 2010. This decrease of $2.9 million was primarily due to:

a decrease of $3.0 million related to non-cash amortization of the fair value of the beneficial conversion feature associated with the convertible bridge loans that were outstanding in 2010 and converted upon completion of our initial public offering;

a decrease of $0.6 million in the non-cash amortization of debt issuance and debt discount costs in connection with the $25.0 million amended Oxford/SVB loan agreement;

a decrease of $0.3 million in interest expense related to the convertible bridge loans that were outstanding in 2010 and converted upon completion of our initial public offering; and

a decrease of $0.2 million in interest expense related to a prepayment of our debt facility with CIT made in connection with the $25.0 million amended Oxford/SVB loan agreement; offset by

an increase of $0.4 million in revenue interest payments and $0.8 million in accrued non-cash interest expense based on our estimate of future revenue interest payments, recognized in connection with the $30.0 million Cowen Royalty Financing Agreement.

Change in Fair Value of Warrant Liability. Change in fair value of warrant liability resulted in $0.5 million of non-cash income during the three months ended September 30, 2011 compared to $0.2 million of non-cash income for the three months ended September 30, 2010. The change in fair value of the warrant liability during the three months ended September 30, 2011 was due to the decrease in fair value of the warrants issued in connection with the Cowen Royalty financing in July 2011. The change in fair value of warrant liability during the three months ended September 30, 2010 of $0.3 million was due to the decrease in fair value of convertible preferred stock warrants, which were converted to warrants of common stock in connection with the initial public offering in November 2010.

Change in Fair Value of Embedded Derivatives. Change in fair value of embedded derivatives resulted in $0.1 million of non-cash income during the three months ended September 30, 2011, which was due to the decrease in fair value of the embedded derivatives associated with the Cowen Royalty financing in July 2011.

Other Income (Expense). Other income (expense) increased to $16,000 of income for the three months ended September 30, 2011 compared to $253,000 of expense for the three months ended September 30, 2010. This increase was due to foreign currency transaction gains which primarily related to the settlement of our liabilities payable in Euro and U.K pounds sterling.

Comparison of the nine months ended September 30, 2011 and 2010

Revenue. Revenue for the nine months ended September 30, 2011 was $29.7 million and $14.6 million for the nine months ended September 30, 2010. Product revenue for the nine months ended September 30, 2011 and 2010 consists of $25.0 million and $11.8 million, respectively. During the third quarter of 2011, we began to recognize net product sales upon the shipment of product to wholesale pharmaceutical distributors and retail pharmacies because we had developed sufficient historical experience and data to reasonably estimate future returns of Sumavel DosePro. Prior to the third quarter of 2011, we recognized product revenue based on product dispensed to patients as estimated by independent third party data providers, which amounts were recorded net of estimated wholesaler and retail pharmacy discounts, stocking allowances, prompt pay discounts, chargebacks, rebates and patient discount programs, as applicable. As a result, product revenue for the first six months of 2011 represents product revenue based on product dispensed to patients net of product related discounts and allowances, as applicable, with the three months ended September 30, 2011 consisting of Sumavel DosePro shipped to wholesale distributors and retail pharmacies, net of related product discounts, allowances and product returns, as applicable. The aggregate $13.2 million increase in product revenue is primarily due to an increase in prescription demand from the initial launch of the Sumavel DosePro in late January 2010. However, in connection with the establishment of an estimate for returned product and the recognition of previously reported deferred product revenues as of June 30, 2011 net product sales for the nine months ended September 30, 2011 were reduced by $1.0 million.

Contract revenue for the nine months ended September 30, 2011 and 2010 consists of $4.7 million and $2.8 million, respectively. Contract revenue represents amortization of license fee payments and milestone payments we received in connection with the co-promotion agreement we entered into with Astellas in July 2009 and which we began recognizing upon the commencement of sales of Sumavel DosePro in January 2010. The contract revenue in the first nine months of 2010 reflects a pro-rata amount of amortization of license fees and milestones as compared to the contract revenues in the first nine months of 2011, which reflects the full amortization of all license fees and milestone payments.

Cost of Sales. Cost of sales for the nine months ended September 30, 2011 was $14.3 million and $8.2 million for the nine months ended September 30, 2010. Product gross margin for the nine months ended September 30, 2011 was 43% compared to 30% for the nine months ended September 30, 2010. Cost of sales, for the nine months ended September 30, 2011 represents the cost of Sumavel DosePro units shipped to wholesale distributors and retail pharmacies and the impact of underutilized production capacity and other manufacturing variances. We developed production capacity to support higher levels of Sumavel DosePro production than initial sample and prescription demand was required to ensure adequate safety stock levels and to maintain the ability to support increased demand, as necessary. Until our prescription and sample demands are at a level where we can fully utilize the capacity committed to our contract manufacturing facilities, we will continue to experience underutilization of our production capacity. In addition, as we adjust production levels in certain periods to manage our inventory levels, we may incur additional charges for excess capacity which will negatively impact our gross margins.

Royalty Expense. Royalty expense increased to $1.0 million for the nine months ended September 30, 2011 from $0.6 million for the nine months ended September 30, 2010. Royalty expense represents the amortization of a $4.0 million milestone payment we

made in connection with the asset purchase agreement with Aradigm payable on the first commercial sale of Sumavel DosePro, which occurred in January 2010, as well as royalties payable to Aradigm from net sales of Sumavel DosePro during the period. The $0.4 million increase in royalty expense is primarily due to the increase in sales.

Research and Development Expenses. Research and development expenses increased to $27.5 million for the nine months ended September 30, 2011 compared to $19.4 million for the nine months ended September 30, 2010. This increase of $8.1 million primarily was due to:

- an increase of $6.3 million in research and development costs as a result of the ongoing Phase 3 clinical trials for Zohydro, which were initiated in March 2010;
- an increase of $2.3 million as a result of the one-time non-refundable upfront license fee paid to Durect in July 2011 upon execution of the Relday license agreement; and
- an increase of $0.8 million as a result of a milestone payment to Alkermes in connection with the completion of Study 801 of the Zohydro Phase 3 clinical trials; offset by
- a decrease of $1.3 million in research and development costs incurred for the Phase 4 study conducted for Sumavel DosePro, completed in the second quarter of 2010, and other costs related to product development.

Selling, General and Administrative Expenses. Selling, general and administrative expenses increased to $42.6 million for the nine months ended September 30, 2011 compared to $38.0 million for the nine months ended September 30, 2010. Selling expenses were $33.0 million for the nine months ended September 30, 2011 compared to $31.8 million for the nine months ended September 30, 2010. General and administrative expenses were $9.6 million for the nine months ended September 30, 2011 compared to $6.2 million for the nine months ended September 30, 2010. The increase of $4.6 million in selling, general and administrative expenses primarily was due to:

- an increase of $1.2 million in sales and marketing expense primarily as a result of increased service fees payable to our co-promotion partner from higher product revenues, offset by a decrease in sampling efforts and other advertising and promotion activities relative to the levels of activity during the initial launch in the first half of 2010 of Sumavel DosePro; and
- an increase of $3.4 million of general and administrative expenses as a result of the costs we incurred for operating as a public company. These costs include salaries and related expenses, stock-based compensation charges, legal and consultant fees, accounting fees, director fees, increased directors and officers insurance premiums and fees for investor relations services.

Interest Income. Interest income increased to $21,000 for the nine months ended September 30, 2011 compared to $4,000 for the nine months ended September 30, 2010. This increase of $17,000 was due primarily to the increase in average cash and cash equivalent balances.

Interest Expense. Interest expense decreased to $5.0 million for the nine months ended September 30, 2011 compared to $6.9 million for the nine months ended September 30, 2010. The decrease of $1.9 million primarily was due to:

- a decrease of $3.0 million related to non-cash amortization of the fair value of the beneficial conversion feature associated with the convertible bridge loans that were outstanding in 2010 and converted upon completion of our initial public offering;
- a decrease of $0.7 million in the non-cash amortization of debt issuance and debt discount costs in connection with the $25.0 million amended Oxford/SVB loan agreement;

a decrease of $0.3 million in interest expense related to the convertible bridge loans that were outstanding in 2010 and converted upon completion of our initial public offering; and

a decrease of $0.1 million in interest expense related to the prepayment of our debt facility with CIT made in connection with the $25.0 million amended Oxford/SVB loan agreement; offset by

an increase of $0.4 million in revenue interest payments and $0.8 million in accrued non-cash interest expense based on our estimate of future revenue interest payments, recognized in connection with the $30.0 million Cowen Royalty Financing Agreement; and

an increase of $1.0 million in interest expense due to higher debt balances associated with the amended Oxford/SVB loan agreement.

Change in Fair Value of Warrant Liability. Change in fair value of warrant liability resulted in $0.5 million of non-cash income during the nine months ended September 30, 2011 compared to $12.8 million of non-cash expense for the nine months ended September 30, 2010. The change in fair value of the warrant liability during the nine months ended September 30, 2011 was due to the decrease in fair value of the warrants issued in connection with the Cowen Royalty financing in July 2011. The change in fair value of warrant liability during the nine months ended September 30, 2010 was due to the increase in fair value of convertible preferred stock warrants, which were converted to warrants of common stock in connection with the initial public offering in November 2010.

Change in Fair Value of Embedded Derivatives. Change in fair value of embedded derivatives resulted in $0.1 million of income during the nine months ended September 30, 2011, which was due to the decrease in fair value of the embedded derivatives associated with the Cowen Royalty financing in July 2011.

Other Income (Expense). Other income (expense) was $0.1 million of expense for each of the nine months ended September 30, 2011 and 2010. Any changes in other income (expense) were primarily related to foreign currency transaction gains and losses which primarily related to the settlement of our liabilities payable in Euro and U.K pounds sterling.

Liquidity and Capital Resources

We have experienced net losses and negative cash flow from operations since inception, and as of September 30, 2011, had an accumulated deficit of $258.3 million, and expect to continue to incur net losses and negative cash flow from operations for at least the next several years primarily as a result of, among other things, the development expenses in connection with our clinical trials and pre-clinical studies for Zohydro and Relday and the cost of the sales and marketing expenses associated with Sumavel DosePro.

As of September 30, 2011, we had cash and cash equivalents of $70.8 million. In addition, on June 30, 2011, we amended certain terms of our loan agreement with Oxford and SVB including the deferral of principal repayment to commence on February 1, 2012 and in July 2011, we entered into equity and royalty financing agreements with Cowen Royalty, pursuant to which we borrowed $30.0 million from Cowen Royalty and sold $1.5 million of our common stock to Cowen Royalty resulting in $29.5 million in net proceeds to us. Although it is difficult to predict future liquidity requirements, we believe that our cash and cash equivalents as of September 30, 2011, together with future revenue and borrowings available under our $10.0 million revolving credit facility, will be sufficient to fund our operations into the second quarter of 2013. We will need to obtain additional capital to finance our operations beyond that point or possibly earlier. We intend to raise additional capital through debt or equity financings or through collaborations or partnerships with other companies. If we are not be able to raise additional capital on terms acceptable to us, or at all, as and when needed, we may be required to reduce or curtail our operations and costs, and we may be unable to continue as a going concern.

In its report on our consolidated financial statements for the year ended December 31, 2010, our independent registered public accounting firm included an explanatory paragraph expressing substantial doubt regarding our ability to continue as a going concern. A going concern opinion means, in general, that our independent registered public accounting firm has substantial doubt about our ability to continue our operations without continuing infusions of capital from external sources and this opinion could impair our ability to finance our operations through the sale of debt or equity securities or commercial bank loans. Our ability to continue as a going concern depends, in large part, on our ability to generate positive cash flow from operations and obtain additional financing, neither of which is certain, as well as the continued availability of borrowings under our amended Oxford/SVB loan agreement. If we are unable to achieve these goals, our business would be jeopardized and we may not be able to continue operations and have to liquidate our assets and may receive less than the value at which those assets were carried on our financial statements, and it is likely that investors will lose all or part of their investment.

Since inception, our operations have been financed primarily through equity and debt financings, the issuance of convertible notes and payments received from Astellas under our co-promotion agreement. Through September 30, 2011, we received aggregate net cash proceeds of approximately $273.1 million from the sale of shares of our preferred and common stock, including the following recent financing transactions:

- in July 2010, we issued unsecured convertible promissory notes in an aggregate amount of $15.0 million under which all the outstanding principal and interest automatically converted to 3,873,756 shares of common stock upon the completion of our initial public offering;

- in November 2010 and December 2010, we issued and sold a total of 14,436,493 shares of common stock in our initial public offering, including shares issued upon the exercise of the underwriters overallotment option, for aggregate net proceeds of $51.7 million;

- in July 2011, we entered into an equity and royalty financing agreement with Cowen Royalty pursuant to which we sold 388,601 shares of our common stock, resulting in $1.4 million of net proceeds; and

in September 2011, we issued and sold a total of 30,000,000 shares of common stock in a follow-on public offering, excluding shares issued upon the exercise of the underwriters option to purchase additional shares, for aggregate net proceeds of $56.6 million.

On June 30, 2011, we amended the existing loan agreement with Oxford and SVB to provide for, among other things, the addition of intellectual property to the collateral securing the Oxford/SVB loan and deferral of principal repayment to commence on February 1, 2012. In connection with entering into the amended Oxford/SVB loan agreement, we issued to Oxford and SVB warrants exercisable into an aggregate of 26,455 shares of our common stock. The warrants are exercisable at $3.78 per share of common stock

and have a term of 7 years. The amended Oxford/SVB Agreement consists of a $25.0 million term loan and a $10.0 million revolving credit facility. The obligations under the amended Oxford/SVB loan agreement are collateralized by our intellectual property (including among other things, copyrights, patents, patent applications, trademarks, service marks and trade secret rights) and personal property (including, among other things, accounts receivable, equipment, inventory, contract rights, rights to payment of money, license agreements, general intangibles and cash).

The amended Oxford/SVB loan agreement includes financial covenants requiring that we achieve, as of the last day of each month measured on a trailing three-month basis, actual revenue of at least a specified percentage of our projected revenue as provided to Oxford and SVB in the event we fail to maintain a liquidity ratio (defined, in general, as the ratio of (a) cash and cash equivalents deposited with SVB plus unused borrowing capacity under that agreement to (b) all debt, capital lease obligations and contingent obligations owed to the lenders) of 1.25 to 1.00. The agreement also includes a covenant that the audit report accompanying our year-end consolidated financial statements for fiscal year 2010 and thereafter not include a going concern qualification. In March 2011, we obtained a waiver from Oxford and SVB for the breach caused by the receipt of the 2010 audit report from our independent registered public accounting firm, which includes a modification of their standard report for the going concern uncertainty. In addition, the amended Oxford/SVB loan agreement prohibits us from (1) incurring any debt other than, among other things, debt under the amended Oxford/SVB loan agreement, and (2) entering into mergers with, or acquisitions of all or substantially all the assets of, another entity with a value in excess of $0.1 million, and also prohibits the occurrence of a change in control of our company as defined in the amended Oxford/SVB loan agreement. The agreement provides that an event of default will occur if, among other customary events of default, (1) there is a material adverse change in our business, operations or condition (financial or otherwise) or material impairment in the prospects of us repaying any portion of our obligations under the agreement, (2) there is a material impairment in the value of the collateral pledged to secure our obligations under the agreement, (3) we default in the payment of any amount payable under the agreement when due, or (4) we breach any covenant in the agreement (subject to a grace period in some cases). The $25.0 million term loan bears an interest rate of 12.06% per annum. Payments consist of monthly interest only payments for the first 12 months followed by principal and interest payments for the subsequent 30 months. The term loan requires a final payment of $1.2 million, in addition to the repayment of unpaid principal, at the loan maturity date, which is January 1, 2014. We have the option to prepay the outstanding balance of the term loan in full subject to a prepayment fee of either 2% or 3% of the principal amount being prepaid depending upon when the prepayment occurs as well as the $1.2 million final payment. Under the terms of the revolving credit facility, we may borrow up to $10.0 million, but not more than a specified percentage of our eligible accounts receivable and inventory balances (as defined in the agreement). Amounts outstanding under the revolving credit facility accrue interest payable monthly at a floating rate per annum equal to the greater of 3.29% above SVB s prime rate or 7.29%. In addition, we pay a monthly fee equal to 0.5% per annum of the average unused portion of the revolving credit facility. If the revolving credit facility is terminated, a final payment is required in the amount of $0.1 million, $0.2 million or $0.3 million depending upon when the termination occurs. The amended Oxford/SVB loan agreement matures on the earliest of January 1, 2014, the occurrence of an event of default resulting in our obligations becoming due and payable in accordance with the amended Oxford/SVB loan agreement or the date of any prepayment of all outstanding obligations under the Amended Oxford/SVB loan agreement, at which time a final payment of $0.1 million, plus all unpaid principal, must be paid in full. As of September 30, 2011, we had borrowed $4.6 million under the revolving credit facility.

On July 18, 2011, we closed the royalty financing agreement with Cowen Royalty, or the financing agreement. Under the terms of the financing agreement, we borrowed $30.0 million and we are obligated to repay such borrowed amount together with a specified return to Cowen Royalty, through the payment of tiered royalties ranging from .5% to 5% of our direct product sales, co-promotion revenues and out-license revenues, or collectively, revenue interest, that we may record or receive as a result of worldwide commercialization of our products including Sumavel DosePro, Zohydro and other future products. Pursuant to the terms of the financing agreement, in the event our co-promotion agreement with Astellas is terminated prior to June 30, 2013, our royalty rate will increase to 5.75%, with a reversion back to 5% possible if certain net sales of Sumavel DosePro are achieved or if Zohydro is commercialized in the four calendar quarters immediately following the effective date of termination.

We are also obligated to make three fixed payments of $10.0 million on (or before at our option) each of January 31, 2015, January 31, 2016 and January 31, 2017. Prepayment requires the consent of the lenders under the amended Oxford/SVB loan agreement while balances remain outstanding under that facility.

We have the option to terminate the financing agreement at our election in connection with a change of control of our company, upon the payment of a base amount of $52.5 million, or, if higher, an amount that generates a 19% internal rate of return on the borrowed amount as of the date of prepayment, in each case reduced by the revenue interest and principal payments received by Cowen Royalty up to the date of prepayment.

Cowen Royalty has the option to terminate the financing agreement at its election in connection with a change of control of our company (which includes the sale, transfer, assignment or licensing of our rights in the United States to either Sumavel DosePro or Zohydro), a bankruptcy event with respect to our company or an event of default under the financing agreement. Upon such a termination by Cowen Royalty, we are obligated to make a payment of a base amount of $45.0 million, or, if higher, an amount that generates a 17% internal rate of return on the borrowed amount as of the date of prepayment, in each case reduced by the Revenue Interest and principal payments received by Cowen Royalty up to the date of prepayment.

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Unless terminated earlier as discussed above, the financing agreement terminates on March 31, 2018.

In connection with the financing agreement, in July 2011 we issued and sold 388,601 shares of our common stock to Cowen Royalty for gross proceeds of $1.5 million and issued to Cowen Royalty a warrant to purchase 225,000 shares of our common stock at an exercise price of $9.00 per share. We received total net proceeds, after expenses, of $29.5 million from the borrowings under the financing agreement and the sale of common stock to Cowen Royalty.

We also granted Cowen Royalty the right to purchase $1.5 million of shares of our common stock in the first bona fide equity financing following the date of the financing agreement that would result in gross proceeds to us of at least $15.0 million, at a price equal to the price paid by other investors participating in such equity financing. Cowen Royalty exercised this right and purchased $1.5 million of shares of our common stock at $2.00 per share in our follow-on public offering completed in September 2011.

We depend in part upon borrowings available under the revolving credit facility provided under the amended Oxford/SVB loan agreement, the term loan obtained under the Oxford/SVB loan agreement and the borrowed amount under the financing agreement to finance our ongoing operations. Accordingly, any termination of those agreements, or any requirement that we repay any of our outstanding term loans or the borrowed amount under the financing agreement, whether as the result of our default under the applicable agreement or otherwise, could have a material adverse effect on our business, results of operations and financial condition.

Cash and Cash Equivalents. Cash and cash equivalents totaled $70.8 million and $49.2 million at September 30, 2011 and December 31, 2010, respectively.

The following table summarizes our cash flows used in operating, investing and financing activities for the nine months ended September 30, 2011 and 2010:

	Nine Months Ended September 30,	
	2011	2010
	(In Thousands)	
Statement of Cash Flows Data:		
Total cash provided by (used in):		
Operating activities	$ (64,235)	$ (58,492)
Investing activities	(426)	(2,084)
Financing activities	86,336	27,338
Increase (decrease) in cash and cash equivalents	$ 21,675	$ (33,238)

Operating Activities. Net cash used in operating activities was $64.2 million and $58.5 million for the nine months ended September 30, 2011 and 2010, respectively. Net cash used for the nine months ended September 30, 2011 and 2010 primarily reflects the use of $54.9 million and $52.1 million, respectively for operations (excluding non-cash items), use of $1.1 million and investment of $4.4 million, respectively, in commercial inventory of Sumavel DosePro, and cash used of $10.4 million and cash provided of $2.0 million, respectively, for other working capital uses.

Investing Activities. Net cash used in investing activities was $0.4 million and $2.1 million for the nine months ended September 30, 2011 and 2010, respectively. These amounts are the result of the purchase of property and equipment primarily for use in manufacturing Sumavel DosePro.

We expect to incur capital expenditures of approximately $0.2 million to $0.3 million in the last three months of 2011. These planned capital expenditures primarily relate to further investments in our manufacturing operations toward enhancing our existing manufacturing technology and equipment.

Financing Activities. Net cash provided by financing activities was $86.3 million and $27.3 million for nine months ended September 30, 2011 and 2010, respectively. Net cash provided by financing activities for the nine months ended September 30, 2011 relates to the net proceeds received in connection with the Financing Agreement of $29.5 million, net proceeds received from the issuance of common stock in our follow-on public offering of $56.6 million, net proceeds received from our revolving credit facility of $6.2 million, proceeds from the exercise of options to purchase common stock of $0.1 million and payments on borrowings of debt of $6.1 million. Net cash provided by financing activities for the nine months ended September 30, 2010 relates to payments on borrowings of debt of $15.4 million, and net proceeds from our

long-term debt and revolving credit facility of $42.7 million.

Our sources of liquidity include our cash balances, cash receipts from the sale of Sumavel DosePro and our debt facilities. As of September 30, 2011, we had $70.8 million in cash and cash equivalents, which includes $29.5 million in cash that we received in July 2011 under our financing agreement and $56.6 million in net proceeds from the sale of common stock in connection with our follow-on public offering completed in September 2011. Other potential sources of near-term liquidity include (i) entering into a commercialization agreement for Zohydro or a licensing arrangement on our DosePro technology, (ii) equity, debt or other financing or (iii) leveraging our sales force capacity to promote a new product.

Since inception, our operations have been financed primarily through equity and debt financings, the issuance of convertible notes and payments received from Astellas under our co-promotion agreement. Through September 30, 2011, we received aggregate net cash proceeds of approximately $273.1 million from the sale of shares of our preferred and common stock, the issuance of a notes and payments from collaborators. Although we will continue to be opportunistic in our efforts to obtain cash, there is no guarantee that additional funding will be available or that, if available, such funding will be adequate or available on terms that we or our stockholders view as favorable. In addition, as a result of our outstanding loan with Oxford and SVB and our financing agreement, our ability to engage in debt financing transactions is subject to certain limitations and certain debt financing transactions, if consummated, may accelerate our repayment obligations to Oxford and SVB and Cowen Royalty.

Successful transition to profitability is dependent upon achieving a level of product revenues adequate to support our cost structure. We will continue to monitor and evaluate our sales progress, the level of our research, development, manufacturing, sales and marketing and general and administrative expenditures and may adjust such expenditures based upon a variety of factors, such as our available cash, our ability to obtain additional cash, the results and progress of our Sumavel DosePro commercialization efforts, results and progress in our clinical program, the time and costs related to clinical trials and regulatory decisions, as well as the U.S. economic environment.

As described above, under our amended Oxford/SVB loan agreement, we are subject to financial covenants that require us to achieve certain revenue targets in the event we fail to maintain a liquidity ratio (defined, in general, as the ratio of (a) cash and cash equivalents deposited with SVB plus unused borrowing capacity under that agreement to (b) all debt, capital lease obligations and contingent obligations owed to the lenders) of 1.25 to 1.00 and we are also subject to other covenants and obligations under that agreement. Likewise, the amended Oxford/SVB loan agreement permits the lenders to demand the immediate repayment of all borrowings and other amounts outstanding thereunder if, among other customary events of default, the lender determines, in its sole discretion that a material adverse change with respect to us has occurred. As noted above, we have agreed to specified positive and negative covenants under the financing agreement with Cowen Royalty and upon a termination by Cowen Royalty, we are obligated to make a payment of a base amount of $45.0 million, or, if higher, an amount that generates a 17% internal rate of return on the borrowed amount as of the date of prepayment, in each case reduced by the payments received by Cowen Royalty up to the date of prepayment. If we were required to accelerate the payment of these amounts upon a default, we would be required to find an alternate source of capital from which to draw funds and there can be no assurances that we would be able to do so on terms acceptable to us, or at all.

If we fail to pay amounts owing under either the amended Oxford/SVB loan agreement or the financing agreement when due, if we breach our other covenants or obligations under either of these agreements, or if other events of default under either of these agreements occur, the applicable lenders would be entitled to demand immediate repayment of all borrowings and other obligations thereunder and to seize and sell the collateral pledged as security under the agreements to satisfy those obligations. If we were to breach our covenants and obligations and we were unable to obtain a waiver or amendment from the lender, we would be required to seek additional equity or debt financing to refinance our obligations under the agreement. Additional debt or equity financing may not be available to us in amounts or on terms we consider acceptable, or at all. In that regard, we have from time to time been required to obtain waivers and amendments under our debt instruments in order to avoid breaches or other defaults. For example, in each of 2009, 2010 and 2011 we were required to obtain amendments or waivers under our credit facilities.

We cannot be certain if, when and to what extent we will generate positive cash flow from operations from the commercialization of our product and, if approved, product candidates. We expect our development and commercialization expenses to be substantial and to increase over the next few years as we continue to grow the Sumavel DosePro brand and continue to advance our Zohydro product through Phase 3 clinical trials and potentially through commercialization and initiate clinical development of Relday.

Although it is difficult to predict future liquidity requirements, we believe that our cash and cash equivalents as of September 30, 2011, together with future product revenue and borrowings available under our $10.0 million revolving credit facility, will be sufficient to fund our operations into the second quarter of 2013. We will need to obtain additional capital to finance our operations beyond that point through public or private equity or debt financings. Although we are currently not a party to any agreement or letter of intent with respect to potential investments in, or acquisitions of, businesses, services or technologies, we may enter into these types of arrangements in the future, which could also require us to seek additional equity or debt financing. There can be no assurance that we will be able to raise additional funds from any of these sources on terms we deem acceptable, or at all. In addition, future issuance of equity, convertible or other equity-linked securities could materially dilute the ownership interests of holders of our common stock and additional debt financing could result in a material increase in the amount of cash necessary to fund debt service payments and also could require that we comply with financial and other covenants that limit our flexibility and operations. In addition, the fact that we have pledged substantially all of our assets to secure our existing loan facilities will likely increase the cost, perhaps substantially, of any additional debt financing we may obtain or prevent us from obtaining additional debt financing altogether.

Contractual Obligations and Commitments

The following table describes our long-term contractual obligations and commitments as of September 30, 2011 (unaudited):

		Payments Due by Period			
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
			(In Thousands)		
Debt obligations (1)	$ 59,588	$ 12,264	$ 17,324	$ 20,000	$ 10,000
Debt interest (2)	5,466	2,749	2,717	0	0
Operating lease obligations (3)	3,451	1,491	1,410	550	0
Co-Promotion marketing & promotional expenses (4)	503	503	0	0	0
Purchase obligations (5)	19,148	12,025	5,123	1,000	1,000
Total	$ 88,156	$ 29,032	$ 26,574	$ 21,550	$ 11,000

(1) Represents principal payments due in each period on our loan and security agreement with Oxford Finance Corporation and Silicon Valley Bank and outstanding balances under our revolving credit facility with Oxford Finance Corporation and Silicon Valley Bank. Also includes annual payments under our financing agreement with Cowen Royalty, which occur on January 1 of 2015, 2016 and 2017.

(2) Includes the interest on regular scheduled debt payments to Oxford Finance Corporation and Silicon Valley Bank at an annual rate of 12.06%.

(3) Includes the minimum rental payments for our San Diego, California office pursuant to a lease entered into in October 2009 and expiring, as extended, in 2012. Also includes the minimum rental payments for our Emeryville, California office pursuant to a lease entered into in July 2007 and expiring, as extended, in September 2015. Also includes the rental payments for a fleet of up to 95 vehicles pursuant to a lease entered into in August 2009. Each vehicle has a lease term of 36 months.

(4) Represents our portion of the shared marketing and promotional costs as agreed between us and Astellas for 2011 joint promotional efforts for Sumavel DosePro. These obligations are determined on an annual basis through the term of the agreement.

(5) Primarily represents non-cancellable purchase orders for the production of key components of Sumavel DosePro, a minimum manufacturing fee payable to Patheon UK Limited, our contract manufacturing organization, and a minimum annual spend in external expenses for the development of Relday under our Durect licensing agreement.

Under our co-promotion agreement with Astellas, we are required to pay Astellas a service fee on a quarterly basis that represents a fixed percentage of between 45% and 55% of Sumavel DosePro net sales to the Astellas Segment. In addition, upon completion of the co-promotion term, Astellas generally will be eligible to receive two additional annual tail payments calculated as decreasing fixed percentages (ranging from a mid-twenties down to a mid-teen percentage) of net sales in the Astellas Segment in the last 12 months of its active promotion.

Under our asset purchase agreement with Aradigm, we are required to pay a 3% royalty on global net sales of Sumavel DosePro by us or one of our licensees and, in the event that we or one of our future licensees, if any, commercializes a non-sumatriptan product in the DosePro delivery system, we are required to pay Aradigm, at our election, either a 3% royalty on net sales of each non-sumatriptan product commercialized or a fixed low-twenties percentage of royalty revenue received by us from the licensee.

Under our license agreement with Alkermes we may be required to pay up to $3.75 million in total future milestone payments with respect to Zohydro depending upon the achievement of various development and regulatory events. In addition, if Zohydro is approved, we will be required to pay a mid single-digit percentage royalty on its net sales for a specified period of time and continue to pay royalties on net sales of the product thereafter at a reduced low single-digit percentage rate in accordance with the terms of the license agreement.

Under our licensing agreement with Durect we are obligated to pay Durect up to $103.0 million in total future milestone payments with respect to the product subject to and upon the achievement of various development, regulatory and sales milestones. In addition, we are required to pay Durect a mid single-digit to low double-digit percentage patent royalty on annual net sales of the product determined on a jurisdiction-by-jurisdiction basis, and we are also required to pay to Durect a tiered percentage of fees received in connection with any sublicense of the licensed rights.

Under our financing agreement with Cowen Royalty we are obligated to pay to Cowen Royalty revenue interest on product sales between 5% and 0.5%, depending upon the level of product sales made.

We also maintain agreements with third parties to manufacture our product, conduct our clinical trials, and perform data collection and analysis. Our payment obligations under these agreements will likely depend upon the progress of our development programs, sales of our product and commercialization efforts. Therefore, we are unable at this time to estimate with certainty the future costs we will incur under these agreements.

Recent Accounting Pronouncements

In October 2009, the Financial Accounting Standards Board, or the FASB, issued an Accounting Standard Update which replaced the concept of allocating revenue consideration amongst deliverables in a multiple-element revenue arrangement according to fair value with an allocation based on selling price. The amended guidance also establishes a hierarchy for determining the selling price of revenue deliverables sold in multiple element revenue arrangements. The selling price used for each deliverable will be based on vendor-specific objective evidence, or VSOE, if available, third-party evidence if VSOE is not available, or management s estimate of an element s stand-alone selling price if neither VSOE nor third-party evidence is available. The amendments in this update also require an allocation of selling price amongst deliverables be performed based upon each deliverable s relative selling price to total revenue consideration, rather than on the residual method previously permitted. The updated guidance is effective for the first annual reporting period beginning on or after June 15, 2010, and may be applied retrospectively for all periods presented or prospectively to arrangements entered into or materially modified after the adoption date. We prospectively adopted the updated guidance on January 1, 2011 and will apply the amended guidance to revenue arrangements containing multiple deliverables that are entered into or significantly modified on or after January 1, 2011. We will now allocate revenue consideration, excluding contingent consideration, based on the relative selling prices of the separate units of accounting contained within an arrangement containing multiple deliverables. Selling prices are determined using fair value, when available, or our estimate of selling price when fair value is not available for a given unit of accounting. As we did not enter into any new collaborations or materially modify any existing collaborations, adoption of this guidance had no impact on our results of operations for the nine months ended September 30, 2011.

In March 2010, the FASB Emerging Issues Task Force, or EITF, ratified a new accounting standard which amends guidance on the milestone method of revenue recognition. The EITF concluded that the milestone method is a valid application of the proportional performance model when applied to research or development arrangements. Milestones, as defined per the revised guidance, are (1) events that can only be achieved in whole or in part on either the entity s performance or on the occurrence of a specific outcome resulting in the entity s performance (2) for which there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved and (3) that would result in additional payments being due to us, we evaluate events under this guidance at the inception of an arrangement to determine the existence of milestones and if they are substantive. This standard allows an entity to make an accounting policy election to recognize a payment that is contingent upon the achievement of a substantive milestone in its entirety in the period in which the milestone is achieved. This standard is effective for fiscal years beginning on or after June 15, 2010 with early adoption permitted. The guidance may be applied prospectively for milestones achieved after the adoption date or retrospectively for all periods presented. We adopted this guidance on January 1, 2011 on a prospective basis. Adoption of this guidance did not have a material impact on our results of operations.

In May 2011, FASB issued accounting guidance related to fair value measurements and disclosures to achieve common fair value measurements and disclosures between GAAP and International Financial Reporting Standards. This guidance clarifies the application of certain existing fair value measurement guidance and expands the disclosures for fair value measurements that are estimated using significant unobservable (Level 3) inputs. This guidance is effective on a prospective basis for annual and interim reporting periods beginning on or after December 15, 2011. The adoption of this updated standard is not expected to have a material effect on our results of operations.

In June 2011, the FASB issued an Accounting Standards Update which requires entities to present reclassification adjustments included in other comprehensive income on the face of the financial statements and allows entities to present the total of comprehensive income, the components of net income and the components of other comprehensive income either in a single continuous statement of comprehensive income or in two separate consecutive statements. It also eliminates the option for entities to present components of other comprehensive income as part of the statement of changes to stockholders equity. The updated guidance is effective for fiscal and interim periods beginning after December 15, 2011, with early adoption permitted. The adoption of this updated standard is not expected to have a material effect on our results of operations.

Off-Balance Sheet Arrangements

We have not engaged in any off-balance sheet activities.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk

Our cash and cash equivalents as of September 30, 2011 consisted primarily of cash and money market funds. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates. The primary objective of our investment activities is to preserve principal while at the same time maximizing the income we receive without significantly increasing risk. Instruments that meet this objective include commercial paper, money market funds and government and non-government debt securities. Some of the investment securities available-for-sale that we invest in may be subject

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to market risk. This means that a change in prevailing interest rates may cause the value of the investment securities available-for-sale to fluctuate. To minimize this risk, we intend to continue to maintain our portfolio of cash and money market funds. Due to the short-term nature of our investments and our ability to hold them to maturity, we believe that there is no material exposure to interest rate risk.

Our $10.0 million revolving credit facility with Oxford and SVB bears interest at the greater of 3.29% above SVB s prime rate or 7.29%. As of September 30, 2011, we had $4.6 million outstanding on this revolving credit facility.

Foreign Exchange Risk

All of the revenues we have generated to date have been paid in U.S. dollars and we expect that our revenues will continue to be generated primarily in U.S. dollars for at least the next several years. Payments to our material suppliers and contract manufactures are denominated in the Euro and U.K. pounds sterling, thereby increasing our exposure to exchange rate gains and losses on non-U.S. currency transactions. Foreign currency gains and losses associated with these expenditures have not been significant to date. However, fluctuations in the rate of exchange between the U.S. dollar and these or other foreign currencies could adversely affect our financial results in the future, particularly to the extent we increase production to support Sumavel DosePro sales demands. For the nine months ended September 30, 2011, approximately $16.6 million (based on exchange rates as of September 30, 2011) of our materials and contract manufacturing costs were denominated in foreign currencies. We do not currently hedge our foreign currency exchange rate risk. As a result, we are exposed to gains and/or losses as the exchange rate of certain foreign currencies fluctuates. A 10% increase or decrease in the average rate of the Euro or the U.K. pound sterling during the nine months ended September 30, 2011 would have resulted in approximately $0.8 or $0.9 million in gains or losses, respectively. We intend to evaluate various options to mitigate the risk of financial exposure from transacting in foreign currencies in the future.

Item 4. Controls and Procedures

Conclusions Regarding the Effectiveness of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the timelines specified in the Securities and Exchange Commission s rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can only provide reasonable assurance of achieving the desired control objectives, and in reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As required by Securities and Exchange Commission Rule 13a-15(b), we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this report. Based on the foregoing, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of September 30, 2011 at the reasonable assurance level.

This Quarterly Report on Form 10-Q does not include a report of management s assessment regarding internal control over financial reporting or an attestation report of the Company s registered public accounting firm due to a transition period established by rules of the Securities and Exchange Commission for newly public companies.

Changes in Disclosure Controls and Procedures

There were no changes in our internal controls over financial reporting during the fiscal quarter ended September 30, 2011 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II OTHER INFORMATION

Item 1. Legal Proceedings

We are not currently a party to any legal proceedings.

Item 1A. Risk Factors

We operate in a dynamic and rapidly changing environment that involves numerous risks and uncertainties. Certain factors may have a material adverse effect on our business prospects, financial condition and results of operations, and you should carefully consider them. Accordingly, in evaluating our business, we encourage you to consider the following discussion of risk factors, in its entirety, in addition to other information contained in this Quarterly Report on Form 10-Q and our other public filings with the SEC. Other events that we do not currently anticipate or that we currently deem immaterial may also affect our business, prospects, financial condition and results of operations.

We have marked with an asterisk (*) those risk factors that reflect substantive changes from the risk factors included in our previously filed Annual Report on Form 10-K for the year ended December 31, 2010.

Risks Related to Our Business and Industry

We will require additional funding and may be unable to raise capital when needed, which would force us to delay, reduce or eliminate our product development programs or commercialization efforts. *

Our operations have consumed substantial amounts of cash since inception. To date, our operations have been primarily financed through the proceeds from the issuance of our common and preferred stock, including the proceeds from our initial public offering completed in November 2010, and borrowings under our loan and financing agreements with Cowen Healthcare Royalty Partners II, L.P, or Cowen Royalty, Oxford Finance LLC, as successor in interest to Oxford Finance Corporation, or Oxford, Silicon Valley Bank, or SVB, and until June 30, 2011, General Electric Capital Corporation, or GE Capital. Although it is difficult to predict future liquidity requirements, we believe that our cash and cash equivalents as of September 30, 2011, together with future product revenue and borrowings available under our $10.0 million revolving credit facility, will be sufficient to fund our operations into the second quarter of 2013. We will need to obtain additional funds to finance our operations beyond that point in order to:

- maintain and continue to increase our sales and marketing activities for Sumavel DosePro, particularly if our co-promotion agreement with Astellas Pharma US, Inc., or Astellas, is terminated, amended or otherwise restructured;
- qualify secondary sources for the manufacturing of Sumavel DosePro;
- fund our operations, continue to conduct clinical trials of Zohydro, initiate clinical trials for Relday and fund development of any other product candidate to support potential regulatory approval of marketing applications; and
- commercialize any of our product candidates or any products or product candidates that we may develop, in-license or otherwise acquire, if any of these product candidates receive regulatory approval.

In addition, our estimates of the amount of cash necessary to fund our business and development and commercialization activities may prove to be wrong, and we could spend our available financial resources much faster than we currently expect. Our future funding requirements will depend on many factors, including, but not limited to:

- the commercial success of Sumavel DosePro;

the timing of regulatory approval, if granted, of Zohydro or any other product candidates;

the rate of progress and cost of our clinical trials and other product development programs for Zohydro, Relday and our other product candidates and any other product candidates that we may develop, in-license or acquire;

the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights associated with Sumavel DosePro, Zohydro, Relday and any of our other product candidates;

the costs and timing of completion of outsourced commercial manufacturing supply arrangements for any product candidate;

the costs of maintaining and expanding our sales and marketing infrastructure or establishing distribution capabilities;

the effect of competing technological and market developments; and

the terms and timing of any additional collaborative, licensing, co-promotion or other arrangements that we may establish.

Until we can generate a sufficient amount of product revenue and cash flow from operations and achieve profitability, we expect to finance future cash needs through public or private equity offerings, debt financings, receivables financings or corporate

collaboration and licensing arrangements. We cannot be certain that additional funding will be available on acceptable terms, or at all. If we are unsuccessful in raising additional required funds, we may be required to significantly delay, reduce the scope of or eliminate one or more of our development programs or our commercialization efforts, or cease operating as a going concern. We also may be required to relinquish, license or otherwise dispose of rights to product candidates or products that we would otherwise seek to develop or commercialize ourselves on terms that are less favorable than might otherwise be available. If we raise additional funds by issuing equity securities, substantial dilution to existing stockholders would result. If we raise additional funds by incurring debt financing, the terms of the debt may involve significant cash payment obligations as well as covenants and specific financial ratios that may restrict our ability to operate our business. If we are unable to maintain sufficient financial resources, including by raising additional funds when needed, our business, financial condition and results of operations will be materially and adversely affected and we may be unable to continue as a going concern. If we are unable to continue as a going concern, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our consolidated financial statements, and it is likely that investors will lose all or a part of their investment.

We are largely dependent on the commercial success of Sumavel DosePro and although we have generated revenue from sales of Sumavel DosePro, we may never significantly increase these sales or become profitable. *

We anticipate that, for at least the next several years, our ability to generate revenues and become profitable will depend in large part on the commercial success of our only marketed product, Sumavel DosePro, which in turn, will depend on several factors, including our ability to:

- successfully maintain and increase market demand for, and sales of, Sumavel DosePro through our sales and marketing efforts and those of Astellas, our co-promotion partner (or, in the event that our co-promotion agreement with Astellas is amended, terminated or otherwise restructured by expanding our sales force and/or through another co-promotion partner, if available);
- obtain greater acceptance of Sumavel DosePro by physicians and patients;
- maintain adequate levels of coverage and reimbursement for Sumavel DosePro from commercial health plans and government health programs, which we refer to collectively as third-party payors, particularly in light of the availability of other branded and generic competitive products;
- maintain compliance with regulatory requirements;
- establish and maintain agreements with wholesalers and distributors on commercially reasonable terms;
- maintain commercial manufacturing arrangements with third-party manufacturers as necessary to meet commercial demand for Sumavel DosePro and continue to manufacture commercial quantities at acceptable cost levels; and
- successfully maintain intellectual property protection for Sumavel DosePro.

We cannot be certain that our continued marketing of Sumavel DosePro will result in increased demand for, and sales of, the product. For example, while we have generally experienced quarterly growth in total prescriptions from the launch of Sumavel DosePro in January 2010 through September 30, 2011, we have at certain times experienced a reduction in total and new prescriptions month over month. In addition, while we have recently expanded our sales force in the United States by 15 sales representatives to further promote Sumavel DosePro, there is no guarantee that this expansion will result in increased sales of Sumavel DosePro. If we fail to successfully increase sales of Sumavel DosePro, we may be unable to generate sufficient revenues to grow or sustain our business and we may never become profitable, and our business, financial condition and results of operations will be materially adversely affected.

We are at an early stage of commercialization and have a history of significant net losses and negative cash flow from operations. We cannot predict if or when we will become profitable and anticipate that our net losses and negative cash flow from operations will continue for at least the next several years. *

We were organized in 2006, have a limited operating history and there is little historical basis upon which to assess how we will respond to competitive, economic or technological challenges. Our business and prospects must be considered in light of the risks and uncertainties frequently encountered by pharmaceutical companies in the early stages of commercialization.

We have generated substantial net losses and negative cash flow from operations since our inception in 2006. For example, for 2009, 2010 and the nine months ended September 30, 2011, we incurred net losses of $45.9 million, $73.6 million and $60.2 million, respectively, our net cash used in operating activities was $32.4 million, $72.0 million, and $64.2 million, respectively, and, at September 30, 2011, our accumulated deficit was $258.3 million. We expect our losses and negative cash flow to continue for at least the next several years as a result of the development expenses in connection with our ongoing clinical development for Zohydro, the initiation of clinical development for Relday and the cost of the sales and marketing expense associated with Sumavel DosePro. Our ability to generate revenues from Sumavel DosePro or any of our product candidates will depend on a number of factors, including, in the case of Sumavel DosePro, the factors described in the following two risk factors and, in the case of our product candidates, our ability to successfully complete clinical trials, obtain necessary regulatory approvals and negotiate arrangements with third parties to help finance the development of, and market and distribute, any product candidates that receive regulatory approval. In addition, we will be subject to the risk that the marketplace will not accept our products.

Because of the numerous risks and uncertainties associated with our product development and commercialization efforts, we are unable to predict the extent of our future losses or when or if we will become profitable and it is possible we will never become profitable. Our failure to increase sales of Sumavel DosePro or to successfully commercialize any of our product candidates that may receive regulatory approval would likely have a material adverse effect on our business, results of operations, financial condition and prospects and could result in our inability to continue operations.

We may not be successful in executing our sales and marketing strategy for the commercialization of Sumavel DosePro and, as part of this strategy, we are dependent on our collaboration with Astellas to promote Sumavel DosePro primarily to primary care physicians, OB/GYNs, emergency medicine physicians and urologists. If we are unable to successfully execute such strategy or if our co-promotion agreement with Astellas is amended, terminated or otherwise restructured, we may not be able to generate significant revenue. *

Prior to the launch of Sumavel DosePro in January 2010, we built a commercial sales and marketing organization including sales, marketing, communications, managed markets, trade and distribution functions, which is now focused exclusively on marketing and selling Sumavel DosePro primarily to physicians, nurses and other healthcare professionals in the United States. Our field sales force includes approximately 94 sales representatives who are promoting Sumavel DosePro primarily to neurologists and other prescribers of migraine medications, including headache clinics and headache specialists in the United States. Although we believe we have adequately sized our sales force in order to reach this targeted audience, we may either increase or decrease the size of our sales force in the future based upon market conditions and actual sales performance. In that regard, if our co-promotion agreement with Astellas is amended, terminated or otherwise restructured, we would expect to either expand our sales force to promote Sumavel DosePro and/or seek another co-promotion partner, if available. In addition, we could lose sales personnel or the performance of our sales personnel as measured by actual sales may be disappointing. Many of our competitors have significantly larger sales and marketing organizations, and significantly greater experience than we do in selling, marketing and distributing pharmaceuticals, and we may not be able to compete successfully with them with the commercial infrastructure we have developed.

To complement our sales force, we entered into an exclusive co-promotion agreement with Astellas in July 2009 under which Sumavel DosePro is also being promoted primarily to primary care physicians, OB/GYNs, emergency medicine physicians and urologists, or collectively the Astellas Segment, in the United States by approximately 400 Astellas sales representatives. Although the agreement stipulates annual minimum levels of sales effort, we have limited control over the amount and timing of resources that Astellas dedicates to the promotion of Sumavel DosePro, and we do not hire, train or manage such resources. For example, Astellas could reduce the number of its sales representatives promoting Sumavel DosePro while still complying with these minimum requirements. The ability to generate revenue from our arrangement with Astellas depends on Astellas efforts in promoting Sumavel DosePro and its ability to achieve broad market acceptance and prescribing of Sumavel DosePro in the Astellas Segment.

We are subject to a number of additional risks associated with our dependence on our co-promotion arrangement with Astellas, including:

- Astellas could fail to devote sufficient resources to the promotion of Sumavel DosePro, including by failing to develop, deploy or expand its sales force as necessary;
- Astellas could terminate the co-promotion agreement for any or no reason upon 180-days written notice at any time, which may negatively impact our ability to generate, or prevent us from generating, sufficient revenue;
- Astellas could fail to comply with applicable regulatory guidelines with respect to the promotion of Sumavel DosePro, which could result in administrative or judicially imposed sanctions, including warning letters, civil and criminal penalties, and injunctions; and
- disputes regarding the co-promotion agreement that negatively impact or terminate the commercialization efforts of Astellas may negatively impact or prevent the generation of sufficient revenue or result in significant litigation or arbitration.

For the three and nine months ended September 30, 2011, sales to the Astellas Segment represented approximately 37% and 39% of our product demand, respectively. Under the terms of the co-promotion agreement, Astellas may terminate the agreement for any reason or no reason upon 180-days written notice to us. The co-promotion agreement may also be terminated by Astellas or us for a number of other specified reasons, some of which are beyond our control. In the event Astellas terminates the agreement for specified reasons, including a material uncured breach by us of our minimum sales effort obligations and our failure to cure such breach within a specified period, we would be required to pay Astellas only the first of the two annual tail payments described below.

In addition, either party may terminate the agreement based upon, among other things, a failure of the Sumavel DosePro brand to achieve certain minimum sales levels in 2011, as defined in the co-promotion agreement. Based on our net product revenue through September 30, 2011, we do not expect to meet these 2011 minimum sales levels for Sumavel DosePro, and therefore expect that both we and Astellas will have the right to terminate the agreement on this basis. If either party were to exercise this termination right, it must provide 90 days written notice to the other party, such notice to be provided within 30 days after the actual net sales of Sumavel DosePro through December 31, 2011 have been provided to Astellas pursuant to the terms of the co-promotion agreement. In the event of such a termination relating to sales levels of Sumavel DosePro, we would be required to make two annual tail payments calculated as decreasing fixed percentages (ranging from a mid-twenties down to a mid-teen percentage) of net sales in the Astellas

Segment in the last 12 months of its active promotion. In the event of a termination by us or Astellas, we would expect to either expand our sales force to promote Sumavel DosePro to certain physicians within the Astellas Segment and/or seek another co-promotion partner, if available. We may also seek to amend or restructure our co-promotion agreement with Astellas.

In addition, Astellas may terminate the co-promotion agreement in the event we undergo a change of control, as defined in the co-promotion agreement, if a governmental authority takes action that prevents or makes it unlawful for Astellas to perform its obligations under the agreement, in the event of our inability to supply commercial product, under certain circumstances where a third party asserts that the making or selling of Sumavel DosePro infringes the intellectual property rights of a third party, upon the occurrence of a large scale recall or market withdrawal of Sumavel DosePro, upon a material uncured breach by us or in the event of our insolvency or bankruptcy or other event which affects our ability to perform our obligations under the agreement. We cannot assure you that Astellas will not terminate the agreement under the circumstances described above. As an alternative to termination, we and Astellas could agree to amend or otherwise restructure the current co-promotion agreement. Such amendment or restructuring could change the financial terms of our agreement, change our respective minimum sales force requirements, or otherwise materially alter our co-promotion relationship. Such an amendment or restructuring could require us to expand our sales force or otherwise invest significant additional financial resources in order to adequately support the successful sales and marketing of Sumavel DosePro.

In addition, our co-promotion agreement with Astellas expires on June 30, 2013, subject to a one-year extension at the option of Astellas. We cannot assure you that Astellas will enter into any extension of the agreement or, if it does so, that it will not condition any such extension upon changes in the agreement that could have a material adverse effect on us. If Astellas were to terminate the agreement or elect not to extend the agreement upon its expiration, we would lose the efforts of their sales force, and we would need to make arrangements with another third party to replace Astellas sales force, or significantly expand our sales and marketing organization. We may not be able to enter into such arrangements with third parties in a timely manner, on acceptable terms or at all. To the extent that we enter into another co-promotion or other licensing arrangement, our portion of retained product revenues is likely to be lower than if we directly marketed and sold Sumavel DosePro solely on our own, and a portion of those revenues generated will depend upon the efforts of such third parties similar to our dependence on Astellas, and these efforts may not be successful. If our co-promotion agreement with Astellas is terminated and we are unable to find another partner for the promotion of Sumavel DosePro in the primary care segment in the United States, we may not be able to expand our own sales and marketing capabilities to cover this segment and any such expansion could, in any event, substantially increase our expenses and capital requirements that we might not be able to fund.

If we are unable to successfully implement our commercialization plans and drive adoption by patients and physicians of Sumavel DosePro through our sales, marketing and commercialization efforts and the efforts of Astellas, then we will not be able to generate significant revenue which will have a material adverse effect on our business, results of operations, financial condition and prospects.

If Sumavel DosePro, and, if approved, Zohydro and Relday, or any other product candidate for which we receive regulatory approval does not achieve broad market acceptance or coverage by third-party payors, the revenues that we generate will be limited.

The commercial success of Sumavel DosePro, and, if approved, Zohydro and Relday, or any other product candidates for which we obtain marketing approval from the FDA or other regulatory authorities will depend upon the acceptance of these products by physicians, patients, healthcare payors and the medical community. Coverage and reimbursement of our approved product by third-party payors is also necessary for commercial success. The degree of market acceptance of Sumavel DosePro and any other product candidates for which we may receive regulatory approval will depend on a number of factors, including:

- our ability to provide acceptable evidence of safety and efficacy;
- acceptance by physicians and patients of the product as a safe and effective treatment;
- the relative convenience and ease of administration;
- the prevalence and severity of adverse side effects;
- limitations or warnings contained in a product s FDA-approved labeling;

the clinical indications for which the product is approved;

in the case of product candidates that are controlled substances, the U.S. Drug Enforcement Agency, or DEA, scheduling classification;

availability and perceived advantages of alternative treatments;

any negative publicity related to our or our competitors products;

the effectiveness of our or any current or future collaborators sales, marketing and distribution strategies;

pricing and cost effectiveness;

our ability to obtain sufficient third-party payor coverage or reimbursement; and

the willingness of patients to pay out of pocket in the absence of third-party payor coverage.

For example, while we believe the needle-free nature of our DosePro technology will appeal to patients, some patients may not react favorably to the subcutaneous delivery of drug products by DosePro. Our experience indicates that some patients will experience pain upon injection with the DosePro technology and/or reactions at the site of injection. Any undesirable side effects have the potential to limit market acceptance of our product candidates.

In addition, products used to treat and manage pain, especially in the case of opioids, are from time to time subject to negative publicity, including illegal use, overdoses, abuse, diversion, serious injury and death. These events have led to heightened regulatory scrutiny. Controlled substances are classified by the DEA as Schedule I through V substances, with Schedule I substances being prohibited for sale in the United States, Schedule II substances considered to present the highest risk of abuse and Schedule V substances being considered to present the lowest relative risk of abuse. Zohydro contains *hydrocodone*, and we anticipate it will be regulated as a Schedule II controlled substance, and despite the strict regulations on the marketing, prescribing and dispensing of such substances, illicit use and abuse of *hydrocodone* is well-documented. Thus, the regulatory approval process and the marketing of Zohydro may generate public controversy that may adversely affect regulatory approval and market acceptance of Zohydro.

Our efforts to educate the medical community and third-party payors on the benefits of Sumavel DosePro, and, if approved, Zohydro and Relday or any of our other product candidates for which we obtain marketing approval from the FDA or other regulatory authorities and gain broad market acceptance may require significant resources and may never be successful. If our products do not achieve an adequate level of acceptance by physicians, third-party payors and patients, we may not generate sufficient revenue from these products to become or remain profitable.

Our business and operations would suffer in the event of system failures.*

Despite the implementation of security measures, our internal computer systems and those of our current and any future partners, contractors and consultants are vulnerable to damage from cyber-attacks, computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. For example, we recently experienced failures in our information systems and computer servers, which may have been the result of a cyber-attack. These failures resulted in an interruption of our normal business operations and required substantial expenditure of financial and administrative resources to remedy. We cannot be sure that similar failures will not occur in the future. System failures, accidents or security breaches can cause interruptions in our operations, and can result in a material disruption of our commercialization activities, drug development programs and our business operations. The loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Similarly, we rely on a large number of third parties to supply components for and manufacture our product and product candidates, warehouse and distribute Sumavel DosePro and conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the commercialization of Sumavel DosePro and development of Zohydro, Relday or any of our other product candidates could be delayed.

Our short operating history makes it difficult to evaluate our business and prospects.

We commenced our operations on August 25, 2006. Our operations to date have been limited to organizing and staffing our company, scaling up manufacturing operations with our third-party contract manufacturers, building a sales and marketing organization, conducting product development activities for our product and product candidates, in-licensing rights to Zohydro and Relday, and commercializing Sumavel DosePro. Moreover, Sumavel DosePro is our only product that is approved for sale. Consequently, any predictions about our future performance may not be as accurate as they could be if we had a history of successfully developing and commercializing pharmaceutical products.

We depend on wholesale pharmaceutical distributors for retail distribution of Sumavel DosePro, and if we lose any of our significant wholesale pharmaceutical distributors, our business could be harmed.

The majority of our sales of Sumavel DosePro are to wholesale pharmaceutical distributors who, in turn, sell the products to pharmacies, hospitals and other customers. Three wholesale pharmaceutical distributors, Cardinal Health, Inc., McKesson Corporation and AmerisourceBergen Corporation, individually comprised 42.8%, 39.7% and 10.2%, respectively, of our total gross sales of Sumavel DosePro for the nine months ended September 30, 2011, which may result in substantial fluctuations in our results of operations from period to period. The loss of any of these wholesale pharmaceutical distributors accounts or a material reduction in their purchases could have a material adverse effect on our business, results of operations, financial condition and prospects.

In addition, these wholesale customers comprise a significant part of the distribution network for pharmaceutical products in the United States. This distribution network has undergone, and may continue to undergo, significant consolidation marked by mergers and acquisitions. As a result, a small number of large wholesale distributors control a significant share of the market. Consolidation of drug wholesalers has increased, and may continue to increase, competitive and pricing pressures on pharmaceutical products. In addition, at times, wholesaler purchases may exceed customer demand, resulting in reduced wholesaler purchases in later quarters, which may result in substantial fluctuations in our results of operations from period to period. We cannot assure you that we can manage these pricing pressures or that wholesaler purchases will not

decrease as a result of this potential excess buying.

Our sales can be greatly affected by the inventory levels our wholesalers carry. We monitor wholesaler inventory of Sumavel DosePro using a combination of methods. Pursuant to distribution service agreements with our three largest wholesale customers, we receive inventory level reports. For most other wholesalers where we do not receive inventory level reports, however, our estimates of wholesaler inventories may differ significantly from actual inventory levels. Significant differences between actual and estimated inventory levels may result in excessive production (requiring us to hold substantial quantities of unsold inventory), inadequate supplies of products in distribution channels, insufficient product available at the retail level, and unexpected increases or decreases in orders from our wholesalers. These changes may cause our revenues to fluctuate significantly from quarter to quarter, and in some cases may cause our operating results for a particular quarter to be below our expectations or the expectations of securities analysts or investors. If our financial results are below expectations for a particular period, the market price of our common stock may drop significantly.

We face intense competition, including from generic products, and if our competitors market and/or develop treatments for migraine, pain or psychotic disorders that are marketed more effectively, approved more quickly than our product candidates or demonstrated to be safer or more effective than our products, our commercial opportunities will be reduced or eliminated.*

The pharmaceutical industry is characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary therapeutics. We face competition from a number of sources, some of which may target the same indications as our product or product candidates, including large pharmaceutical companies, smaller pharmaceutical companies, biotechnology companies, academic institutions, government agencies and private and public research institutions, many of which have greater financial resources, sales and marketing capabilities, including larger, well-established sales forces, manufacturing capabilities, experience in obtaining regulatory approvals for product candidates and other resources than us. Many large, well-capitalized companies offer products in the United States that compete with Sumavel DosePro. Sumavel DosePro currently competes with branded products in the triptan class such as Imitrex and Treximet marketed by GlaxoSmithKline, or GSK, as well as six other branded triptan therapies being sold by AstraZeneca PLC, Endo Pharmaceuticals Holdings Inc., Johnson & Johnson, Merck & Co., Inc., and Pfizer Inc. In addition to those migraine therapeutics, there are other marketed non-triptan migraine therapeutics such as Cambia sold by Nautilus Neurosciences, Inc. and Migranal sold by Valeant Pharmaceutical International. We also face competition from generic *sumatriptan* oral tablets and *sumatriptan* injection, now marketed in the United States as an authorized generic of the Imitrex STATdose System, or Imitrex STATdose, by Par Pharmaceutical Companies, Inc. and Sandoz Inc. (a Novartis AG company). In addition, in June 2010 the FDA approved Alsuma (*sumatriptan* injection), a needle-based autoinjector which was developed and is manufactured and marketed by Pfizer and its subsidiary, Meridian Medical Technologies. Finally, generic injectable sumatriptan in the form of vials and prefilled syringes is available from a number of pharmaceutical companies, and most recently, the FDA granted approval for a needle-based generic *sumatriptan* auto-injector from Sun Pharmaceutical Industries Limited in June 2011. Although these products may not be directly substituted for Sumavel DosePro, generic versions of *sumatriptan* injection and alternative autoinjector forms of *sumatriptan* injection may reduce the future adoption of Sumavel DosePro by third-party payors and consumers, as financial pressure to use generic products may encourage the use of a generic product over Sumavel DosePro. Sumavel DosePro is currently more expensive on a per dose basis than most of the competing branded and all of the generic triptan products for migraine, which may also limit the coverage and reimbursement by third-party payors, which could adversely affect adoption by physicians and patients.

If approved for the treatment of moderate to severe chronic pain, we anticipate that Zohydro would compete against other marketed branded and generic pain therapeutics. Opioid therapeutics generally fall into two classes: *codeines*, which include *oxycodones* and *hydrocodones,* and *morphines*. Zohydro is a *hydrocodone*, the most commonly prescribed opioid in the United States, and we expect Zohydro will compete with therapeutics within both the *codeine* and *morphine* classes. These therapeutics include both Schedule II and Schedule III products (meaning that they are considered controlled substances by the DEA) being marketed by companies such as Endo Pharmaceuticals Holdings Inc., Johnson & Johnson, Mallinckrodt Inc., Pfizer, Purdue Pharma L.P., Teva Pharmaceutical Industries Limited and Watson Pharmaceuticals, Inc.

In addition to already marketed therapeutics, we also face competition from product candidates that are or could be under development by many of the above-mentioned entities and others. For example, there are several products for the treatment of migraine under development by large pharmaceutical companies such as GSK and Merck & Co., and other smaller companies such as NuPathe, Inc. and MAP Pharmaceuticals, Inc. If approved, Zohydro may also compete with at least 15 opioid product candidates under development, including abuse and diversion resistant formulations of currently available opioids, novel opioids and alternative delivery forms of various opioids under development at other pharmaceutical companies, including single-entity extended-release *hydrocodone* product candidates being developed by Cephalon, Inc., Egalet A/S, Pfizer and Purdue Pharma L.P. Zohydro may also face competition from non-opioid product candidates including new chemical entities, as well as alternative delivery forms of non-steroidal anti-inflammatory drugs. These new opioid and non-opioid product candidates are being developed by companies such as Acura Pharmaceuticals, Inc., Altea Therapeutics Corporation, Collegium Pharmaceutical, Inc., Eli Lilly and Company, Elite Pharmaceuticals, Inc., Hospira Inc., Inspirion Delivery Technologies, Inc, LLC, Intellipharmaceuticals International, Inc., Pfizer and QRxPharma Ltd.

If approved for the treatment of schizophrenia, we anticipate that Relday will compete against other marketed, branded and generic, typical and atypical antipsychotics, including both long-acting injectable and oral products. Currently marketed long-acting injectable atypical antipsychotic products include Risperdal Consta, and Invega Sustenna marketed by Johnson & Johnson, and Zyprexa Relprevv marketed by Eli Lilly & Company. Currently approved and marketed oral atypical antipsychotics include Risperdal (*risperidone*) and Invega (*paliperidone*) marketed by Johnson & Johnson, generic *risperidone*, Zyprexa (*olanzapine*) marketed by Eli Lilly and Company, Seroquel (*quetiapine*) marketed by AstraZeneca PLC, Abilify (*aripiprazole*) marketed by BMS/Otsuka Pharmaceutical Co., Ltd., Geodon (*ziprasidone*) marketed by Pfizer, Fanapt (*iloperidone*) marketed by Novartis AG, Saphris (*asenapine*) marketed by Merck & Co., Latuda (*lurasidone*) marketed by Dainippon Sumitomo Pharma, and generic *clozapine*. Finally, in addition to these currently marketed products, we may also face competition from additional long-acting injectable product candidates that could be developed by the large companies listed above, as well and by other pharmaceutical companies such as Alkermes, Inc., NuPathe, Inc. and Novartis AG, each of which has announced they are developing long-acting antipsychotic product candidates.

We expect Sumavel DosePro and, if approved, Zohydro, Relday and any of our other product candidates to compete on the basis of, among other things, product efficacy and safety, time to market, price, patient reimbursement by third-party payors, extent of adverse side effects and convenience of treatment procedures. One or more of our competitors may develop needle-free injectable products, products to address chronic pain or other products that compete with ours, obtain necessary approvals for such products from the FDA, or other agencies, if required, more rapidly than us or develop alternative products or therapies that are safer, more effective and/or more cost effective than any products developed by us. If any of our product candidates receive the requisite regulatory approval and classification and are marketed, the competition which we will encounter will have, and the competition we are currently encountering with our Sumavel DosePro product has had and will continue to have, an effect on our product prices, market share and results of operations. We may not be able to differentiate any products that we are able to market from those of our competitors, successfully develop or introduce new products that are less costly or offer better results than those of our competitors, or offer purchasers of our products payment and other commercial terms as favorable as those offered by our competitors.

In addition, competitors may seek to develop alternative formulations of our product candidates and/or alternative drug delivery technologies that address our targeted indications. The commercial opportunity for Sumavel DosePro and our product candidates could be significantly harmed if competitors are able to develop alternative formulations and/or drug delivery technologies outside the scope of our products. Compared to us, many of our potential competitors have substantially greater:

- capital resources;
- research and development resources and experience, including personnel and technology;
- drug development, clinical trial and regulatory resources and experience;
- sales and marketing resources and experience;
- manufacturing and distribution resources and experience;
- name recognition; and
- resources, experience and expertise in prosecution and enforcement of intellectual property rights.

As a result of these factors, our competitors may obtain regulatory approval of their products more rapidly than we are able to or may obtain patent protection or other intellectual property rights that limit or block us from developing or commercializing our product candidates. Our competitors may also develop drugs that are more effective, more useful, better tolerated, subject to fewer or less severe side effects, more widely prescribed or accepted or less costly than ours and may also be more successful than us in manufacturing and marketing their products. If we are unable to compete effectively with the marketed therapeutics of our competitors or if such competitors are successful in developing products that compete with Sumavel DosePro or any of our product candidates that are approved, our business, results of operations, financial condition and prospects may be materially adversely affected.

We are dependent on numerous third parties in our supply chain, all of which are currently single source suppliers, for the commercial supply of Sumavel DosePro and for the clinical supply of Zohydro and Relday, and if we experience problems with any of these suppliers, the manufacturing of Sumavel DosePro, Zohydro and Relday could be delayed.

While we own most of the specialized equipment used to manufacture critical components of Sumavel DosePro, we do not own or operate manufacturing facilities and currently lack the in-house capability to manufacture Sumavel DosePro, Zohydro, Relday or any other products or product candidates. Our DosePro device and Sumavel DosePro are manufactured by contract manufacturers, component fabricators and secondary service providers. Final aseptic fill, finish, assembly and packaging of Sumavel DosePro are performed at Patheon UK Limited, Swindon, United Kingdom, a specialist in the aseptic fill/finish of injectables and other sterile pharmaceutical products. In addition, Nypro Limited, located in Bray, Ireland, manufactures the actuator assemblies and injection molded components for our DosePro device and MGlas AG, located in Münnerstadt, Germany, manufactures the specialized glass capsule that houses the *sumatriptan* active pharmaceutical ingredient, or API, in our DosePro device. Each of these manufacturers and

each other company that supplies, fabricates or manufactures any component used in our DosePro device is currently the only qualified source of their respective components. We currently rely on Dr. Reddy s Laboratories as the only supplier of *sumatriptan* API for use in Sumavel DosePro. We also outsource all manufacturing and packaging of the clinical trial materials for Zohydro and Relday to third parties. Although we plan to qualify additional manufacturers and suppliers of some of the components used in Sumavel DosePro, there can be no assurance that we will be able to do so and the current manufacturers and suppliers of these components will likely be single source suppliers to us for a significant period of time. Similarly, under our license agreements, Alkermes Pharma International Ltd., or Alkermes, is the exclusive manufacturer of Zohydro and Durect is the exclusive manufacturer of Relday for all clinical trials through Phase 2 clinical trials and has the option to supply Relday for Phase 3 clinical trials and, if approved, commercial distribution. We may never be able to establish additional sources of supply for Zohydro or Relday.

Manufacturers and suppliers are subject to regulatory requirements covering, among other things, manufacturing, testing, quality control and record keeping relating to our product and product candidates, and are subject to ongoing inspections by regulatory agencies. Failure by any of our manufacturers or suppliers to comply with applicable regulations may result in long delays and interruptions to our manufacturing supply, and increase our costs, while we seek to secure another supplier who meets all regulatory requirements. Accordingly, the loss of any of our current third-party manufacturers or suppliers could have a material adverse effect on our business, results of operations, financial condition and prospects.

Reliance on third-party manufacturers and suppliers entails risks to which we would not be subject if we manufactured Sumavel DosePro or our product candidates ourselves, including:

- reliance on the third parties for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreements by the third parties because of factors beyond our control or the insolvency of any of these third parties or other financial difficulties, labor unrest, natural disasters or other factors adversely affecting their ability to conduct their business; and
- the possibility of termination or non-renewal of the agreements by the third parties, at a time that is costly or inconvenient for us, because of our breach of the manufacturing agreement or based on their own business priorities.

If our contract manufacturers or suppliers fail to deliver the required commercial quantities of Sumavel DosePro and its various components, the quantities of Zohydro, Relday or any of our other product candidates required for our clinical trials and, if approved, for commercial sale, on a timely basis and at commercially reasonable prices, and we are unable to find one or more replacement manufacturers or suppliers capable of production at a substantially equivalent cost, in substantially equivalent volumes and quality, and on a timely basis, we would likely be unable to meet demand for our products and would have to delay or terminate our pre-clinical or clinical trials, and we would lose potential revenue. It may also take a significant period of time to establish an alternative source of supply for our product, product candidates and components and to have any such new source approved by the FDA or any applicable foreign regulatory authorities. Furthermore, any of the above factors could cause the delay or suspension of initiation or completion of clinical trials, regulatory submissions or required approvals of our product candidates, cause us to incur higher costs and could prevent us from commercializing our product candidates successfully.

We may encounter delays in the manufacturing of Sumavel DosePro or fail to generate revenue if our supply of the components of our DosePro drug delivery system is interrupted.

Our DosePro drug delivery system is sourced, manufactured and assembled by multiple third parties across different geographic locations in Europe, including the United Kingdom, Germany and Ireland. All contract manufacturers and component suppliers have been selected for their specific competencies in the manufacturing processes and materials that make up the DosePro system. The components of DosePro include the actuator subassembly, capsule subassembly, and the setting mechanism. The actuator subassembly is comprised of nine individual components which are collectively supplied by six different third-party manufacturers. The capsule subassembly that houses the sterile drug formulation *sumatriptan* is comprised of five different components also supplied by four third-party manufacturers. Each of these third-party manufacturers is currently the single source of their respective components. If any of these manufacturers is unable to supply its respective component for any reason, including due to violations of the FDA s Quality System Regulation, or QSR, requirements, our ability to manufacture the finished DosePro device will be adversely affected and our ability to meet the distribution requirements for any product sales of Sumavel DosePro and the resulting revenue therefrom will be negatively affected. Accordingly, there can be no assurance that any failure in any part of our supply chain will not have a material adverse effect on our ability to generate revenue from Sumavel DosePro, which in turn could have a material adverse effect on our business, results of operations, financial condition and prospects.

We rely on third parties to perform many necessary services for our commercial products, including services related to the distribution, invoicing, storage and transportation of our products.

We have retained third-party service providers to perform a variety of functions related to the sale and distribution of our products, key aspects of which are out of our direct control. For example, we rely on Cardinal Health 105, Inc. (a/k/a Specialty Pharmaceutical Services) to provide key services related to logistics, warehousing and inventory management, distribution, contract

administration and chargeback processing, accounts receivable management and call center management, and, as a result, most of our inventory is stored at a single warehouse maintained by the service provider. We place substantial reliance on this provider as well as other third-party providers that perform services for us, including entrusting our inventories of products to their care and handling. If these third-party service providers fail to comply with applicable laws and regulations, fail to meet expected deadlines, or otherwise do not carry out their contractual duties to us, or encounter physical damage or natural disaster at their facilities, our ability to deliver product to meet commercial demand would be significantly impaired. In addition, we utilize third parties to perform various other services for us relating to sample accountability and regulatory monitoring, including adverse event reporting, safety database management and other product maintenance services. If the quality or accuracy of the data maintained by these service providers is insufficient, our ability to continue to market our products could be jeopardized or we could be subject to regulatory sanctions. We do not currently have the internal capacity to perform these important commercial functions, and we may not be able to maintain commercial arrangements for these services on reasonable terms.

The perception that our DosePro needle-free drug delivery system should be pain free may limit patient adoption.

We believe that there is a perception among some patients, physicians and other customers that a needle-free delivery system should be pain free. While our experience indicates that some patients will experience pain upon injection with the DosePro technology, this pain sensation is consistent with the pain sensation associated with injection with a fine gauge needle and can be generally characterized as transient mild discomfort. In addition, some patients will experience local injection site signs and reactions following injection with DosePro. The fact that the use of our DosePro system may be accompanied by a certain amount of pain upon injection and local injection site signs and reactions may limit its adoption by patients, physicians and other customers.

***Zohydro and Relday are subject to extensive regulation, and we cannot give any assurance that they or any of our other product candidates will receive regulatory approval or be successfully commercialized. **

We currently are developing Zohydro for the treatment of moderate to severe chronic pain and we plan to initiate clinical studies for Relday to treat the symptoms of schizophrenia. The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of opioid drug products, among other things, are subject to extensive regulation by the FDA, the DEA (in the case of Zohydro) and other regulatory authorities in the United States. We are not permitted to market Zohydro, Relday or any of our other product candidates in the United States unless and until we receive regulatory approval from the FDA. We cannot provide any assurance that we will obtain regulatory approval for Zohydro, Relday or any of our other product candidates, or that any such product candidates will be successfully commercialized.

We have not yet completed all necessary studies, nor submitted a new drug application, or NDA, or received marketing approval, for Zohydro and we have not yet commenced clinical studies for Relday. Obtaining approval of an NDA is a lengthy, expensive and uncertain process. The FDA also has substantial discretion in the drug approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons. For example:

- the FDA may not deem a product candidate safe and effective;
- the FDA may not find the data from pre-clinical studies and clinical trials sufficient to support approval;
- the FDA may require additional pre-clinical studies or clinical trials;
- the FDA may not approve of our third-party manufacturers processes and facilities; or
- the FDA may change its approval policies or adopt new regulations.

Zohydro has undergone Phase 1 pharmacokinetics studies as well as Phase 2 clinical trials. However, these studies and trials were conducted by a third party and, accordingly, we did not directly participate in their design or execution. In addition, we will also need to successfully complete Phase 3 clinical trials to establish its safety and efficacy, additional Phase 1 studies, and additional pre-clinical studies prior to our submission of an NDA to the FDA for approval. We initiated the Phase 3 clinical development program for Zohydro in March 2010 and reported positive top-line results from our pivotal Phase 3 efficacy trial, Study 801, in August 2011 and completed enrollment in our open-label Phase 3 safety trial, Study 802, in November 2010. Zohydro and any of our other product candidates may fail to achieve their specified endpoints in clinical trials. Furthermore, product candidates such as Zohydro may not be approved even if they achieve their specified endpoints in clinical trials. The

FDA may disagree with our trial design and our interpretation of data from clinical trials, or may change the requirements for approval even after it has reviewed and commented on the design for our clinical trials. The FDA may also approve a product candidate for fewer or more limited indications than we request, or may grant approval contingent on the performance of costly post-approval clinical trials. In addition, the FDA may not approve the labeling claims that we believe are necessary or desirable for the successful commercialization of our product candidates. Although we have not yet begun clinical studies for Relday, the development of Relday will be subject to most of the risks described in this paragraph.

If we are unable to obtain regulatory approval for Zohydro, Relday or any other product candidates on the timeline we anticipate, we will not be able to execute our business strategy effectively and our ability to generate additional revenues beyond Sumavel DosePro will be limited, which would have a material adverse impact on our business, results of operations, financial condition and prospects.

Our clinical trials may fail to demonstrate acceptable levels of safety and efficacy for Zohydro, Relday or any of our other product candidates, which could prevent or significantly delay their regulatory approval. *

Our Zohydro and Relday product candidates and any other product candidates are prone to the risks of failure inherent in drug development. Before obtaining U.S. regulatory approval for the commercial sale of Zohydro, Relday or any other product candidate, we must gather substantial evidence from well-controlled clinical trials that demonstrate to the satisfaction of the FDA that the product candidate is safe and effective, and similar regulatory approvals would be necessary to commercialize the product candidate in other countries.

In light of widely publicized events concerning the safety risk of certain drug products, particularly opioid drug products, regulatory authorities, members of Congress, the Government Accountability Office, medical professionals and the general public have raised concerns about potential drug safety issues. These events have resulted in the withdrawal of drug products, revisions to drug labeling that further limit use of the drug products and establishment of risk management programs that may, for instance, restrict distribution of drug products after approval. In addition, the Federal Food, Drug, and Cosmetic Act, or FFDCA, as amended by the Food and Drug Administration Amendments Act of 2007, grants significant expanded authority to the FDA, much of which is aimed at improving the safety of drug products before and after approval. In particular, the FFDCA authorizes the FDA to, among other things, require post-approval studies and clinical trials, mandate changes to drug labeling to reflect new safety information and require a risk evaluation and mitigation strategy, or REMS, for certain drugs, including certain currently approved drugs. It also significantly expands the federal government s clinical trial registry and results databank, which we expect will result in significantly increased government oversight of clinical trials. Under the FFDCA, companies that violate these and other provisions of the law are subject to substantial civil monetary penalties, among other regulatory, civil and criminal penalties.

The increased attention to drug safety issues may result in a more cautious approach by the FDA in its review of our clinical trials. Data from clinical trials may receive greater scrutiny with respect to safety, which may make the FDA or other regulatory authorities more likely to terminate clinical trials before completion, or require longer or additional clinical trials that may result in a delay or failure in obtaining approval or approval for a more limited indication than originally sought.

With regard to Zohydro, top-line results from our pivotal Phase 3 efficacy clinical trial in patients with chronic lower back pain has shown what we believe is a clinically acceptable efficacy and safety profile which supports submission of an NDA for the treatment of moderate to severe pain in patients requiring around-the-clock opioid therapy. The trial successfully met the primary efficacy endpoint of the study in demonstrating a significant difference (p=0.008) between the mean changes in daily pain intensity Numeric Rating Scale (NRS) scores between Zohydro and placebo groups. The two key secondary endpoints were also met, specifically, the proportion of patients with at least 30% improvement in pain intensity and the improvement of overall satisfaction of medication. In the pivotal Phase 3 efficacy trial, the observed adverse events were similar to the side effects we observed in prior Phase 2 trials of Zohydro and consistent with the reported side effects of opioids currently prescribed for chronic pain. The incidence of adverse events was 33.7% and 28.8% in the open-label titration and double blind treatment periods, respectively. Overall, the most commonly reported adverse events (2%) were constipation, nausea, somnolence, vomiting, diarrhea, insomnia, fatigue, headache, dizziness and dry mouth. These results may not be predictive of results obtained in our ongoing Phase 3 safety trial or any other required future trials, and we may be unable to demonstrate sufficient safety and efficacy to obtain the requisite regulatory approvals or approvals for commercially viable uses. In addition, the top-line data we have reported and may continue to report from our Zohydro clinical trials is based on preliminary analysis of key efficacy and safety data, and such data may change following a more comprehensive review of the data related to the applicable clinical trial, and may also change in connection with the continued review of such data as part our planned submission and the FDA s review of our NDA. A number of companies in the biotechnology and pharmaceutical industries have suffered significant setbacks in advanced clinical trials, even after promising results in earlier trials. If Zohydro is not shown to be safe and effective in clinical trials, this program could be delayed or terminated, which could have a material adverse effect on our business, results of operations, financial condition and prospects.

Delays in the commencement or completion of clinical testing for Zohydro or pre-clinical or clinical testing for Relday or any of our other product candidates could result in increased costs to us and delay or limit our ability to pursue regulatory approval for, or generate revenues from, such product candidates. *

Clinical trials are very expensive, time consuming and difficult to design and implement. Delays in the commencement or completion of clinical testing for Zohydro or pre-clinical or clinical testing for Relday or any of our other product candidates could significantly affect our product development costs and business plan. In March 2010, we initiated a Phase 3 clinical development program for Zohydro, including a pivotal efficacy trial. We reported positive top-line results from our pivotal Phase 3 efficacy trial in August 2011 and are still conducting our fully-enrolled Phase 3 safety trial for Zohydro. Phase 3 clinical efficacy trials, in general, are significantly more complex and time-consuming and involve more patients than the Phase 1 and 2 clinical trials. We do not know whether our ongoing Phase 3 clinical trial of Zohydro will be completed on schedule, if at all. We expect to initiate clinical testing for Relday in patients with schizophrenia in early 2012. In addition, we do not know whether this or any other pre-clinical or clinical trials

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will begin on time or be completed on schedule, if at all. The commencement and completion of clinical trials can be delayed for a number of reasons, including delays related to:

- obtaining regulatory authorization to commence a clinical trial;
- reaching agreement on acceptable terms with prospective clinical research organizations, or CROs, clinical investigators and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs, clinical investigators and trial sites;
- manufacturing or obtaining sufficient quantities of a product candidate for use in clinical trials;
- obtaining institutional review board, or IRB, approval to initiate and conduct a clinical trial at a prospective site;
- identifying, recruiting and training suitable clinical investigators;
- identifying, recruiting and enrolling subjects to participate in clinical trials for a variety of reasons, including competition from other clinical trial programs for the treatment of pain, migraine or similar indications;
- retaining patients who have initiated a clinical trial but may be prone to withdraw due to side effects from the therapy, lack of efficacy, personal issues, or for any other reason they choose, or who are lost to further follow-up;
- uncertainty regarding proper dosing; and
- scheduling conflicts with participating clinicians and clinical institutions.

We believe that we have planned and designed an adequate Phase 3 clinical trial program for Zohydro, and we presented the trial design for our Phase 3 trials to the FDA at our End of Phase 2 meeting in June 2008. Although we believe the FDA has generally agreed with the design of our Phase 3 clinical trial program, the FDA could still determine that it is not satisfied with our plan, the details of our pivotal clinical trial protocols and designs or the results of our studies. While the FDA has provided us with a written record of our discussions and responses to our questions at our End of Phase 2 meeting, such records and responses do not guarantee that the FDA will deem our trial design to be sufficient for the purpose of obtaining marketing approval for Zohydro. We did not seek a Special Protocol Assessment from the FDA for our pivotal Phase 3 efficacy study for Zohydro (Study 801).

In addition, while we completed enrollment in our open-label Phase 3 trial, Study 802, in November 2010, chronic pain patients have historically been difficult to keep enrolled in clinical trials. If a significant number of patients fail to stay enrolled in any of our current or future clinical trials of Zohydro, Relday or any of our other product candidates and such failure is not adequately accounted for in our trial design and enrollment assumptions, our clinical development program could be delayed. Clinical trials may also be delayed or repeated as a result of ambiguous or negative interim results or unforeseen complications in testing. In addition, a clinical trial may be suspended or terminated by us, the FDA, the IRB overseeing the clinical trial at issue, any of our clinical trial sites with respect to that site, or other regulatory authorities due to a number of factors, including:

- failure to design appropriate clinical trial protocols;

failure by us, our employees, our CROs or their employees to conduct the clinical trial in accordance with all applicable FDA, DEA or other regulatory requirements or our clinical protocols;

inspection of the clinical trial operations or trial sites by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;

discovery of serious or unexpected toxicities or side effects experienced by study participants or other unforeseen safety issues;

lack of adequate funding to continue the clinical trial, including the incurrence of unforeseen costs due to enrollment delays, requirements to conduct additional trials and studies and increased expenses associated with the services of our CROs and other third parties;

lack of effectiveness of any product candidate during clinical trials;

slower than expected rates of subject recruitment and enrollment rates in clinical trials;

failure of our CROs or other third-party contractors to comply with all contractual requirements or to perform their services in a timely or acceptable manner;

inability or unwillingness of medical investigators to follow our clinical protocols;

in the case of Zohydro, regulatory concerns with opioid products generally and the potential for abuse and diversion of the drugs; and

unfavorable results from on-going clinical trials and pre-clinical studies.

Additionally, changes in applicable regulatory requirements and guidance may occur and we may need to amend clinical trial protocols to reflect these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for reexamination,

which may impact the costs, timing or successful completion of a clinical trial. If we experience delays in completion of, or if we terminate, any of our clinical trials, the commercial prospects for Zohydro, Relday and our other product candidates may be harmed, which may have a material adverse effect on our business, results of operations, financial condition and prospects.

Our competitors could receive FDA approval for an extended-release hydrocodone product before we receive FDA approval for Zohydro, and thus could be granted regulatory exclusivity that could significantly delay our ability to receive approval for and commercialize Zohydro and therefore dramatically reduce its market potential. Our competitors could also pursue regulatory and other strategies to combat competition from 505(b)(2) products, which also may negatively affect the approval and commercialization of Zohydro and any of our other product candidates.

The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Amendments, added Section 505(b)(2) to the FFDCA, or Section 505(b)(2). Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. For example, we obtained FDA marketing approval of Sumavel DosePro under Section 505(b)(2), and we intend to submit the NDA for Zohydro under Section 505(b)(2), and as such the NDA will rely, in part, on the FDA s previous findings of safety and effectiveness for *hydrocodone*.

Certain of our competitors may file a 505(b)(2) application for extended-release *hydrocodone* either before or shortly after we submit our own NDA for Zohydro. The first approved 505(b)(2) applicant for a particular condition of use, or change to a marketed product, such as a new extended-release formulation for a previously approved product, may be granted three-year Hatch-Waxman exclusivity if one or more clinical studies, other than bioavailability or bioequivalence studies, was essential to the approval of the application and was conducted/sponsored by the applicant. Three-year Hatch-Waxman exclusivity delays the FDA s approval of other 505(b)(2) applicants for the same condition of use or change to the drug product that was granted exclusivity, regardless of the date of submission of each NDA. We believe that several competitors are developing extended-release *hydrocodone* products, and if the FDA approves a competitor s 505(b)(2) application for its extended-release *hydrocodone* product before our application, and granted the competitor three-year exclusivity, the FDA would be precluded from making effective our NDA for Zohydro until after that three-year exclusivity period has run, and such delay would dramatically reduce our expected market potential for Zohydro. Additionally, even if our 505(b)(2) application for extended-release *hydrocodone* is approved first, we may still be subject to competition by other *hydrocodone* products, including approved products or other 505(b)(2) applications for different conditions of use that would not be restricted by the three-year exclusivity.

In addition, approval under Section 505(b)(2) generally requires the absence of any other patents covering the product candidate in question and competitors and others have the ability to take numerous steps to block or delay approval of product candidates under Section 505(b)(2), including:

- extending patent protection for existing products that would block Section 505(b)(2) approval of the product candidate by pursuing new patents for existing products that may be granted just before the expiration of one patent, which could extend patent protection for a number of years or otherwise delay the launch of generic, 505(b)(2) or other competing products;
- submitting Citizen Petitions to request the FDA to take adverse administrative action with respect to approval of a generic, 505(b)(2) or other competing product;
- filing patent infringement lawsuits, whether or not meritorious, to trigger up to a 30-month stay in the approval of a generic, 505(b)(2) or other competing product; and
- engaging in state-by-state initiatives to enact legislation or regulatory policies that restrict the substitution of some generic, 505(b)(2) or other competing drugs for brand-name drugs.

If any of these strategies are successful, our ability to obtain approval of and commercialize Zohydro and any of our other product candidates for which we rely on Section 505(b)(2) will be adversely affected.

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

We have agreements with third-party CROs to conduct our Phase 3 trials for Zohydro, and anticipate that we may enter into other such agreements in the future regarding Relday or any of our other product candidates. We rely heavily on these parties for the execution of our clinical and pre-clinical studies, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol. We and our CROs are required to comply with current good clinical practices, or GCPs. The FDA enforces these GCP regulations through periodic inspections of trial sponsors, principal investigators and trial sites. If we or our CROs fail to comply with applicable GCP regulations, the data generated in our clinical trials may be deemed unreliable and the FDA may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA and similar foreign regulators will determine that any of our clinical trials comply or complied with GCP regulations. In addition, our clinical trials must be conducted with product produced under current good manufacturing practices, or cGMPs, regulations, and require a large number of test subjects. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs on commercially reasonable terms, or at all. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate additional revenues could be delayed.

Switching or adding additional CROs can involve substantial cost and require extensive management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays may occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, results of operations, financial condition and prospects.

The development of a REMS for Zohydro could cause significant delays in the approval process for Zohydro and will add additional layers of regulatory requirements, including the requirement for a Medication Guide and educational requirements for prescribers and patients, which could significantly impact our ability to commercialize Zohydro and dramatically reduce its market potential. *

The Food and Drug Administration Amendments Act, or FDAAA, added Section 505-1 to the FFDCA. Section 505-1 permits FDA to require a REMS for a drug product to ensure the safe use of the drug. A REMS is a strategic safety program that the FDA requires to ensure that the benefits of a drug outweigh its risks. In determining whether a REMS is necessary, the FDA must consider the size of the population likely to use the drug, the seriousness of the disease or condition to be treated, the expected benefit of the drug, the duration of treatment, the seriousness of known or potential adverse events, and whether the drug is a new molecular entity. If the FDA determines a REMS is necessary, the drug sponsor must agree to the REMS plan at the time of approval. A REMS may be required to include various elements, such as a medication guide or patient package insert, a communication plan to educate health care providers of the drug s risks, limitations on who may prescribe or dispense the drug, requirements that patients enroll in a registry or undergo certain health evaluations or other measures that the FDA deems necessary to assure the safe use of the drug. In addition, the REMS must include a timetable to assess the strategy at 18 months, three years and seven years after the strategy s approval.

In February 2009, the FDA informed drug manufacturers that it will require a class-wide REMS for all long-acting and sustained-release opioid drug products. The FDA has since initiated efforts to develop a new standardized REMS for these opioid medications to ensure their safe use. In April 2011, FDA announced that it had finalized the elements of a class-wide REMS for these products. The central component of the opioid REMS program is an education program for prescribers and patients. Specifically, the REMS for these products must include a Medication Guide available for distribution to patients who are dispensed the drug, as well as a number of elements to assure safe use. These elements include training for prescribers who prescribe the drug; information provided to prescribers that prescribers can use to educate patients in the safe use, storage, and disposal of opioids; and information provided to prescribers of the existence of the REMS and the need to successfully complete the necessary training. Moreover, the REMS must include a timetable for submission of assessments that shall be no less frequent than 6 months, 12 months, and annually after the REMS is approved to assess the extent to which the elements to assure safe use are meeting the goals of the REMS and whether the goals or elements should be modified. The FDA expects that manufacturers of long-acting and extended-release opioids work together to provide educational materials as part of a class-wide single shared system to reduce the burden of the REMS on the healthcare system.

An extended-release formulation of *hydrocodone*, such as Zohydro, will be required to have a REMS that contains the elements of the recently-issued class-wide REMS for long-acting and sustained-release opioids. We intend to submit a REMS at the time of the NDA submission for Zohydro. The development of the REMS could cause significant delays in the approval process for Zohydro, and the educational requirements and requirements for a Medication Guide for patients could significantly impact our ability to commercialize Zohydro and dramatically reduce its market potential.

Our commercialization partner for Sumavel DosePro in the European Union and three other countries, Desitin Arzneimittel GmbH, or Desitin, may not successfully develop, obtain approval for or commercialize Sumavel DosePro in those territories, which may adversely affect our ability to commercialize Sumavel DosePro both inside and outside the United States.

In March 2008, we entered into a licensing and distribution agreement with Desitin pursuant to which we granted Desitin the exclusive right under our intellectual property rights related to Sumavel DosePro to develop, use, distribute, sell, offer for sale, and import Sumavel DosePro and any potential modified versions of Sumavel DosePro in the European Union, Norway, Switzerland and Turkey. In that regard, Desitin is not obligated under the agreement to pursue regulatory approval or commercialization of Sumavel DosePro in any of these countries except for Germany. Since we will depend on Desitin to develop, obtain regulatory approval for

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and, if regulatory approval is granted, commercialize Sumavel DosePro in these countries, we will have limited control over the success of Desitin s development, regulatory approval and commercialization efforts. Desitin submitted a Marketing Authorization Application for Sumavel DosePro to the Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM)) in Germany, the reference member state, through the Decentralized Procedure in October 2009, following completion of a European pivotal bioequivalence trial comparing needle-free Sumavel DosePro to a traditional needle-based autoinjector, Imigran-Inject, the European brand of Imitrex STATdose. In November 2010, Denmark became the first member of the European Union to approve marketing of Sumavel DosePro in that country. Subsequently, Sumavel DosePro has received marketing approval in Germany, Sweden, Norway and the United Kingdom.

Any additional clinical studies Desitin may be required to conduct as part of the regulatory approval process may not corroborate the results of the clinical studies we have conducted or may have adverse results or effects on our ability to maintain regulatory approvals in the United States or obtain them in other countries. In addition, although we believe that the U.S. market represents the largest commercial opportunity for Sumavel DosePro, Desitin may not develop Sumavel DosePro as fast or generate as large of a market as we would like or as the market may expect and Desitin may not seek to develop, obtain approval for or commercialize Sumavel DosePro in countries for which it has exclusive rights, other than in Germany, where Desitin is required to develop, seek approval for and commercialize Sumavel DosePro. Any failure by Desitin to successfully commercialize Sumavel DosePro or to successfully obtain applicable foreign regulatory approval for Sumavel DosePro would limit our opportunity to receive revenue from the territories licensed to Desitin. Furthermore, negative developments occurring in those territories controlled by Desitin could have a negative impact on physician and patient impressions of our product in the United States and elsewhere.

Our failure to successfully establish new partnerships with pharmaceutical companies or contract sales organizations to co-promote any additional product candidates that may receive regulatory approval may impair our ability to effectively market and sell such product candidates.

Major pharmaceutical companies usually employ groups of sales representatives numbering in the thousands to call on the large number of primary care physicians. In connection with the launch of Sumavel DosePro in January 2010 we built a sales and marketing organization to promote Sumavel DosePro in the United States, including a focused sales force of approximately 94 representatives primarily targeting neurologists and other prescribers of migraine medications, including headache clinics and headache specialists. In addition, in July 2009, we entered into an exclusive agreement with Astellas under which Sumavel DosePro is also being marketed by Astellas in the United States and promoted primarily to primary care physicians, OB/GYNs, emergency medicine physicians and urologists by approximately 400 Astellas sales representatives. In order to expand the market opportunity for any additional product candidates that receive regulatory approval into the broader primary care physician audiences, we will need to continue to expand our sales and marketing personnel and commercial infrastructure and/or establish partnerships with pharmaceutical companies or contract sales organizations to co-promote such product candidates, particularly if our co-promotion agreement with Astellas is amended, terminated or otherwise restructured. We currently, and on an ongoing basis will have to, compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain sales and marketing personnel. We also face competition in our search for collaborators and potential co-promoters. To the extent we rely on additional third parties to commercialize any product candidates that may receive regulatory approval, we are likely to receive less revenues than if we commercialized these products ourselves. Further, by entering into strategic partnerships or similar arrangements, we may rely in part on such third parties for financial and commercialization resources. Even if we are able to identify suitable partners to assist in the commercialization of our product candidates, they may fail to devote the resources necessary to realize the full commercial potential of our products. In addition, we may lack the financial and managerial resources to increase the size of our sales and marketing organization to adequately commercialize any product candidates that may be approved, and any increase in our sales force would result in an increase in our expenses, which could be significant before we generate revenues from any newly approved product candidate. If we are unable to expand our sales and marketing infrastructure or enter into a third-party arrangement, we would not be able to successfully commercialize any approved products. Even if we are able to expand our sales and marketing personnel or successfully establish partnership arrangements, such sales force and marketing teams may not be successful in commercializing our products, which would adversely affect our ability to generate revenue for such products, which will have a material adverse effect on our business, results of operations, financial condition and prospects.

Our failure to successfully acquire, develop and market additional product candidates or approved products would impair our ability to grow our business. In that regard, our DosePro delivery system cannot be used with drug formulation volumes greater than 0.5 mL, which will likely limit its use with drugs requiring larger formulation volumes. *

As part of our growth strategy we intend to seek to expand our product pipeline by exploring acquisition or in-licensing opportunities of proven drugs that can be paired with our DosePro needle-free drug delivery system. However, the current version of our DosePro drug delivery system cannot be used with drug formulation volumes greater than 0.5 mL. Many marketed and development-stage injectable products, including most biologics, have formulation volumes greater than 0.5 mL and would require reformulation, if possible, to accommodate the approved doses in smaller volumes that are compatible with DosePro. Any reformulation may increase the risk of failure during development, extend the development timelines, increase development costs and add complexity to the regulatory approval process and in some cases reformulation may not be possible. If we are not able to identify additional drug compounds that can be delivered via the current version of our DosePro technology, or if we are unable to successfully

develop higher dose versions of this technology, our ability to develop additional product candidates and grow our business would be adversely affected. We will also seek opportunities to out-license the DosePro technology to partners seeking to enhance, differentiate, or extend the life-cycle of their injectable products. If we are unable to secure partnerships with companies that have compounds that can be delivered via the current version of our DosePro technology, or if we are unable to successfully develop higher dose versions of this technology, we will not be able to generate revenues from out-licensing our DosePro technology.

We have initiated early stage design and development of a larger volume, second generation version of our DosePro technology to accommodate drug formulation volumes greater than 0.5 mL, which if successfully developed, would allow for a broader range of potential applications for our technology. However, the full development of such technology will require substantial investment and we may consider entering into a third-party collaboration in order to obtain third-party financing to help fully develop such technology. There is no guarantee that we or any potential future third-party collaborator will be able to successfully develop such a device technology, whether for financial or technical reasons or otherwise.

Furthermore, we intend to in-license, acquire, develop and/or market additional products and product candidates in the areas of pain and central nervous system, or CNS, disorders. For example, in July 2011, we entered into a development and license agreement with Durect Corporation for a proprietary, long-acting, injectable formulation of *risperidone* using Durect s SABER controlled-release formulation technology in combination with our DosePro technology. Durect will be responsible for non-clinical, formulation and chemistry, manufacturing and controls development responsibilities. As a result, we will be dependent on Durect s successful completion of its responsibilities for Relday. In addition, because our internal research and development capabilities are limited, we may be dependent upon other pharmaceutical and biotechnology companies, academic scientists and other researchers to sell or license products or technology to us. The success of this strategy depends partly upon our ability to identify and select promising pharmaceutical product candidates and products, negotiate licensing or acquisition agreements with their current owners and finance these arrangements.

The process of proposing, negotiating and implementing a license or acquisition of a product candidate or approved product is lengthy and complex. Other companies, including some with substantially greater financial, marketing, sales and other resources, may compete with us for the license or acquisition of product candidates and approved products. We have limited resources to identify and execute the acquisition or in-licensing of third-party products, businesses and technologies and integrate them into our current infrastructure. Moreover, we may devote resources to potential acquisitions or licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts. We may not be able to acquire the rights to additional product candidates, or license the rights to our DosePro technology, on terms that we find acceptable, or at all.

Further, any product candidate that we acquire may require additional development efforts prior to commercial sale, including pre-clinical or clinical testing and approval by the FDA and applicable foreign regulatory authorities. We expect to initiate clinical testing for Relday in patients in schizophrenia in early 2012. We may not be able to obtain necessary approvals to initiate such clinical testing in a timely manner or at all. In addition, all product candidates are prone to risks of failure typical of pharmaceutical product development, including the possibility that a product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities. In addition, we cannot provide assurance that any products that we develop or approved products that we acquire will be manufactured or sold profitably or achieve market acceptance.

If we are unable to license or acquire additional product candidates or approved products and successfully develop and commercialize them, or if we are otherwise unable to pair our DosePro delivery system with other drugs or out-license the DosePro technology to others, it would likely have a material adverse effect on our business, results of operations, financial condition and prospects.

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

We increased our full-time employees from 48 as of October 31, 2009 to 161 as of September 30, 2011. In addition, we have expanded our sales force in the United States from approximately 80 sales representatives to approximately 94 sales representatives at the end of the third quarter of 2011 and m