AVANIR PHARMACEUTICALS, INC.
Form 10-Q
May 09, 2012
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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.**
For the quarterly period ended March 31, 2012

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 No. 1-15803

AVANIR PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**33-0314804**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
20 Enterprise Suite 200, Aliso Viejo, California	**92656**
(Address of principal executive offices)	**(Zip Code)**

(949) 389-6700

(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 and Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES x 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. (Check one):

Large accelerated filer ¨	Accelerated filer x
Non-accelerated filer ¨ (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 ¨ NO x

As of May 3, 2012, the registrant had 135,684,912 shares of common stock issued and outstanding.

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PART I. FINANCIAL INFORMATION

Item 1. FINANCIAL STATEMENTS

AVANIR PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

	March 31, 2012 (unaudited)	September 30, 2011 (audited)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 66,702,363	$ 79,542,564
Trade receivables, net	3,792,820	2,011,165
Royalty receivables		389,902
Inventories, net	342,344	252,244
Prepaid expenses	1,516,975	1,445,256
Other current assets	513,160	130,590
Current portion of restricted investments in marketable securities	1,003,923	618,314
Total current assets	73,871,585	84,390,035
Restricted investments in marketable securities, net of current portion	1,302,136	1,634,625
Property and equipment, net	2,213,968	1,695,329
Non-current inventories, net	1,030,327	792,933
Other assets	905,718	1,136,072
TOTAL ASSETS	$ 79,323,734	$ 89,648,994
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 5,170,432	$ 3,260,588
Accrued expenses and other liabilities	4,821,746	2,936,973
Accrued compensation and payroll taxes	4,767,761	4,251,866
Deferred product revenues, net		1,652,788
Current portion of deferred royalty revenues	2,021,189	2,087,226
Total current liabilities	16,781,128	14,189,441
Accrued expenses and other liabilities, net of current portion		68,487
Deferred royalty revenues, net of current portion	3,180,810	4,051,402
Total liabilities	19,961,938	18,309,330
Commitments and contingencies		
Stockholders equity:		
Preferred stock $0.0001 par value, 10,000,000 shares authorized, no shares issued or outstanding as of March 31, 2012 and September 30, 2011		
Common stock $0.0001 par value, 200,000,000 shares authorized; 135,684,856 and 125,443,788 shares issued and outstanding as of March 31, 2012 and September 30, 2011, respectively	13,568	12,544
Additional paid-in capital	457,652,743	436,643,319
Accumulated deficit	(398,304,515)	(365,316,199)
Total stockholders equity	59,361,796	71,339,664

TOTAL LIABILITIES AND STOCKHOLDERS EQUITY	$ 79,323,734	$ 89,648,994

The accompanying notes to condensed consolidated financial statements are an integral part of this statement.

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AVANIR PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)

	Three Months Ended March 31,		Six Months Ended March 31,	
	2012	2011	2012	2011
REVENUES AND COSTS FROM PRODUCT SALES				
Gross product sales	$ 11,185,298	$ 504,966	$ 17,470,929	$ 504,966
Less: discounts and allowances	2,043,425	42,952	2,840,293	42,952
Net product sales	9,141,873	462,014	14,630,636	462,014
Cost of product sales	534,345	114,327	844,148	114,327
Product gross margin	8,607,528	347,687	13,786,488	347,687
OTHER REVENUES				
Revenues from royalties	898,515	974,489	2,574,635	2,792,976
Total other revenues	898,515	974,489	2,574,635	2,792,976
Total gross margin	9,506,043	1,322,176	16,361,123	3,140,663
OPERATING EXPENSES				
Research and development	6,395,155	2,519,390	10,139,670	6,363,179
Selling, general and administrative	20,161,004	13,278,773	39,236,023	23,372,211
Total operating expenses	26,556,159	15,798,163	49,375,693	29,735,390
Loss from operations	(17,050,116)	(14,475,987)	(33,014,570)	(26,594,727)
OTHER INCOME (EXPENSE)				
Interest income	7,882	10,051	22,173	17,183
Other, net	75	348	4,081	37
Net loss and comprehensive loss	$ (17,042,159)	$ (14,465,588)	$ (32,988,316)	$ (26,577,507)
Basic and diluted net loss per share	$ (0.13)	$ (0.12)	$ (0.25)	$ (0.23)
Basic and diluted weighted average number of common shares outstanding	133,463,300	121,635,339	130,683,671	114,943,284

The accompanying notes to condensed consolidated financial statements are an integral part of this statement.

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AVANIR PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)

	Six Months Ended March 31, 2012	2011
OPERATING ACTIVITIES:		
Net loss	$ (32,988,316)	$ (26,577,507)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	336,105	177,229
Share-based compensation expense	2,396,287	1,784,816
Changes in operating assets and liabilities:		
Trade receivables, net	(1,781,655)	(3,215,758)
Royalty receivables	389,902	29,471
Inventories, net	(327,494)	(48,348)
Prepaid expenses and other assets	(223,935)	(1,513,404)
Accounts payable	1,909,844	(671,544)
Accrued expenses and other liabilities	1,751,036	346,361
Accrued compensation and payroll taxes	515,895	188,704
Deferred product revenues, net	(1,652,788)	2,647,091
Deferred royalty revenues	(936,629)	(1,114,735)
Net cash used in operating activities	(30,611,748)	(27,967,624)
INVESTING ACTIVITIES:		
Purchase of property and equipment	(789,494)	(339,285)
Purchase of investments in securities	(53,120)	(1,500,175)
Net cash used in investing activities	(842,614)	(1,839,460)
FINANCING ACTIVITIES:		
Proceeds from issuances of common stock, net of commissions and offering costs	10,062,996	87,739,859
Collection of stock subscriptions receivable		580,910
Proceeds from exercise of stock options and warrants	8,551,165	5,767,558
Shares surrendered to pay for tax withholding		(5,665)
Net cash provided by financing activities	18,614,161	94,082,662
Net (decrease) increase in cash and cash equivalents	(12,840,201)	64,275,578
Cash and cash equivalents at beginning of period	79,542,564	38,771,469
Cash and cash equivalents at end of period	$ 66,702,363	$ 103,047,047
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:		
Income taxes paid	$ 3,200	$ 3,200
SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Purchase of property and equipment in accounts payable and accrued expenses and other liabilities	$ 65,250	$ 193,290

The accompanying notes to condensed consolidated financial statements are an integral part of this statement.

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AVANIR PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

1. BASIS OF PRESENTATION

The accompanying unaudited condensed consolidated financial statements of Avanir Pharmaceuticals, Inc. (Avanir , we , or the Company) have been prepared in accordance with the rules and regulations of the Securities and Exchange Commission (SEC) for interim reporting including the instructions to Form 10-Q. These condensed consolidated financial statements do not include all disclosures for annual audited financial statements required by accounting principles generally accepted in the United States of America (U.S. GAAP) and should be read in conjunction with the Company s audited consolidated financial statements and related notes included in the Company s Annual Report on Form 10-K for the year ended September 30, 2011. The Company believes these condensed consolidated financial statements reflect all adjustments (consisting only of normal, recurring adjustments) that are necessary for a fair presentation of the financial position and results of operations for the periods presented. Results of operations for the interim periods presented are not necessarily indicative of results to be expected for the year.

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts and the disclosures of commitments and contingencies in the financial statements and accompanying notes. Actual results could differ from those estimates.

Certain amounts in the accompanying condensed consolidated financial statements have been reclassified to conform to the current period presentation.

2. DESCRIPTION OF BUSINESS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Description of Business

Avanir is a pharmaceutical company focused on acquiring, developing and commercializing novel therapeutic products for the treatment of central nervous system disorders. In October 2010, the U.S. Food and Drug Administration (FDA) approved NUEDEXTA® (referred to as AVP-923 during clinical development), a unique proprietary combination of dextromethorphan (DM) and low-dose quinidine, for the treatment of pseudobulbar affect (PBA). The Company commenced promotion of NUEDEXTA in the United States in February 2011 and is currently pursuing the approval of NUEDEXTA in Europe.

The Company is also studying AVP-923 for use in different types of neuropathic pain. The Company has filed an Investigational New Drug application (IND) with the FDA and has initiated a large Phase II clinical trial of AVP-923 for the treatment of central neuropathic pain in patients with multiple sclerosis. In addition, the Company is pursuing studies to assess the efficacy, safety and tolerability of AVP-923 for treatment of agitation in patients with Alzheimer s disease.

AVP-923 has also completed a Phase III trial for the treatment of patients with diabetic peripheral neuropathic pain (DPN pain) with positive results. Additional phase III trials would need to be completed for approval of this indication.

On February 29, 2012, the Company entered into a license agreement with Concert Pharmaceuticals, Inc. (Concert) pursuant to which the Company licensed from Concert exclusive, worldwide rights to develop and commercialize Concert s deuterium-modified dextromethorphan (d-DM) for the potential treatment of neurologic and psychiatric disorders, as well as certain rights to other deuterium-modified dextromethorphan compounds. The Company believes that d-DM compounds may provide therapeutically effective levels of DM, potentially without the need for an enzyme inhibitor such as quinidine. The Company intends to explore the utility of d-DM in neurological and psychiatric disorders where dual N-Methyl-D-aspartic acid, or NMDA, antagonists and sigma-1 agonists may be beneficial.

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In addition to the Company s focus on products for the central nervous system, the Company also has partnered programs in other therapeutic areas which may generate future income. The Company s first commercialized product, docosanol 10% cream, (sold in the United States and Canada as Abreva® by its marketing partner GlaxoSmithKline Consumer Healthcare) is the only over-the-counter treatment for cold sores that has been approved by the FDA. In 2008, the Company licensed all its monoclonal antibodies and remains eligible to receive milestone payments and royalties related to the sale of these assets.

The Company s operations are subject to certain risks and uncertainties frequently encountered by companies in the early stages of operations, particularly in the evolving market for small biotech and specialty pharmaceutical companies. Such risks and uncertainties include, but are not limited to, the occurrence of adverse safety events with NUEDEXTA; that NUEDEXTA may not gain broader acceptance by the medical field or that the indicated use may not be clearly understood; the Company s dependence on third parties for manufacturing and distribution of NUEDEXTA; that the Company may not adequately build or maintain the necessary sales, marketing, supply chain management and reimbursement capabilities on its own or enter into arrangements with third parties to perform these functions in a timely manner or on acceptable terms; the ability to successfully defend our intellectual property rights relating to NUEDEXTA; timing and uncertainty of achieving milestones in clinical trials; and obtaining approvals by the FDA, European Medicines Agency (EMA) and regulatory agencies in other countries. The Company s ability to generate revenues in the future may depend on market acceptance of NUEDEXTA for the treatment of PBA and the timing and success of reaching clinical development milestones and obtaining regulatory approvals for other formulations for NUEDEXTA (referred to as AVP-923). The Company s operating expenses depend substantially on the level of expenditures for the ongoing marketing of NUEDEXTA, clinical development activities for NUEDEXTA as well as AVP-923 and the rate of progress being made on such activities.

Avanir was incorporated in California in August 1988 and was reincorporated in Delaware in March 2009.

Significant Accounting Policies

The following represents an update for the six months ended March 31, 2012 to the significant accounting policies described in the Company s Annual Report on Form 10-K for the fiscal year ended September 30, 2011.

Concentration of credit risk and sources of supply

As of March 31, 2012, $13.3 million of the Company s cash and cash equivalents were maintained in three separate money market mutual funds, and approximately $53.4 million of the Company s cash and cash equivalents were maintained at three major financial institutions in the United States. At times, deposits held with financial institutions exceed the amount of insurance provided by the Federal Deposit Insurance Corporation (FDIC), which provides basic deposit coverage with limits up to $250,000 per owner. In addition to the basic insurance deposit coverage, the FDIC is providing temporary unlimited coverage for noninterest-bearing transaction accounts from December 31, 2010 through December 31, 2012. At March 31, 2012, such uninsured deposits totaled approximately $61.3 million of the $69.0 million of total cash and cash equivalents and restricted investments. Generally, these deposits may be redeemed upon demand and, therefore, are believed to bear minimal risk.

Financial instruments that potentially subject the Company to concentrations of credit risk consist of cash and cash equivalents and trade receivables. The Company s cash and cash equivalents are placed in various money market mutual funds and at financial institutions of high credit standing. The Company performs ongoing credit evaluations of customers financial condition and would limit the amount of credit extended if necessary; however, the Company has historically required no collateral.

The Company currently has sole suppliers for the active pharmaceutical ingredients (APIs) for NUEDEXTA and a sole manufacturer for the finished form of NUEDEXTA. In addition, these materials are custom and available from only a limited number of sources. Any material disruption in manufacturing could cause a delay in shipments and possible loss of revenue. If the Company is required to change manufacturers, the Company may experience delays associated with finding an alternative manufacturer that is properly qualified to produce NUEDEXTA in accordance with FDA requirements and the Company s specifications.

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Fair value of financial instruments

At March 31, 2012 and September 30, 2011, the Company s financial instruments include cash and cash equivalents, trade receivables, royalty receivables, restricted investments in marketable securities, accounts payable, accrued expenses and other liabilities, and accrued compensation and payroll taxes. The carrying amount of cash and cash equivalents, trade receivables, royalty receivables, accounts payable, accrued expenses and other liabilities, and accrued compensation and payroll taxes approximates fair value due to the short-term maturities of these instruments. The Company s short-term and long-term restricted investments in marketable securities are carried at amortized cost which approximates fair value.

Revenue recognition

The Company has historically generated revenues from product sales, collaborative research and development arrangements, and other commercial arrangements such as royalties, the sale of royalty rights and sales of technology rights. Payments received under such arrangements may include non-refundable fees at the inception of the arrangements, milestone payments for specific achievements designated in the agreements, royalties on sales of products resulting from collaborative arrangements, and payments for the sale of rights to future royalties.

The Company recognizes revenue when all of the following criteria are met: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the Company s price to the buyer is fixed or determinable; and (4) collectability is reasonably assured. In addition, certain product sales are subject to rights of return. For products sold where the buyer has the right to return the product, the Company recognizes revenue at the time of sale only if (1) the Company s price to the buyer is substantially fixed or determinable at the date of sale, (2) the buyer has paid the Company, or is obligated to pay the Company and the obligation is not contingent on resale of the product, (3) the buyer s obligation to the Company would not be changed in the event of theft or physical destruction or damage of the product, (4) the buyer acquiring the product for resale has economic substance apart from that provided by the seller, (5) the Company does not have significant obligations for future performance to directly bring about resale of the product by the buyer, and (6) the amount of future returns can be reasonably estimated. The Company recognizes such product revenues when either it has met all the above criteria, including the ability to reasonably estimate future returns, or when it can reasonably estimate that the return privilege has substantially expired, whichever occurs first.

Product Sales NUEDEXTA. NUEDEXTA is sold primarily to third-party wholesalers that, in turn, sell this product to retail pharmacies, hospitals, and other dispensing organizations. The Company has entered into agreements with wholesale customers, certain medical institutions and third-party payers throughout the United States. These agreements frequently contain commercial terms, which may include favorable product pricing and discounts and rebates payable upon dispensing the product to patients. Additionally, these agreements customarily provide the customer with rights to return the product, subject to the terms of each contract. Consistent with pharmaceutical industry practice, wholesale customers can return purchased product during an 18-month period that begins six months prior to the product s expiration date and ends 12 months after the expiration date.

The Company s net product sales represent gross product sales less allowances for customer credits, including estimated discounts, rebates, chargebacks and co-pay assistance. These allowances provided by the Company to a customer are presumed to be a reduction of the selling prices of the Company s products or services and, therefore, are characterized as a reduction of revenue when recognized in the Company s condensed consolidated statement of operations. Allowances for discounts, rebates, chargebacks and co-pay assistance are estimated based on contractual terms with customers and sell-through data purchased from third parties. Product shipping and handling costs are included in cost of product sales.

Prior to the second quarter of fiscal 2012, the Company was unable to reasonably estimate future returns due to the lack of sufficient historical return data for NUEDEXTA. Accordingly, the Company invoiced the wholesaler, recorded deferred revenue at gross invoice sales price less estimated cash discounts and distribution fees, and classified the inventory shipped as finished goods. The Company deferred recognition of revenue and the related cost of product sales on shipments of NUEDEXTA until the right of return no longer existed, i.e. when the Company received evidence that the products had been dispensed to patients. The Company estimated patient prescriptions dispensed using an analysis of third-party information.

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Change in Accounting Estimate

Based on historical data gathered from January 2011 through the end of the second quarter of fiscal 2012, the Company has developed a methodology to reasonably estimate product returns and provide a basis for recognizing revenue on sales to customers at the time of product shipment. Historically, NUEDEXTA product returns have been immaterial. The Company analyzed many factors including the sell-down of launch inventory, actual experience of returned NUEDEXTA product, taking into account expiration dating at the time of shipment, levels of inventory in the wholesaler channel in relation to prescription units dispensed, and retail pharmacy reorder activity. Accordingly, beginning in the quarter ended March 31, 2012, the Company began to recognize revenue upon shipment of NUEDEXTA to its wholesalers and other customers to provide a more accurate estimate of product sales activity.

As a result of recognizing revenue upon shipment of NUEDEXTA to its wholesalers and other customers, the Company recognized as a one-time adjustment to net product revenue of approximately $1.9 million in the second quarter of fiscal 2012, which was recorded as deferred revenue at December 31, 2011. This increase in net product revenue, resulted in a reduction to net loss for the three and six months ended March 31, 2012, of approximately $1.7 million, or a reduction to net loss per share of $0.01 for each period.

Product Sales Active Pharmaceutical Ingredient docosanol (docosanol). Revenue from sales of the Company s docosanol is recorded when title and risk of loss have passed to the buyer, provided the criteria for revenue recognition has been met. The Company sells the docosanol to various licensees upon receipt of a written order for the materials. Shipments generally occur fewer than three times a year. The Company s contracts for sales of the docosanol include buyer acceptance provisions that give the Company s buyers the right of replacement if the delivered product does not meet specified criteria. That right requires that they give the Company notice within 30 days after receipt of the product. The Company has the option to refund or replace any such defective materials; however, it has historically demonstrated that the materials shipped from the same pre-inspected lot have consistently met the specified criteria and no buyer has rejected any of the Company s shipments from the same pre-inspected lot to date. Therefore, the Company recognizes revenue at the time of delivery without providing any returns reserve.

Multiple Element Arrangements. The Company has, in the past, entered into arrangements whereby it delivers to the customer multiple elements including technology and/or services. Such arrangements have included some combination of the following: antibody generation services; licensed rights to technology, patented products, compounds, data and other intellectual property; and research and development services. At the inception of the arrangement, the Company analyzes its multiple element arrangements to determine whether the elements can be separated. If a product or service is not separable, the combined deliverables will be accounted for as a single unit of accounting.

A delivered element can be separated from other elements when it meets both of the following criteria: (1) the delivered item has value to the customer on a standalone basis; and (2) if the arrangement includes a general right of return relative to the delivered item, delivery or performance of the undelivered item is considered probable and substantially in the Company s control. If an element can be separated, the Company allocates amounts based upon the selling price of each element. The Company determines the selling price of a separate deliverable using the price it charges other customers when it sells that product or service separately; however, if the Company does not sell the product or service separately, it uses third-party evidence of selling price of a similar product or service to a similarly situated customer. The Company considers licensed rights or technology to have standalone value to its customers if it or others have sold such rights or technology separately or its customers can sell such rights or technology separately without the need for the Company s continuing involvement. The Company has not entered into any multiple element arrangements which required the Company to estimate selling prices during the first half of fiscal 2012 or during fiscal 2011.

License Arrangements. License arrangements may consist of non-refundable upfront license fees, data transfer fees, research reimbursement payments, exclusive licensed rights to patented or patent pending compounds, technology access fees, and various performance or sales milestones. These arrangements are often multiple element arrangements.

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Non-refundable, up-front fees that are not contingent on any future performance by the Company, and require no consequential continuing involvement on its part, are recognized as revenue when the license term commences and the licensed data, technology and/or compound is delivered. Such deliverables may include physical quantities of compounds, design of the compounds and structure-activity relationships, the conceptual framework and mechanism of action, and rights to the patents or patents pending for such compounds. The Company defers recognition of non-refundable upfront fees if it has continuing performance obligations without which the technology, right, product or service conveyed in conjunction with the non-refundable fee has no utility to the licensee that is separate and independent of the Company s performance under the other elements of the arrangement. In addition, if the Company has required continuing involvement through research and development services that are related to its proprietary know-how and expertise of the delivered technology, or can only be performed by the Company, then such up-front fees are deferred and recognized over the period of continuing involvement.

Payments related to substantive, performance-based milestones in a research and development arrangement are recognized as revenues upon the achievement of the milestones as specified in the underlying agreements when they represent the culmination of the earnings process.

Royalty Arrangements. The Company recognizes royalty revenues from licensed products when earned in accordance with the terms of the license agreements. Net sales amounts generally required to be used for calculating royalties include deductions for returned product, pricing allowances, cash discounts, freight and warehousing. These arrangements are often multiple element arrangements.

Certain royalty arrangements provide that royalties are earned only if a sales threshold is exceeded. Under these types of arrangements, the threshold is typically based on annual sales. For royalty revenue generated from the license agreement with GlaxoSmithKline (GSK), the Company recognizes royalty revenue in the period in which the threshold is exceeded. During the six months ended March 31, 2012 and 2011, sales in excess of the threshold resulted in recognized royalty revenues from GSK of approximately $1.2 million in each period. For royalty revenue generated from the license agreement with Azur Pharma (Azur), the Company recognizes revenue when it has determined that the threshold has been exceeded. During the six months ended March 31, 2012 and 2011, sales in excess of the threshold resulted in recognized royalty revenues from Azur of approximately $492,000 and $527,000, respectively.

When the Company sells its rights to future royalties under license agreements and also maintains continuing involvement in earning such royalties, it defers recognition of any upfront payments and recognizes them as revenues over the life of the license agreement. The Company recognizes revenues for the sale of an undivided interest of its Abreva® license agreement to Drug Royalty USA under the units-of-revenue method. Under this method, the amount of deferred revenues to be recognized in each period is calculated by multiplying the ratio of the royalty payments due to Drug Royalty USA by GSK for the period to the total remaining royalties the Company expects GSK will pay Drug Royalty USA over the remaining term of the agreement by the unamortized deferred revenues.

Cost of product sales

Cost of product sales includes third-party royalties and direct and indirect costs to manufacture product sold, including packaging, storage, shipping and handling costs and the write-off of obsolete inventory.

Recognition of expenses in outsourced contracts

Pursuant to management s assessment of the services that have been performed on clinical trials and other contracts, the Company recognizes expense as the services are provided. Such management assessments include, but are not limited to: (1) an evaluation by the project manager of the work that has been completed during the period, (2) measurement of progress prepared internally and/or provided by the third-party service provider, (3) analyses of data that justify the progress, and (4) management s judgment. Several of the Company s contracts extend across multiple reporting periods.

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Research and development expenses

Research and development expenses consist of expenses incurred in performing research and development activities including salaries and benefits, facilities and other overhead expenses, clinical trials, contract services and outsource contracts. Research and development expenses are charged to operations as they are incurred. Up-front payments to collaborators made in exchange for the avoidance of potential future milestone and royalty payments on licensed technology are also charged to research and development expense when the drug is still in the development stage, has not been approved by the FDA for commercialization and currently has no alternative uses.

The Company assesses its obligations to make milestone payments that may become due under licensed or acquired technology to determine whether the payments should be expensed or capitalized. The Company charges milestone payments to research and development expense when:

The technology is in the early stage of development and has no alternative uses;

There is substantial uncertainty regarding the future success of the technology or product;

There will be difficulty in completing the remaining development; and

There is substantial cost to complete the work.

Acquired contractual rights. Payments to acquire contractual rights to a licensed technology or drug candidate are expensed as incurred when there is uncertainty in receiving future economic benefits from the acquired contractual rights. The Company considers the future economic benefits from the acquired contractual rights to a drug candidate to be uncertain until such drug candidate is approved by the FDA or when other significant risk factors are abated.

Share-based compensation

The Company grants options, restricted stock units and restricted stock awards to purchase its common stock to employees, directors and consultants under its equity incentive plans. The benefits provided under these plans are share-based payments that the Company accounts for using the fair value method.

The fair value of each option award is estimated on the date of grant using a Black-Scholes-Merton option pricing model (Black-Scholes model) that uses assumptions regarding a number of complex and subjective variables. These variables include, but are not limited to, the Company s expected stock price volatility, actual and projected employee stock option exercise behaviors, risk-free interest rate and expected dividends. Expected volatilities are based on historical volatility of the Company s common stock and other factors. The expected terms of options granted are based on analyses of historical employee termination rates and option exercises. The expected risk-free interest rate is based on the U.S. Treasury yield in effect at the time of the grant. Since the Company does not expect to pay dividends on its common stock in the foreseeable future, the Company estimated the dividend yield to be 0%.

Share-based compensation expense recognized during a period is based on the value of the portion of share-based payment awards that is ultimately expected to vest and is amortized under the straight-line attribution method. As share-based compensation expense recognized in the consolidated statements of operations for periods in fiscal 2012 and 2011 is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures. The fair value method requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. The Company estimates forfeitures based on its historical experience.

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Total compensation expense related to all of the Company s share-based awards for the three and six month periods ended March 31, 2012 and 2011, was comprised of the following:

	For the three months ended March 31,		For the six months ended March 31,	
	2012	2011	2012	2011
Share-based compensation classified as:				
Selling, general and administrative expense	$ 967,117	$ 798,723	$ 1,888,352	$ 1,485,633
Research and development expense	267,133	152,485	507,935	299,183
Total	$ 1,234,250	$ 951,208	$ 2,396,287	$ 1,784,816

	For the three months ended March 31,		For the six months ended March 31,	
	2012	2011	2012	2011
Share-based compensation expense from:				
Stock options	$ 930,430	$ 622,724	$ 1,740,965	$ 1,114,077
Restricted stock units	303,820	328,484	655,322	670,739
Total	$ 1,234,250	$ 951,208	$ 2,396,287	$ 1,784,816

Since the Company provided a full valuation allowance related to its net deferred tax assets as of March 31, 2012, no excess tax benefits for the tax deductions related to share-based awards were recognized in the condensed consolidated statements of operations. Additionally, no incremental tax benefits were recognized from stock options exercised in the six month periods ended March 31, 2012 and 2011 that would have resulted in a reclassification to reduce net cash used in operating activities with an offsetting increase in net cash provided by financing activities (See Note 10, Employee Equity Incentive Plans).

Income taxes

The Company accounts for income taxes and the related accounts under the liability method. Deferred tax assets and liabilities are determined based on the differences between the condensed consolidated financial statement carrying amounts and the income tax bases of assets and liabilities. A valuation allowance is applied against any net deferred tax asset if, based on available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

The Company recognizes any uncertain income tax positions on the income tax returns at the largest amount that is more-likely-than-not to be sustained upon audit by the relevant taxing authority. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained.

At March 31, 2012, the total unrecognized tax benefit resulting in a decrease in deferred tax assets and corresponding decrease in the valuation allowance is approximately $3.3 million. There are no unrecognized tax benefits included in the condensed consolidated balance sheet that would, if recognized, affect the effective tax rate.

The Company s policy is to recognize interest and/or penalties related to income tax matters in income tax expense. The Company had $0 accrued for interest and penalties on the Company s condensed consolidated balance sheets at March 31, 2012 and September 30, 2011.

The Company is subject to taxation in the U.S. and various state jurisdictions. The Company s tax years for 1994 and forward are subject to examination by the U.S. and California tax authorities due to the carryforward of unutilized net operating losses and research and development credits.

The Company does not foresee material changes to its gross uncertain income tax liability within the next twelve months.

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Recent Authoritative Accounting Guidance

Proposed Amendments to Current Accounting Standards. The Financial Accounting Standard Board (FASB) is currently working on amendments to existing accounting standards governing a number of areas including, but not limited to, revenue recognition and lease accounting.

In June 2010, the FASB issued an exposure draft, *Revenue from Contracts with Customers*, which would supersede most of the existing guidance on revenue recognition in Accounting Standards Codification (ASC) Topic 605, *Revenue Recognition*. In November 2011, the FASB re-exposed this draft. As the standard-setting process is still ongoing, the Company is unable to determine the impact this proposed change in accounting will have in the Company s consolidated financial statements at this time.

In August 2010, the FASB issued an exposure draft, *Leases*, which would result in significant changes to the accounting requirements for both lessees and lessors in ASC Topic 840, *Leases*. In July 2011, the FASB announced its intention to re-expose the draft which is currently scheduled for the second half of 2012. As the standard-setting process is still ongoing, the Company is unable to determine the impact this proposed change in accounting will have in the Company s consolidated financial statements at this time.

Fair Value Measurement. In May 2011, the FASB issued Accounting Standards Update No. 2011-04, *Fair Value Measurement (Topic 820): Amendment to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs* (ASU No. 2011-04). ASU No. 2011-04 amends the wording used to describe many of the requirements in U.S. GAAP for measuring fair value and disclosing information about fair value measurements. The amendments in this update achieve the objective of developing common fair value measurement and disclosure requirements, as well as improving consistency and understandability. Some of the requirements clarify the FASB s intent about the application of existing fair value measurement requirements while other amendments change a particular principle or requirement for measuring fair value or for disclosing information about fair value measurements. The amendments in this ASU are effective prospectively for interim and annual periods beginning after December 15, 2011, with no early adoption permitted. The Company adopted this guidance effective January 1, 2012. The adoption of this guidance did not have a material impact on the Company s consolidated financial position, results of operations and cash flows.

3. FAIR VALUE MEASUREMENTS

The Company measures the fair value of certain of its financial assets on a recurring basis. A fair value hierarchy is used to rank the quality and reliability of the information used to determine fair values. Financial assets and liabilities carried at fair value will be classified and disclosed in one of the following three categories:

Level 1-Quoted prices (unadjusted) in active markets for identical assets and liabilities.

Level 2-Inputs other than Level 1 that are observable, either directly or indirectly, such as unadjusted quoted prices for similar assets and liabilities, unadjusted quoted prices in the markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3-Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

As of March 31, 2012 and September 30, 2011, the Company s cash equivalents held in money market mutual funds of approximately $13.3 million and $38.4 million, respectively, are all valued using quoted prices generated by market transactions involving identical assets, or Level 1, as defined by the fair value hierarchy noted above.

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4. RESTRICTED INVESTMENTS IN MARKETABLE SECURITIES

Restricted investments in marketable securities at March 31, 2012 and September 30, 2011 consist of certificates of deposit, which are classified as held-to-maturity. At March 31, 2012 and September 30, 2011, the fair value of these investments approximated their cost basis.

At March 31, 2012 and September 30, 2011, restricted investments in marketable securities totaling approximately $1.3 million consist of two certificates of deposit and are related to irrevocable standby letters of credit connected to fleet rentals and an office lease with an expiration date in 2016, and are classified as non-current assets. These certificates of deposit automatically renew annually.

Restricted investments in marketable securities also consist of two certificates of deposit totaling approximately $1.0 million and are related to the Company s corporate credit card agreement and an irrevocable standby letter of credit connected to the short-term portion of an office lease with an expiration date in 2013, and are classified as current assets. The certificate of deposit related to the Company s credit card agreement automatically renews every three months and the certificate of deposit related to the office lease renews automatically every 30 days.

5. INVENTORIES

Inventories are comprised of NUEDEXTA product and the active pharmaceutical ingredients of NUEDEXTA, dextromethorphan and quinidine, as well as the active pharmaceutical ingredient docosanol.

The composition of inventories as of March 31, 2012 and September 30, 2011 is as follows:

	March 31, 2012	September 30, 2011 (audited)
Raw materials	$ 1,069,935	$ 834,049
Work in progress	22,295	32,328
Finished goods	280,441	178,800
Total inventory, net	1,372,671	1,045,177
Less: current portion	(342,344)	(252,244)
Non-current portion	$ 1,030,327	$ 792,933

The amount classified as non-current inventories is comprised of the raw material components for NUEDEXTA, dextromethorphan and quinidine, which will be used in the manufacture of NUEDEXTA capsules in the future. As of March 31, 2012 and September 30, 2011, raw materials represent gross raw materials of approximately $1.8 million and $1.5 million, respectively, offset by previously recorded permanent inventory write-downs of approximately $695,000 as of March 31, 2012 and September 30, 2011.

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6. ACCRUED EXPENSES AND OTHER LIABILITIES

Accrued expenses and other liabilities at March 31, 2012 and September 30, 2011 are as follows:

	March 31, 2012	September 30, 2011 (audited)
Accrued royalties, rebates, chargebacks, and distribution fees	$ 1,469,480	$ 595,595
Accrued research and development expenses	856,304	901,252
Accrued selling, general and administrative expenses	1,883,408	978,605
Other liabilities	421,395	195,739
Lease restructuring liability (1)	191,159	334,269
Total accrued expenses and other liabilities	4,821,746	3,005,460
Less: Current portion	(4,821,746)	(2,936,973)
Non-current total accrued expenses and other liabilities	$	$ 68,487

(1) In fiscal 2006, the Company relocated all operations other than research and development from San Diego, California to Aliso Viejo, California. In fiscal 2007, the Company subleased a total of approximately 49,000 square feet of laboratory and office space in San Diego and relocated remaining personnel and clinical trial support functions to the Company s offices in Aliso Viejo, California. Restructuring expenses included recognition of the estimated loss due to the exit of the Company s leases of approximately $2.1 million. No further costs were incurred related to these restructuring events in fiscal 2008. In April 2009, the Company entered into a sublease for office space in San Diego, California. Sublease rental payments commenced in September 2009 pursuant to this sublease.

The following table presents the restructuring activities in fiscal 2012:

	Balance at September 30, 2011 (audited)	Payments/ Reductions	Balance at March 31, 2012
Accrued Restructuring			
Total lease restructuring liability	$ 334,269	$ (143,110)	$ 191,159
Less current portion	(265,782)		(191,159)
Non-current portion	$ 68,487		$

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7. NET DEFERRED REVENUES

The following table sets forth as of March 31, 2012 the deferred royalty revenue balances for the Company s sale of future Abreva® royalty rights to Drug Royalty USA and NUEDEXTA product shipments:

	NUEDEXTA Product Shipments, Net	Drug Royalty USA Agreement	Total
Net deferred revenues as of October 1, 2011	$ 1,652,788	$ 6,138,628	$ 7,791,416
Changes during the period:			
Shipments, net	5,968,371		5,968,371
Recognized as revenues during period	(5,766,315)	(936,629)	(6,702,944)
Recognized as a result of a change in accounting estimate (1)	(1,854,844)		(1,854,844)
Net deferred revenues as of March 31, 2012	$	$ 5,201,999	$ 5,201,999
Classified and reported as:			
Current portion of deferred revenues	$	$ 2,021,189	$ 2,021,189
Deferred revenues, net of current portion		3,180,810	3,180,810
Total deferred revenues	$	$ 5,201,999	$ 5,201,999

(1) The amount ultimately recognized as net product sales was approximately $1.7 million due to other discounts and allowances recognized, including, but not limited to, rebates, chargebacks and co-pay assistance totaling approximately $191,000.

NUEDEXTA Product The amount of deferred revenue from NUEDEXTA product shipments is shown net of estimated prompt-pay discounts and wholesaler fees based on wholesaler purchases. The amount that ultimately will be recognized as net product sales in the Company s condensed consolidated financial statements may be different due to other discounts and allowances, including, but not limited to, wholesaler fees based on wholesaler shipments, rebates, chargebacks and co-pay assistance. See Note 2, Description of Business and Summary of Significant Accounting Policies Revenue recognition Product Sales NUEDEXTA for further discussion.

Drug Royalty Agreement In November 2002, the Company sold to Drug Royalty USA an undivided interest in the Company s rights to receive future Abreva royalties under the license agreement with GlaxoSmithKline for $24.1 million (the Drug Royalty Agreement and the GSK License Agreement, respectively). Under the Drug Royalty Agreement, Drug Royalty USA has the right to receive royalties from GlaxoSmithKline on sales of Abreva until December 2013. The Company retained the right to receive 50% of all royalties (a net of 4%) under the GSK License Agreement for annual net sales of Abreva in the U.S. and Canada in excess of $62 million.

Revenues are recognized when earned, collection is reasonably assured and no additional performance of services is required. The Company classified the proceeds received from Drug Royalty USA as deferred revenue and is recognizing the revenue over the life of the license agreement because of the Company s continuing involvement over the term of the Drug Royalty Agreement. Such continuing involvement includes overseeing the performance of GlaxoSmithKline and its compliance with the covenants in the GSK License Agreement, monitoring patent infringement, adverse claims or litigation involving Abreva, and undertaking to find a new license partner in the event that GlaxoSmithKline terminates the agreement. The Drug Royalty Agreement contains both covenants and events of default that require such performance on the Company s part. Therefore, nonperformance on the Company s part could result in default of the arrangement, and could give rise to additional rights in favor of Drug Royalty USA under a separate security agreement with Drug Royalty USA, which could result in loss of the Company s rights to share in future Abreva royalties if wholesale sales by GlaxoSmithKline exceed $62 million a year. The deferred revenue is being recognized as revenue using the units-of-revenue method over the life of the license agreement. Based on a review of the Company s continuing involvement, the Company concluded that the sale proceeds did not meet any of the rebuttable presumptions that would require classification of the proceeds as debt.

8. COMPUTATION OF NET LOSS PER COMMON SHARE

Basic net loss per common share is computed by dividing net loss by the weighted-average number of common shares outstanding during the period, excluding restricted stock that has been issued but is not yet vested. Diluted net

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loss per common share is computed by dividing net loss by the weighted-average number of common shares outstanding during the period plus additional weighted-average common equivalent shares outstanding during the period. Common equivalent shares result from the assumed exercise of outstanding stock options and warrants (the proceeds of which are then presumed to have been used to repurchase outstanding stock using the treasury stock method) and the vesting of restricted shares of common stock. In loss periods, certain of the common equivalent shares are excluded from the computation of diluted net loss per share, because their effect would have been anti-dilutive.

For the six month periods ended March 31, 2012 and 2011, the following options and warrants to purchase shares of common stock and restricted stock units were excluded from the computation of diluted net loss per share, as the inclusion of such shares would be anti-dilutive:

	2012	2011
Stock options	8,625,468	7,405,242
Stock warrants	710,109	8,505,170
Restricted stock units (1)	2,583,805	1,779,410

(1) Includes 1,505,564 and 1,320,981 shares of restricted stock at March 31, 2012 and 2011, respectively, awarded to directors that have vested but are still restricted until the directors resign.

9. STOCKHOLDERS EQUITY

On July 30, 2009, the Company entered into a Controlled Equity Offering Sales Agreement (the Sales Agreement) with Cantor Fitzgerald & Co. (Cantor), providing for the sale of up to 12,500,000 shares of common stock from time to time into the open market at prevailing prices. Pursuant to the Sales Agreement, sales of common stock could be made in such quantities and on such minimum price terms as the Company may set from time to time. During the six months ended March 31, 2012, the Company issued 3,668,656 shares of common stock under the Sales Agreement raising proceeds of approximately $10.1 million, net of offering costs, including commissions. As of March 31, 2012, a total of 12,355,166 shares of common stock have been issued under the Sales Agreement at an average price of $2.83 per share raising gross proceeds of approximately $35.0 million ($33.8 million, net of offering costs, including commissions).

During the six months ended March 31, 2012, the Company received proceeds of approximately $7.8 million from the exercise of warrants to purchase 5,445,061 shares of the Company s common stock. The warrants had been issued in connection with the Company s registered securities offering in April 2008 at an exercise price of $1.43 per share. As of March 31, 2012, warrants to purchase 710,109 shares of the Company s common stock at a weighted-average exercise price per share of $1.43 remained outstanding, all of which are exercisable. The warrants expire in April 2013. The warrants outstanding at March 31, 2012, are callable by the Company when the Company s stock price reaches 400% of the warrant s exercisable price for at least twenty trading days during any consecutive sixty day period.

During the six months ended March 31, 2012, the Company issued 204,064 shares of common stock in connection with the vesting of restricted stock units and 923,287 shares of common stock in connection with the exercise of stock options resulting in proceeds of approximately $765,000. During the six months ended March 31, 2012, restricted stock unit awards for a total of 92,083 shares awarded to directors vested, but the issuance and delivery of these shares are deferred until the director resigns.

10. EMPLOYEE EQUITY INCENTIVE PLANS

The Company currently has five equity incentive plans under which awards are outstanding (the Plans), two of which are currently in active use as described below. The Plans are: the 2005 Equity Incentive Plan (the 2005 Plan), the 2003 Equity Incentive Plan (the 2003 Plan), the 2000 Stock Option Plan (the 2000 Plan), the 1998 Stock Option Plan (the 1998 Plan) and the 1994 Stock Option Plan (the 1994 Plan), which are described in the Company s Annual Report on Form 10-K for the year ended September 30, 2011. All of the Plans were approved by the stockholders, except for the 2003 Plan, which was approved solely by the Board of Directors. Share-based awards are subject to terms and conditions established by the Compensation Committee of the Company s Board of Directors. The Company s policy is to issue new common shares upon the exercise of stock options, conversion of restricted share units or purchase of restricted stock.

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During the six month periods ended March 31, 2012 and 2011, the Company granted share-based awards under both the 2003 Plan and the 2005 Plan. Under the 2003 Plan and the 2005 Plan, options to purchase shares, restricted stock units, restricted stock and other share-based awards may be granted to the Company s directors, employees and consultants. Pursuant to the provisions of annual increases of the 2003 Plan and 2005 Plan, the number of authorized shares of common stock for issuance under the 2003 Plan and the 2005 Plan increased by 4,642,723 effective February 16, 2012 and 325,000 effective November 10, 2011, respectively. Under the Plans, as of March 31, 2012, the Company had an aggregate of 21,850,268 shares of its common stock reserved for future issuance. Of those shares, 11,209,273 were related to outstanding options and other awards and 10,640,995 shares were available for future grants of share-based awards. As of March 31, 2012, no equity awards were outstanding to consultants. The Company may also, from time to time, issue share-based awards outside of the Plans to the extent permitted by NASDAQ rules. As of March 31, 2012, there were no equity awards that were issued outside of the Plans (inducement option grants) outstanding. None of the share-based awards are classified as a liability as of March 31, 2012.

Stock Options. Stock options are granted with an exercise price equal to the current market price of the Company s common stock at the grant date and have 10-year contractual terms. For option grants to employees, generally 25% of the option shares vest and become exercisable on the first anniversary of the grant date and the remaining 75% of the option shares vest and become exercisable quarterly in equal installments thereafter over three years; for option grants to non-employee directors, one-third of the option shares vest and become exercisable on the first anniversary of the grant date and the remaining two-thirds of the option shares vest and become exercisable daily or quarterly in equal installments thereafter over two years; and for certain option grants to non-employee directors, options have been granted as fully vested and exercisable at the date of grant. Certain option awards provide for accelerated vesting if there is a change in control (as defined in the Plans).

Summaries of stock options outstanding and changes during the six months ended March 31, 2012 are presented below.

	Number of Shares	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Term (In Years)	Aggregate Intrinsic Value
Outstanding September 30, 2011	8,083,896	$ 2.46		
Granted	1,753,117	$ 1.95		
Exercised	(923,287)	$ 0.83		
Forfeited	(288,258)	$ 4.24		
Outstanding March 31, 2012	8,625,468	$ 2.47	7.9	$ 11,541,448
Vested and expected to vest in the future, March 31, 2012	8,262,005	$ 2.47	7.9	$ 11,156,651
Exercisable, March 31, 2012	3,194,971	$ 2.61	6.8	$ 5,047,833

The weighted average grant-date fair value of options granted during the six month periods ended March 31, 2012 and 2011 was $1.59 and $3.34 per share, respectively. The total intrinsic value of options exercised during the six month periods ended March 31, 2012 and 2011 was approximately $1.8 million and $1.9 million, respectively, based on the differences in market prices on the dates of exercise and the option exercise prices. As of March 31, 2012, the total unrecognized compensation cost related to unvested options was approximately $9.7 million which is expected to be recognized over the weighted-average period of 2.7 years, based on the vesting schedules. No tax benefit was realized for the tax deductions from option exercise of the share-based payment arrangements in the six month periods ended March 31, 2012 and 2011.

The fair value of each option award is estimated on the date of grant using the Black-Scholes model, which uses the assumptions noted in the following table. Expected volatilities are based on historical volatility of the Company s common stock and other factors. The expected term of options granted is based on analyses of historical employee termination rates and option exercises. The expected risk-free interest rate is based on the U.S. Treasury yield for a period consistent with the expected term of the option in effect at the time of the grant.

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Assumptions used in the Black-Scholes model for options granted during the six months ended March 31, 2012 were as follows:

Expected volatility	108% 109%
Weighted-average volatility	108%
Expected term in years	5.8
Expected risk-fee interest rate (zero coupon U.S. Treasury Note)	1.1% - 1.3%
Expected dividend yield	0%

The following table summarizes information concerning outstanding and exercisable stock options as of March 31, 2012:

	Options Outstanding			Options Exercisable	
Range of Exercise Prices	Number Outstanding	Weighted Average Remaining Contractual Life in Years	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
$0.47-$0.79	738,817	6.7	$ 0.53	428,699	$ 0.53
$0.88	1,296,008	6.3	$ 0.88	773,700	$ 0.88
$1.29-$1.74	1,507,816	7.4	$ 1.70	822,650	$ 1.67
$1.80-$2.08	1,658,417	9.6	$ 1.86	52,813	$ 1.96
$2.41-$4.18	3,135,973	8.7	$ 3.50	828,672	$ 3.41
$4.60-$15.84	288,437	3.5	$ 10.79	288,437	$ 10.79
	8,625,468	7.9	$ 2.47	3,194,971	$ 2.61

Restricted stock units (RSU). RSUs granted to employees generally vest based on three or four years of continuous service from the date of grant. RSUs granted to non-employee directors generally vest over the term of one year from the grant date and are not released until the awardee s termination of service. In fiscal 2010, vesting for non-employee director grants was amended to allow for accelerated vesting of RSUs in the case of a non-employee director s resignation where either: (i) he/she has served for at least four years as a member of the Board and is in good standing at the time of resignation, or (ii) he/she resigns for reasons related to health or family matters and is otherwise in good standing at the time of resignation.

The following table summarizes the RSU activities for the six months ended March 31, 2012:

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested, October 1, 2011	384,663	$ 3.50
Granted	1,009,725	$ 2.05
Vested	(296,147)	$ 3.23
Forfeited	(20,000)	$ 4.17
Unvested, March 31, 2012	1,078,241	$ 2.21

The grant-date fair value of RSUs granted during the six month periods ended March 31, 2012 and 2011 was approximately $2.1 million and $1.5 million, respectively. As of March 31, 2012, the total unrecognized compensation cost related to unvested shares was approximately $2.2 million which is expected to be recognized over a weighted-average period of 3.3 years, based on the vesting schedules. The Company received no cash from restricted stock awards under all share-based payment arrangements during the six month periods ended March 31, 2012 and 2011.

At March 31, 2012, there were 1,505,564 shares of restricted stock with a weighted-average grant date fair value of $1.91 per share awarded to directors that have vested but are still restricted until the director resigns.

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In fiscal 2010, the Company awarded an RSU representing the right to acquire a total of 120,000 shares of common stock to a non-employee. The grant date fair value of this award was $2.08 per share. The restricted stock units vested on October 15, 2011, and were remeasured at each balance sheet date and remeasured on the date vested at $3.22 per share.

Performance RSUs. During the six months ended March 31, 2012, the Company granted RSUs to purchase 612,042 shares of common stock from the 2003 Stock Option Plan. The performance RSUs are included in the above unvested RSU table. The RSUs have a performance goal related to fiscal 2012 revenue that determines when vesting begins and the actual number of shares to be awarded ranging from 0% to 100% of target. Vesting is over 4 years beginning on the date the performance goal is achieved (Achievement Date), with 25% of the RSU shares vesting on the first anniversary of the Achievement Date and the remaining 75% of the RSU shares vesting quarterly in equal installments thereafter over three years. At March 31, 2012, the performance goal had not been met and all performance RSUs were outstanding.

11. COMMITMENTS AND CONTINGENCIES

Center for Neurologic Study (CNS) The Company holds the exclusive worldwide marketing rights to NUEDEXTA for certain indications pursuant to an exclusive license agreement with CNS.

The Company paid a $75,000 milestone upon FDA approval of NUEDEXTA for the treatment of PBA in the first quarter of fiscal 2011. In addition, the Company is obligated to pay CNS a royalty ranging from approximately 5% to 8% of net U.S. GAAP revenue generated by sales of NUEDEXTA. During the six months ended March 31, 2012, royalties of approximately $727,000 are recorded to cost of product sales in the accompanying condensed consolidated statements of operations. Under certain circumstances, the Company may have the obligation to pay CNS a portion of net revenues received if the Company sublicenses NUEDEXTA to a third party.

Under the agreement with CNS, the Company is required to make payments on achievements of up to a maximum of ten milestones, based upon five specific medical indications. Maximum payments for these milestone payments could total approximately $1.1 million if the Company pursued the development of NUEDEXTA for all five of the licensed indications. In general, individual milestones range from $75,000 to $125,000 for each accepted new drug application (NDA) and a similar amount for each approved NDA in addition to the royalty discussed above on net U. S. GAAP revenues. The Company does not have the obligation to develop additional indications under the CNS license agreement.

Concert Pharmaceuticals, Inc.(Concert) The Company holds the exclusive worldwide marketing rights to develop and commercialize Concert s d-DM compounds for the potential treatment of neurological and psychiatric disorders, as well as certain rights to other deuterium-modified dextromethorphan compounds pursuant to a license agreement with Concert.

Under the agreement with Concert, the Company is obligated to make milestone and royalty payments to Concert based on successful advancement of d-DM products for one or more indications in the United States, Europe, and Japan. Individual milestone payments range from $2.0 6.0 million, $1.5 15.0 million, and $25.0 60.0 million for clinical, regulatory and commercial targets respectively, and in aggregate could total over $200 million. Royalty payments are tiered, beginning in the single-digits and increasing to the low double-digits for worldwide net sales of d-DM products exceeding $1 billion annually.

Legal Contingencies

NUEDEXTA ABBREVIATED NEW DRUG APPLICATION (ANDA) Litigation

In fiscal 2011 and January 2012, the Company received Paragraph IV certification notices from five separate companies contending that certain of its patents listed in the FDA s publication, Approved Drug Products with Therapeutic Equivalence Evaluation (FDA Orange Book) (U.S. Patents 7,659,282 (282 Patent) and RE 38,115 (115 Patent), which expire in August 2026 and January 2016, respectively) are invalid, unenforceable and/or will

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not be infringed by the manufacture, use, sale or offer for sale of a generic form of NUEDEXTA as described in those companies ANDA s. The FDA Orange Book provides potential competitors, including generic drug companies, with a list of issued patents covering approved drugs. In August 2011 and March 2012, the Company filed lawsuits in the U.S District Court for the District of Delaware against Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc. (collectively Par), Actavis South Atlantic LLC and Actavis, Inc. (collectively Actavis), Wockhardt USA, LLC and Wockhardt, Ltd. (collectively, Wockhardt), Impax Laboratories, Inc. (Impax) and Watson Pharmaceuticals, Inc., Watson Laboratories, Inc. and Watson Pharma, Inc. (collectively Watson) (Par, Actavis, Wockhardt, Impax and Watson, collectively the Defendants). In March 2012, the Company also filed a protective suit in the U.S District Court for the District of New Jersey against Watson. All lawsuits (collectively, the ANDA Actions) were filed on the basis that the Defendants submissions of their respective ANDAs to obtain approval to manufacture, use, sell, or offer for sale generic versions of NUEDEXTA prior to the expiration of the 282 Patent and the 115 Patent listed in the FDA Orange Book constitute infringement of one or more claims of those patents.

Pursuant to the provisions of the Hatch-Waxman Act, FDA final approval of the ANDAs submitted by the Defendants can occur no earlier than October 29, 2013. Further, as a result of the 30-month stay associated with the filing of the ANDA Actions, the FDA cannot grant final approval to any ANDA before December 30, 2013, unless there is an earlier court decision holding that the 282 and 115 patents are not infringed and/or are invalid. The Company intends to vigorously enforce its intellectual property rights relating to NUEDEXTA, but the Company cannot predict the outcome of these matters.

Alamo and Azur Litigation

In October 2011, Neal R. Cutler, M.D., the founder of Alamo Pharmaceuticals, LLC (Alamo), filed a lawsuit in California Superior Court against Azur Pharma International III Limited and Azur Pharma Limited (collectively, Azur) and Avanir (the Cutler Action). The Company purchased Alamo in 2006 to acquire rights to FazaClo, an approved anti-psychotic drug. In connection with this acquisition of Alamo, the Company agreed to provide the Alamo equity holders, including Dr. Cutler, with milestone payments tied to the aggregate net revenues of FazaClo. In 2007, the Company sold FazaClo and its related assets and operations to Azur. In connection with this sale, Azur agreed to assume the milestone payment obligations due to Dr. Cutler under the Alamo purchase agreement, although the Company could remain liable for these payments if Azur defaults on these obligations. In the Cutler Action, Dr. Cutler alleges that Azur has failed to make certain information reasonably available to Dr. Cutler and has withheld payments to which Dr. Cutler is entitled. Dr. Cutler alleges that Avanir has acquiesced in this conduct, and Dr. Cutler seeks to hold both Azur and Avanir liable for these actions. Azur has now agreed to indemnify Avanir in full for the claims asserted in the Cutler Action.

General and Other

In the ordinary course of business, the Company may face various claims brought by third parties and it may, from time to time, make claims or take legal actions to assert the Company s rights, including intellectual property rights as well as claims relating to employment and the safety or efficacy of its products. Any of these claims could subject the Company to costly litigation and, while the Company generally believes that it has adequate insurance to cover many different types of liabilities, the Company s insurance carriers may deny coverage or the Company s policy limits may be inadequate to fully satisfy any damage awards or settlements. If this were to happen, the payment of any such awards could have a material adverse effect on the Company s operations, cash flows and financial position. Additionally, any such claims, whether or not successful, could damage the Company s reputation and business. Management believes the outcomes of currently pending claims and lawsuits are not likely to have a material effect on the Company s operations or financial position.

In addition, it is possible that the Company could incur termination fees and penalties if it elected to terminate contracts with certain vendors.

Guarantees and Indemnities The Company indemnifies its directors and officers to the maximum extent permitted under the laws of the State of Delaware, and various lessors in connection with facility leases for certain claims arising from such facilities or leases. Additionally, the Company periodically enters into contracts that contain indemnification obligations, including contracts for the purchase and sale of assets, wholesale distribution

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agreements, clinical trials, pre-clinical development work and securities offerings. These indemnification obligations provide the contracting parties with the contractual right to have the Company pay for the costs associated with the defense and settlement of certain claims, typically in circumstances where the Company has failed to meet its contractual performance obligations in some fashion.

The maximum amount of potential future payments under such indemnifications is not determinable. The Company has not incurred significant costs related to these guarantees and indemnifications, and no liability has been recorded in the condensed consolidated financial statements for guarantees and indemnifications as of March 31, 2012.

12. SEGMENT INFORMATION

The Company operates its business on the basis of a single reportable segment, which is the business of discovery, development and commercialization of novel therapeutics for chronic diseases. The Company s chief operating decision-maker is the Chief Executive Officer, who evaluates the Company as a single operating segment.

The Company categorizes revenues by geographic area based on selling location. All the Company s operations are currently located in the United States; therefore, total revenues for the three and six month periods ended March 31, 2012 and 2011 are attributed to the United States. All long-lived assets at March 31, 2012 and September 30, 2011 are located in the United States.

For the three month periods ended March 31, 2012 and 2011, the revenues from prior sale of rights to royalties under the GSK license agreement were less than 10% and 48% of total net revenues, respectively. For the three month periods ended March 31, 2012 and 2011, royalty revenues from Azur were less than 10% and 20% of total net revenues, respectively.

For the six month periods ended March 31, 2012 and 2011, the revenues from prior sale of rights to royalties under the GSK license agreement were 12% and 70% of total net revenues, respectively. For the six month periods ended March 31, 2012 and 2011, royalty revenues from Azur were less than 10% and 16% of total net revenues, respectively.

13. SUBSEQUENT EVENTS

The Company has evaluated subsequent events through the filing date of this Form 10-Q, and determined that no subsequent events have occurred that would require recognition in the condensed consolidated financial statements or disclosure in the notes thereto other than discussed in the accompanying notes.

From April 1, 2012 through May 3, 2012, 56 shares of the Company s common stock were issued pursuant to the vesting of restricted stock units that were outstanding at March 31, 2012.

On May 7, 2012 the Company secured a $30 million term loan from Oxford Finance and Silicon Valley Bank. Under the loan agreement, the Company will repay interest only on a monthly basis through June 2013, or upon meeting certain conditions, through January 2014, and thereafter the Company will repay the principal and interest on a monthly basis through the maturity date of December 31, 2015. The interest rate for borrowings under the term loan will be fixed upon drawdown at a rate per annum equal to the greater of (i) 8.95% or (ii) the sum of (a) 8.38% and (b) the three month LIBOR rate. The loan is secured by a first priority security interest in all of the Company s assets, other than its intellectual property and its rights under license agreements granting it rights to intellectual property. The loan is expected to fund on or around June 1, 2012. In connection with entering into the loan agreement, the Company issued to the lenders warrants to purchase shares of the Company s common stock equal to 4.55% of the term loan at a price per share equal to the lower of the 10-day average share price prior to closing or the price per share on the day of closing.

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Item 2. MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

This Quarterly Report on Form 10-Q contains forward-looking statements concerning future events and performance of the Company. When used in this report, the words intend, estimate, anticipate, believe, plan or expect and similar expressions are included to identify forward-looking statements. These forward-looking statements are based on our current expectations and assumptions and many factors could cause our actual results to differ materially from those indicated in these forward-looking statements. You should review carefully the factors identified in Risk Factors in this report in Part II, Item 1A. and in Part I, Item 1A. in our most recent Annual Report on Form 10-K filed with the SEC. We disclaim any intent to update or announce revisions to any forward-looking statements to reflect actual events or developments. Except as otherwise indicated herein, all dates referred to in this report represent periods or dates fixed with reference to the calendar year, rather than our fiscal year ending September 30. The three months ended March 31, 2012 are also referred to as the second quarter of fiscal 2012.

EXECUTIVE OVERVIEW

Avanir is a pharmaceutical company focused on acquiring, developing and commercializing novel therapeutic products for the treatment of central nervous system disorders. In October 2010, the U.S. Food and Drug Administration (FDA) approved NUEDEXTA® (referred to as AVP-923 during clinical development), a unique proprietary combination of dextromethorphan (DM) and low dose quinidine, for the treatment of pseudobulbar affect (PBA). We commenced promotion of NUEDEXTA in the United States in February 2011 and we are currently pursuing the approval of NUEDEXTA in Europe.

The table below shows dispensed prescription data for NUEDEXTA for the past four quarterly periods. The average capsules per prescription is 51.

	Three Months Ended			
	June 30, 2011	September 30, 2011	December 31, 2011	March 31, 2012
Total dispensed prescriptions	5,136	10,210	14,626	19,823

We are also studying AVP-923 for use in different types of neuropathic pain. We have filed an Investigational New Drug application (IND) with the FDA and have initiated a large Phase II clinical trial of AVP-923 for the treatment of central neuropathic pain in patients with multiple sclerosis. In addition, we are pursuing studies to assess the efficacy, safety and tolerability of AVP-923 for treatment of agitation in patients with Alzheimer s disease.

AVP-923 has also completed a Phase III trial for the treatment of patients with diabetic peripheral neuropathic pain with positive results. Additional phase III trials would need to be completed for approval of this indication.

On February 29, 2012, we entered into a license agreement with Concert Pharmaceuticals, Inc. (Concert) pursuant to which we licensed from Concert exclusive, worldwide rights to develop and commercialize Concert s deuterium-modified dextromethorphan (d-DM) for the potential treatment of neurologic and psychiatric disorders, as well as certain rights to other deuterium-modified dextromethorphan compounds. We believe that d-DM compounds may provide therapeutically effective levels of DM, potentially without the need for an enzyme inhibitor such as quinidine. We intend to explore the utility of d-DM in neurological and psychiatric disorders where dual N-Methyl-D-aspartic acid (NMDA) antagonists and sigma-1 agonists may be beneficial.

In addition to our focus on products for the central nervous system, we also have partnered programs in other therapeutic areas that may generate future revenue for us. Our first commercialized product, docosanol 10% cream (sold in the United States and Canada as Abreva® by our marketing partner GlaxoSmithKline Consumer Healthcare), is the only over-the-counter treatment for cold sores that has been approved by the FDA. In 2008, we out-licensed all of our monoclonal antibodies and we remain eligible to receive milestone payments and royalties related to the sale of these assets.

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NUEDEXTA ***for the Treatment of PBA***

NUEDEXTA is the first and only FDA-approved treatment for PBA. PBA occurs secondary to a variety of otherwise unrelated neurological conditions, and is characterized by involuntary, sudden, and frequent episodes of laughing and/or crying. PBA episodes typically occur out of proportion or incongruent to the patient s underlying emotional state.

NUEDEXTA is an innovative combination of two well-characterized components: dextromethorphan hydrobromide (20 mg), the ingredient that is pharmacologically active in the central nervous system, and quinidine sulfate (10 mg), a metabolic inhibitor enabling dextromethorphan to reach therapeutic plasma concentrations. NUEDEXTA acts on sigma-1 and NMDA receptors in the brain, although the mechanism by which NUEDEXTA exerts therapeutic effects in patients with PBA is unknown.

Studies to support the effectiveness of NUEDEXTA were performed in patients with PBA and underlying amyotrophic lateral sclerosis, or ALS, and multiple sclerosis. The primary outcome measure, the number of laughing and crying episodes, was significantly lower in the NUEDEXTA cohort compared with placebo. The secondary outcome measure, the Center for Neurologic Studies Lability Scale (CNS-LS), demonstrated a significantly greater mean decrease in CNS-LS score from baseline for the NUEDEXTA cohort compared with placebo. NUEDEXTA has not been shown to be safe and effective in other types of emotional lability that can commonly occur, for example, in Alzheimer s disease and other dementias.

AVP-923 for the Potential Treatment of Neuropathic Pain

AVP-923 for the treatment of MS-related pain

Multiple Sclerosis (MS) is one of the most frequent chronic neurologic disease causing significant disability in young adults. Among the many neurological complications of MS, chronic pain has a significant impact on the daily life of patients with this disease.

Several distinct pain conditions associated with MS have been characterized in various literature, including optic neuritis, headache, musculoskeletal pain (which includes painful tonic spasms, back pain and muscle spasms) and central neuropathic pain (which includes extremity pain, trigeminal neuralgia and Lhermitte s sign). While the specific pain mechanisms associated with each condition have not been fully identified, it is believed that neuropathic pain results from neurologic damage caused by demyelinating lesions. Pain is a common symptom experienced by many MS patients and, in particular, approximately 30% of MS patients experience central neuropathic pain during the course of the disease.

In September 2009, we reported on secondary efficacy endpoints from the double-blind phase of the AVP-923 STAR trial in PBA, including an endpoint measuring reduction of MS-related pain. AVP-923 30/10 mg demonstrated statistically significant decrease in pain scores compared to placebo in the subset of MS patients with moderate-to-severe pain. Based on these results, we filed an IND application with the FDA to begin a Phase II clinical trial of AVP-923 for the treatment of central neuropathic pain in patients with MS. The FDA accepted the proposed clinical investigational plan included in the submission and we enrolled the first patient in November 2011.

The objectives of the study, known as Pain Research In Multiple sclErosis (PRIME), are to evaluate the safety, tolerability, and efficacy of three dose levels of AVP-923 capsules for the treatment of central neuropathic pain in a population of patients with MS. The trial is a multicenter, randomized, double-blind, placebo-controlled, 4-arm parallel group study. Eligible patients will be randomized to receive one of the three dose levels of AVP-923 containing either 45mg DM/10mg Q, 30mg DM/10mg Q, 20mg DM/10mg Q or placebo, daily for 12 weeks. The primary efficacy endpoint is the Pain Rating Scale obtained from daily patient diaries. Secondary endpoints include measure of fatigue, impact of MS on daily life, sleep quality, cognition and depression. Safety will be assessed by monitoring adverse events, clinical laboratory tests, electrocardiograms, physical examinations, and vital signs. We expect to enroll approximately 400 patients both in the U.S. and internationally.

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AVP-923 for the treatment of diabetic neuropathic pain

Diabetic peripheral neuropathic pain (DPN pain), which arises from nerve injury, can result in a chronic and debilitating form of pain that has historically been poorly diagnosed and treated. It is often described as burning, tingling, stabbing, or pins and needles in the feet, legs, hands or arms. An estimated 3.5 million people in the United States experience DPN pain according to the American Diabetes Association. DPN pain currently is most commonly treated with antidepressants, anticonvulsants, opioid analgesics and local anesthetics. Most of these treatments have limited effectiveness or undesirable side effects resulting in a high degree of unmet medical need. The neuropathic pain market is continuing to grow rapidly, and in 2006, was estimated to be worth $2.6 billion in sales among the seven largest markets, consisting of the United States, Japan, France, Germany, Italy, Spain and the United Kingdom.

Avanir has completed a Phase III clinical trial for AVP-923 in the treatment of patients with DPN pain. In April 2007, we announced positive top-line data from our first Phase III clinical trial of AVP-923 for the treatment of patients with DPN pain. The most commonly reported adverse events from this Phase III study were dizziness, nausea, diarrhea, fatigue and somnolence, which were mild to moderate in nature. We are continuing to evaluate our options for this program and next steps.

Docosanol 10% Cream Cold Sore Treatment

Docosanol 10% cream is a topical treatment for cold sores. In 2000, we received FDA approval for marketing docosanol 10% cream as an over-the-counter product. Since that time, docosanol 10% cream has been approved by regulatory agencies in Asia, North America, and Europe. In March 2000, we granted a subsidiary of GlaxoSmithKline, SB Pharmco Puerto Rico, Inc. (GSK), the exclusive rights under a license to market docosanol 10% cream in the United States and Canada (GSK License Agreement). GSK markets the product under the name Abreva® in these markets. Under the terms of the GSK License Agreement, GSK is responsible for all sales and marketing activities and the manufacturing and distribution of docosanol 10% cream. Under the GSK license agreement, the Company received a total of $25 million in milestone payments from GSK and the Company was entitled to receive an 8% royalty on net sales of Abreva by GSK.

In November 2002, the Company sold to Drug Royalty USA an undivided interest in the Company s rights to receive future Abreva royalties under the GSK License Agreement for $24.1 million (the Drug Royalty Agreement). Under the Drug Royalty Agreement, Drug Royalty USA has the right to receive royalties from GSK on sales of Abreva until December 2013. The Company retained the right to receive 50% of all royalties (a net of 4%) under the GSK License Agreement for annual net sales of Abreva in the U.S. and Canada in excess of $62 million. From the effective date of the GSK License Agreement up to the 2002 sale of the Company s royalty rights to Drug Royalty USA, Inc., the Company received a total of approximately $5.9 million in royalty payments from GSK attributed to the 8% royalty on net sales by GSK.

General Information

Our principal executive offices are located at 20 Enterprise, Suite 200, Aliso Viejo, California 92656. Our telephone number is (949) 389-6700 and our e-mail address is *info@avanir.com*. Our Internet website address is *www.avanir.com*. We make our periodic and current reports available on our Internet website, free of charge, as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC. No portion of our website is incorporated by reference into this Quarterly Report on Form 10-Q. The public may read and copy the materials we file with the SEC at the SEC s Public Reference Room, located at 100 F Street, NE, Washington, D.C. 20549. The public may obtain information regarding the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The public may also read and copy the materials we file with the SEC by visiting the SEC s website, www.sec.gov.

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CRITICAL ACCOUNTING POLICIES AND ESTIMATES

To understand our financial statements, it is important to understand our critical accounting policies and estimates. The preparation of our financial statements in conformity with accounting principles generally accepted in the United States of America requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Significant estimates and assumptions are required in the determination of revenue recognition and allowances, certain royalties and returns and losses. Significant estimates and assumptions are also required in the appropriateness of amounts recognized for inventories, income taxes, contingencies, and share-based compensation. Some of these judgments can be subjective and complex, and, consequently, actual results may differ from these estimates. For any given individual estimate or assumption made by us, there may also be other estimates or assumptions that are also reasonable. Although we believe that our estimates and assumptions are reasonable, they are based upon information available at the time the estimates and assumptions are made. Actual results may differ significantly from our estimates.

A summary of significant accounting policies and a description of accounting policies that are considered critical may be found in Part II, Item 7 of our Annual Report on Form 10-K for the year ended September 30, 2011 in the Critical Accounting Policies and Estimates section, as updated and amended in Note 2 of the Notes to our Condensed Consolidated Financial Statements included herein.

RESULTS OF OPERATIONS

COMPARISON OF THREE MONTH PERIODS ENDED MARCH 31, 2012 AND 2011

Revenues

	Three months ended March 31,			
	2012	2011	$ Change	% Change
REVENUES				
Net product sales	$ 9,141,873	$ 462,014	$ 8,679,859	1879%
Revenues from royalties	898,515	974,489	(75,974)	-8%
Total net revenues	$ 10,040,388	$ 1,436,503	$ 8,603,885	599%

Total net revenues were approximately $10.0 million for the three months ended March 31, 2012 compared to approximately $1.4 million for the three months ended March 31, 2011. The increase in net revenues of approximately $8.7 million was primarily attributed to the product sales of NUEDEXTA which we began promoting commercially in February 2011. Included in net product sales for the three months ended March 31, 2012, is an approximately $1.7 million one-time adjustment resulting from a change in accounting estimate. The change in accounting estimate was a change from recognizing revenue when the right of return no longer existed to recognizing revenue upon shipment to wholesalers and other customers.

Potential revenue-generating contracts that remained active as of March 31, 2012 include licensing revenue from our agreement with GSK, potential royalties from our agreement with Emergent Biosolutions, Inc. and modest potential revenue generated from various other licensing agreements. Partnering, licensing and research collaborations have been, and may continue to be, an important part of our business development strategy. We may continue to seek partnerships with pharmaceutical companies that can help fund our operations in exchange for sharing in the success of any licensed compounds or technologies.

Cost of Product Sales

Cost of product sales were approximately $534,000 for the three months ended March 31, 2012 compared to cost of product sales of approximately $114,000 in the same period of fiscal 2011. The increase in cost of product sales is attributable to the increase in sales of NUEDEXTA which we began promoting commercially in February 2011.

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Operating Expenses

	Three months ended March 31,			
	2012	2011	$ Change	% Change
OPERATING EXPENSES				
Research and development	$ 6,395,155	$ 2,519,390	$ 3,875,765	154%
Selling and marketing	14,814,014	9,347,735	5,466,279	58%
General and administrative	5,346,990	3,931,038	1,415,952	36%
Total operating expenses	$ 26,556,159	$ 15,798,163	$ 10,757,996	68%

Research and Development Expenses

Research and development expenses increased by approximately $3.9 million from approximately $2.5 million in the second quarter of fiscal 2011 to approximately $6.4 million for the second quarter of fiscal 2012. The increase is primarily due to d-DM program costs of $2.0 million and costs associated with the Phase II clinical trial of AVP-923 for the treatment of central neuropathic pain in patients with MS that began in the third quarter of fiscal 2011. We expect the quarterly expenditures for research and development expenses over the next six months to be lower than the second quarter of fiscal 2012 level primarily due to lower d-DM program costs partially offset by an increase in other research and development expenses as we continue to execute on our regulatory filing plan for NUEDEXTA in Europe and continue development of AVP-923 for treatment of central neuropathic pain in patients with MS. Medical affairs initiatives related to our marketed product, NUEDEXTA, are also included in research and development expenses.

Selling and Marketing Expenses

Selling and marketing expenses increased by approximately $5.5 million from approximately $9.3 million for the second quarter of fiscal 2011 compared to approximately $14.8 million for the second quarter of fiscal 2012. The increase is primarily attributed to costs associated with the commercial launch of NUEDEXTA, including increased personnel costs of approximately $3.4 million resulting from a sales force expansion and other key commercial headcount; increased marketing and market research costs of approximately $1.9 million; and increased other costs of approximately $209,000. Selling and marketing expenses are expected to remain at the same level as the second quarter of fiscal 2012 through the end of fiscal 2012.

General and Administrative Expenses

General and administrative expenses increased by approximately $1.4 million from approximately $3.9 million for the second quarter of fiscal 2011 compared to approximately $5.3 million for the second quarter of fiscal 2012. The increase is primarily attributed to increased personnel costs of approximately $338,000 resulting from the hiring of key corporate headcount to support the commercialization of NUEDEXTA; increased legal expense of approximately $857,000 primarily due to the enforcement of our intellectual property rights; and increased other corporate costs of approximately $225,000. General and administrative expenses are expected to increase as we incur legal defense costs attributed to the enforcement of our intellectual property rights related to NUEDEXTA.

Share-Based Compensation

Total share-based compensation expense in the three month periods ended March 31, 2012 and 2011 was approximately $1.2 million and $951,000, respectively. Selling and marketing expense in the three month periods ended March 31, 2012 and 2011 includes share-based compensation expense of approximately $235,000 and $137,000, respectively. General and administrative expense in the three month periods ended March 31, 2012 and 2011 includes share-based compensation expense of approximately $732,000 and $662,000, respectively. Research and development expense in the three month periods ended March 31, 2012 and 2011 includes share-based compensation expense of approximately $267,000 and $152,000, respectively. As of March 31, 2012, approximately $11.9 million of total unrecognized compensation costs related to non-vested options and awards is expected to be recognized over a weighted average period of 2.8 years. See Note 10, Employee Equity Incentive Plans in the Notes to Condensed Consolidated Financial Statements (Unaudited) for further discussion.

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Other Income (Expense)

For the three months ended March 31, 2012, other income (expense) was approximately $8,000, compared to approximately $10,000 for the same period in the prior year.

Net Loss

Net loss was approximately $17.0 million, or $0.13 per share, in the three months ended March 31, 2012 compared to a net loss of approximately $14.5 million, or $0.12 per share, for the three months ended March 31, 2011.

COMPARISON OF SIX MONTH PERIODS ENDED MARCH 31, 2012 AND 2011

Revenues

	Six months ended March 31,			
	2012	2011	$ Change	% Change
REVENUES				
Net product sales	$ 14,630,636	$ 462,014	$ 14,168,622	3067%
Revenue from royalties	2,574,635	2,792,976	(218,341)	-8%
Total revenues	$ 17,205,271	$ 3,254,990	$ 13,950,281	429%

Total net revenues were approximately $17.2 million for the six months ended March 31, 2012 compared to approximately $3.3 million for the six months ended March 31, 2011. The increase in net revenues of approximately $14.2 million was primarily attributed to the product sales of NUEDEXTA which we began promoting commercially in February 2011. Included in net product sales for the three months ended March 31, 2012, is an approximately $1.7 million one-time adjustment resulting from a change in accounting estimate. The change in accounting estimate was a change from recognizing revenue when the right of return no longer existed to recognizing revenue upon shipment to wholesalers and other customers.

Cost of Product Sales

Cost of product sales were approximately $844,000 for the six months ended March 31, 2012 compared to cost of product sales of approximately $114,000 in the same period of fiscal 2011. The increase in cost of product sales is attributable to the sales of NUEDEXTA which we began promoting commercially in February 2011.

Operating Expenses

	Six months ended March 31,			
	2012	2011	$ Change	% Change
OPERATING EXPENSES				
Research and development	$ 10,139,670	$ 6,363,179	$ 3,776,491	59%
Selling and marketing	28,596,850	15,610,467	12,986,383	83%
General and administrative	10,639,173	7,761,744	2,877,429	37%
Total operating expenses	$ 49,375,693	$ 29,735,390	$ 19,640,303	66%

Research and Development Expenses

Research and development expenses increased by approximately $3.8 million from approximately $6.4 million in the first half of fiscal 2011 to approximately $10.1 million for the first half of fiscal 2012. The increase is primarily due to d-DM program costs of $2.0 million and costs associated with the Phase II clinical trial of AVP-923 for the treatment of central neuropathic pain in patients with MS that began in the third quarter of fiscal 2011.

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Selling and Marketing Expenses

Selling and marketing expenses increased by approximately $13.0 million from approximately $15.6 million for the first half of fiscal 2011 compared to approximately $26.6 million for the first half of fiscal 2012. The increase is primarily attributed to costs associated with the commercial launch of NUEDEXTA, including increased personnel costs of approximately $7.6 million resulting from a sales force expansion and other key commercial headcount; increased marketing and market research costs of approximately $4.8 million; and increased other costs of approximately $555,000.

General and Administrative Expenses

General and administrative expenses increased by approximately $2.9 million from approximately $7.8 million for the first half of fiscal 2011 compared to approximately $10.6 million for the first half of fiscal 2012. The increase is primarily attributed to increased personnel costs of approximately $1.1 million resulting from the hiring of key corporate headcount to support the commercialization of NUEDEXTA; increased legal expense of approximately $1.4 million primarily due to the enforcement of our intellectual property rights; and increased other corporate costs of approximately $408,000.

Share-Based Compensation

Total share-based compensation expense in the six month periods ended March 31, 2012 and 2011 was approximately $2.4 million and $1.8 million, respectively. Selling and marketing expense in the six month periods ended March 31, 2012 and 2011 includes share-based compensation expense of approximately $365,000 and $218,000, respectively. General and administrative expense in the six month periods ended March 31, 2012 and 2011 includes share-based compensation expense of approximately $1.5 million and $1.3 million, respectively. Research and development expense in the six month periods ended March 31, 2012 and 2011 includes share-based compensation expense of approximately $508,000 and $299,000, respectively.

Other Income (Expense)

For the six months ended March 31, 2012, other income (expense) was approximately $26,000, compared to approximately $17,000 for the same period in the prior year.

Net Loss

Net loss was approximately $33.0 million, or $0.25 per share, in the six months ended March 31, 2012 compared to a net loss of approximately $26.6 million, or $0.23 per share, for the six months ended March 31, 2011.

LIQUIDITY AND CAPITAL RESOURCES

We assess our liquidity by our ability to fund current and future operations. Key factors in the management of our liquidity are: cash required to fund operating activities including expected operating losses and the levels of inventories, accounts payable and capital expenditures; the timing and extent of cash received from milestone payments under license agreements; ability to obtain adequate credit facilities; and financial flexibility to attract long-term equity capital on favorable terms. Historically, cash required to fund on-going business operations has been provided by financing activities and used to fund operations, working capital requirements and investing activities.

On May 7, 2012 we secured a $30 million term loan from Oxford Finance and Silicon Valley Bank. Under the loan agreement, we will repay interest only on a monthly basis through June 2013, or upon meeting certain conditions, through January 2014, and thereafter we will repay the principal and interest on a monthly basis through the maturity date of December 31, 2015. The interest rate for borrowings under the term loan will be fixed upon drawdown at a rate per annum equal to the greater of (i) 8.95% or (ii) the sum of (a) 8.38% and (b) the three month LIBOR rate. The loan is expected to fund on or around June 1, 2012.

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Net cash provided by or used in operating, investing and financing activities, are summarized in the table below.

	Six Months Ended March 31, 2012	Change Between Periods	Six Months Ended March 31, 2011
Net cash used in operating activities	$ (30,611,748)	$ (2,644,124)	$ (27,967,624)
Net cash used in investing activities	(842,614)	996,846	(1,839,460)
Net cash provided by financing activities	18,614,161	(75,468,501)	94,082,662
Net (decrease) increase in cash and cash equivalents	$ (12,840,201)	$ (77,115,779)	$ 64,275,578

Operating activities. Net cash used in operating activities was approximately $30.6 million for the six months ended March 31, 2012 compared to approximately $28.0 million for the six months ended March 31, 2011. The increase is due to increased expenses of $19.6 million, primarily due to commercial activities, partially offset by increased product gross margin of approximately $13.4 million and an increase in non-cash and changes in operating assets and liabilities of approximately $3.8 million.

Investing activities. Net cash used in investing activities was approximately $843,000 for the six months ended March 31, 2012, compared to approximately $1.8 million for the six months ended March 31, 2011. The decrease in cash used in investing activities was primarily related to our investments in restricted securities of approximately $1.5 million in the first half of fiscal 2011 that was required to support our commercial activities compared to an additional investment of $50,000 in the first half of fiscal 2012, This decrease was partially offset by an increase in the purchase of property and equipment in the first half of fiscal 2012 as compared to the same period in the prior year.

Financing activities. Net cash provided by financing activities was approximately $18.6 million for the six months ended March 31, 2012 compared to approximately $94.1 million for the six months ended March 31, 2011. In the first half of fiscal 2012, we raised approximately $10.1 million from the sale of our common stock under our at-the-market facility, received proceeds of approximately $7.8 million from the exercise of warrants and approximately $765,000 from the exercise of stock options. In the first half of fiscal 2011, we raised approximately $83.0 million in proceeds, net of offering costs, including commissions, from our public offering and approximately $5.3 million in proceeds, net of offering costs, including commissions, from our at-the-market offering facility. Additionally, we received proceeds of approximately $5.3 million from the exercise of warrants.

In April 2009, we filed with the SEC a shelf registration statement on Form S-3 to sell an aggregate of up to $35.0 million in common stock, preferred stock, debt securities and warrants. On May 6, 2009, the registration statement was declared effective. On July 30, 2009 we entered into a financing facility with Cantor Fitzgerald & Co., providing for the sale of up to 12,500,000 shares of our common stock from time to time into the open market at prevailing prices. As of March 31, 2012, 12.4 million shares of common stock had been sold for total gross proceeds of $35.0 million through this facility under our registration statement. As of May 3, 2012, no funds remain available on the April 2009 shelf registration statement.

In September 2009, we filed with the SEC a shelf registration statement on Form S-3 to sell an aggregate of up to $75.0 million in common stock, preferred stock, debt securities and warrants. On September 23, 2009, the registration statement was declared effective. In May 2010, we sold an aggregate of 10,000,000 shares of our common stock in an underwritten offering at a public offering price of $2.75 per share, resulting in $27.5 million in gross offering proceeds and approximately $26.6 million in net proceeds to us, after deducting underwriting discounts, commissions and estimated offering expenses. As of May 3, 2012, approximately $34.5 million of the September 2009 shelf registration statement remains available.

In September 2010, we filed with the SEC a shelf registration statement on Form S-3 to sell an aggregate of up to $75.0 million in common stock, preferred stock, debt securities and warrants. In November 2010, we completed an underwritten public offering of 20,000,000 shares of our common stock offered at a public offering price of $4.40 per share. Gross offering proceeds resulting from the offering were approximately $88.0 million, with net proceeds of approximately $83.0 million, after deducting offering discounts, costs and commissions. As of May 3, 2012, no funds remain available on the September 2010 shelf registration statement.

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As of March 31, 2012 we have contractual obligations for long-term debt and operating lease obligations, as summarized in the table that follows.

	Payments Due by Period				
	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Operating lease obligations (1)	$ 4,683,156	$ 1,675,828	$ 1,628,338	$ 1,378,990	$
Purchase obligations (2)	7,910,282	7,910,282			
Total	$ 12,593,438	$ 9,586,110	$ 1,628,338	$ 1,378,990	$

(1) Operating lease obligations are exclusive of payments we expect to receive under subleases.
(2) Purchase obligations consist of the total of trade accounts payable and trade related accrued expenses at March 31, 2012 which approximates our contractual commitments for goods and services in the normal course of our business.

NUEDEXTA License Milestone Payments. We hold the exclusive worldwide marketing rights to NUEDEXTA for certain indications pursuant to an exclusive license agreement with the Center for Neurologic Study (CNS).

We paid a $75,000 milestone upon FDA approval of NUEDEXTA for the treatment of PBA in the first quarter of fiscal 2011. In addition, we are obligated to pay CNS a royalty ranging from approximately 5% to 8% of net U.S. GAAP revenue generated by sales of NUEDEXTA. During the six months ended March 31, 2012, royalties of approximately $727,000 are recorded to cost of product sales in the condensed consolidated statements of operations. Under certain circumstances, we may have the obligation to pay CNS a portion of net revenues received if we sublicense NUEDEXTA to a third party.

Under the agreement with CNS, we are required to make payments on achievements of up to a maximum of ten milestones, based upon five specific clinical indications. Maximum payments for these milestone payments could total approximately $1.1 million if we pursued the development of NUEDEXTA for all five of the licensed indications. In general, individual milestones range from $75,000 to $125,000 for each accepted new drug application (NDA) and a similar amount for each approved NDA in addition to the royalty discussed above on net U.S. GAAP revenues. We do not have the obligation to develop additional indications under the CNS license agreement.

d-DM License Milestone Payments We hold the exclusive worldwide marketing rights to develop and commercialize Concert s d-DM compounds for the potential treatment of neurological and psychiatric disorders, as well as certain rights to other deuterium-modified dextromethorphan compounds pursuant to a license agreement with Concert.

Under the agreement with Concert, we are obligated to make milestone and royalty payments to Concert based on successful advancement of d-DM products for one or more indications in the United States, Europe, and Japan. Individual milestone payments range from $2 6 million, $1.5 15 million, and $25 60 million for clinical, regulatory and commercial targets respectively, and in aggregate could total over $200 million. Royalty payments are tiered, beginning in the single-digits and increasing to the low double-digits for worldwide net sales of d-DM products exceeding $1 billion annually.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements.

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Management Outlook

We believe that cash and cash equivalents and restricted investments of approximately $69.0 million at March 31, 2012, along with the $30 million from our term loan expected to be funded in June 2012, will be sufficient to sustain our planned level of operations for the next 12 months. However, we cannot provide assurances that our forecasted revenues and planned level of expenditures will not change or will not result in the depletion of capital resources more rapidly than anticipated.

For information regarding the risks associated with our need to raise capital to fund our ongoing and planned operations, please see Part II, Item 1A, Risk Factors.

Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

As described below, we are exposed to market risks related to changes in interest rates. Because substantially all of our revenue, expenses and capital purchasing activities are transacted in U.S. dollars, our exposure to foreign currency exchange rates is immaterial. However, in the future we could face increasing exposure to foreign currency exchange rates as we expand international distribution of docosanol 10% cream and purchase additional services from outside the U.S. Until such time as we are faced with material amounts of foreign currency exchange rate risks, we do not plan to use derivative financial instruments, which can be used to hedge such risks. We will evaluate the use of derivative financial instruments to hedge our exposure as the needs and risks should arise.

Interest rate sensitivity

The primary objective of our investments in securities is to preserve principal. We do not purchase financial instruments for trading purposes. Our investment portfolio consists primarily of cash fixed income instruments invested in government money market funds. We classify our restricted investments, which are primarily certificates of deposit, as of March 31, 2012 as held-to-maturity. These held-to-maturity securities are subject to interest rate risk. Based on our current low yield, any decrease in interest rates is not likely to have a material effect on interest income.

As of March 31, 2012, approximately $13.3 million of our cash and cash equivalents were maintained in three separate money market mutual funds, and approximately $53.4 million of our cash and cash equivalents were maintained at three major financial institutions in the United States. At times, deposits held with the financial institution may exceed the amount of insurance provided by the Federal Deposit Insurance Corporation (FDIC), which provides deposit coverage with limits up to $250,000 per owner. In addition to the basic insurance deposit coverage, the FDIC is providing temporary unlimited coverage for noninterest-bearing transaction accounts from December 31, 2010 through December 31, 2012. At March 31, 2012, such uninsured deposits totaled approximately $61.3 million. Generally, these deposits may be redeemed upon demand and, therefore, are believed to bear minimal risk.

Financial instruments that potentially subject us to concentrations of credit risk consist of cash and cash equivalents and trade receivables. However, we seek to mitigate the risk related to cash and cash equivalents by placing our cash and cash equivalents in various money market mutual funds and at financial institutions of high credit standing. To mitigate the risk related to trade receivables, we perform ongoing credit evaluations of our customers financial condition and would limit the amount of credit extended if necessary; however, we have usually required no collateral.

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Item 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and our Vice President, Finance (our principal financial and accounting officer), of the effectiveness of our disclosure controls and procedures as of the end of the period covered by this report, pursuant to Rules 13a-15(b) and 15d-15(b) under the Securities Exchange Act of 1934, as amended.

In connection with that evaluation, our CEO and Vice President, Finance concluded that our disclosure controls and procedures were effective and designed to provide reasonable assurance that the information required to be disclosed is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission rules and forms as of March 31, 2012. For the purpose of this review, disclosure controls and procedures means controls and procedures designed to ensure that information required to be disclosed by the Company in the reports that we file or submit is recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms. These disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by the Company in the reports that we file or submit is accumulated and communicated to management, including our principal executive officer and principal financial and accounting officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, our management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Changes in Internal Controls over Financial Reporting

There has been no change in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) during our second quarter ended March 31, 2012, that has materially affected, or is reasonably likely to materially affect our internal control over financial reporting.

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PART II OTHER INFORMATION

Item 1. LEGAL PROCEEDINGS

NUEDEXTA ANDA Litigation

In fiscal 2011 and January 2012, we received Paragraph IV certification notices from five separate companies contending that certain of our patents listed in the FDA s publication, Approved Drug Products with Therapeutic Equivalence Evaluation (FDA Orange Book) (U.S. Patents 7,659,282 (282 Patent) and RE 38,115 (115 Patent), which expire in August 2026 and January 2016, respectively) are invalid, unenforceable and/or will not be infringed by the manufacture, use, sale or offer for sale of a generic form of NUEDEXTA as described in those companies ANDAs. The FDA Orange Book provides potential competitors, including generic drug companies, with a list of issued patents covering approved drugs. In August 2011 and March 2012, we filed lawsuits in the U.S District Court for the District of Delaware against Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc. (collectively Par), Actavis South Atlantic LLC and Actavis, Inc. (collectively Actavis), Wockhardt USA, LLC and Wockhardt, Ltd. (collectively, Wockhardt), Impax Laboratories, Inc. (Impax) and Watson Pharmaceuticals, Inc., Watson Laboratories, Inc. and Watson Pharma, Inc. (collectively Watson) (Par, Actavis, Wockhardt,Impax Nd Watson, collectively the Defendants). In March 2012, we also filed a protective suit in the U.S District Court for the District of New Jersey against Watson. All lawsuits (collectively, the ANDA Actions) were filed on the basis that the Defendants submissions of their respective ANDAs to obtain approval to manufacture, use, sell, or offer for sale generic versions of NUEDEXTA prior to the expiration of the 282 Patent and the 115 Patent listed in the FDA Orange Book constitute infringement of one or more claims of those patents.

Pursuant to the provisions of the Hatch-Waxman Act, FDA final approval of the ANDAs submitted by the Defendants can occur no earlier than October 29, 2013. Further, as a result of the 30-month stay associated with the filing of the ANDA Actions, the FDA cannot grant final approval to any ANDA before December 30, 2013, unless there is an earlier court decision holding that the 282 and 115 patents are not infringed and/or are invalid. We intend to vigorously enforce our intellectual property rights relating to NUEDEXTA, but we cannot predict the outcome of these matters.

Alamo and Azur Litigation

In October 2011, Neal R. Cutler, M.D., the founder of Alamo Pharmaceuticals, LLC (Alamo), filed a lawsuit in California Superior Court against Azur Pharma International III Limited and Azur Pharma Limited (collectively, Azur) and Avanir (the Cutler Action). We purchased Alamo in 2006 to acquire rights to FazaClo, an approved anti-psychotic drug. In connection with this acquisition of Alamo, we agreed to provide the Alamo equity holders, including Dr. Cutler, with milestone payments tied to the aggregate net revenues of FazaClo. In 2007, we sold FazaClo and its related assets and operations to Azur. In connection with this sale, Azur agreed to assume the milestone payment obligations due to Dr. Cutler under the Alamo purchase agreement, although we may remain liable for these payments if Azur defaults on these obligations. In the Cutler Action, Dr. Cutler alleges that Azur has failed to make certain sales information available to Dr. Cutler and has withheld payments to which Dr. Cutler is entitled. Dr. Cutler alleges that Avanir has acquiesced in this conduct, and Dr. Cutler seeks to hold both Azur and Avanir liable for these actions. Azur has now agreed to indemnify Avanir in full for the claims asserted in the Cutler Action.

General and Other

In the ordinary course of business, we may face various claims brought by third parties. Any of these claims could subject us to costly litigation. Management believes the outcome of currently identified claims and lawsuits will not have a material adverse effect on our financial condition or results of operations.

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Item 1A. RISK FACTORS

This Quarterly Report on Form 10-Q contains forward-looking information based on our current expectations. Because our actual results may differ materially from any forward-looking statements that we make or that are made on our behalf, this section includes a discussion of important factors that could affect our actual future results, including, but not limited to, our product sales, capital resources, commercial market estimates, safety of NUEDEXTA, future development efforts, patent protection, effects of healthcare reform, reliance on third parties, and other risks set forth below. We disclaim any intent to update forward-looking statements to reflect subsequent developments or actual results.

Risks Relating to Our Business

Our prospects depend on reaching profitability from the commercialization of NUEDEXTA. If we are unable to continue to increase NUEDEXTA revenues, including through raising PBA awareness among patients and physicians, driving higher rates of physician adoption and obtaining reimbursement and third party payer coverage, our ability to generate significant revenue or achieve profitability will be adversely affected.

Although NUEDEXTA has been approved for marketing, our current ability to generate significant revenue is entirely dependent upon our ability to continue the successful commercialization of NUEDEXTA. To continue to be successful we must:

- maintain successful sales, marketing and educational programs for our targeted physicians and other health care providers;
- raise patient and physician awareness of PBA and encourage physicians to screen patients for the condition;
- obtain adequate reimbursement for NUEDEXTA from a broad range of payers; and
- maintain and defend our patent protection and maintain regulatory exclusivity for NUEDEXTA.

Supplying the market for NUEDEXTA requires us to manage relationships with an increasing number of collaborative partners, suppliers and third-party contractors. If we are unable to successfully maintain the required sales and marketing infrastructure, as well as successfully manage an increasing number of relationships, including with suppliers, manufacturers, distributors, insurance carriers and prescribers, we will have difficulty growing our business. In addition, pharmacies, institutions and prescribers may rely on third-party medical information systems to interpret the NUEDEXTA approved product label and guide utilization of NUEDEXTA. If these information systems load incorrect information or misinterpret the approved product label, it may result in lower adoption or utilization than expected. For example, because NUEDEXTA contains quinidine, which is a known pro-arrhythmic drug at antiarrhythmic doses exceeding 600 mg per day, it is possible that medical information systems may incorrectly identify NUEDEXTA as contraindicated or otherwise inappropriate for a patient, even in situations where the risks are substantially less than perceived.

In addition, we may enter into co-promotion or out-licensing arrangements with other pharmaceutical or biotechnology partners where necessary to reach customers in domestic or foreign market segments and when deemed strategically and economically advantageous. To the extent that we enter into co-promotion or other licensing arrangements, our product revenues are likely to be lower than if we directly marketed and sold NUEDEXTA, and some or all of the revenues we receive will depend upon the efforts of third parties, which may not be successful. If we are unable to accomplish any of these key objectives, we may not be able to generate significant product revenue or become profitable.

We have a history of net losses and an accumulated deficit, and we may be unable to generate sufficient revenue to achieve or maintain profitability in the future.

We have experienced significant net losses and negative cash flows from operations and we expect our negative cash flow from operations to continue until we are able to generate significant revenues from sales of NUEDEXTA. As of March 31, 2012, we had an accumulated deficit of approximately $398.3 million. We have incurred these

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losses principally from costs incurred in funding the research, development and clinical testing of our drug candidates, from our general and administrative expenses and from our commercialization activities for NUEDEXTA. We may continue incurring net losses for the foreseeable future and we expect our operating losses to continue for at least the short term as we continue to expand NUEDEXTA sales.

Our ability to generate revenue and achieve profitability is dependent on our ability, alone or with partners, to successfully manufacture and market NUEDEXTA for the treatment of patients with PBA. We expect to continue to spend substantial amounts on the ongoing marketing of NUEDEXTA domestically for the treatment of PBA, as well as seeking regulatory approvals for use of NUEDEXTA in other geographic markets and indications. As a result, we may be unable to generate sufficient revenue from product sales to become profitable or generate positive cash flows.

Certain of our key issued patents are currently being challenged and our pending patent applications may be denied. An adverse outcome in either case would adversely affect our ability to generate significant product revenue or become profitable.

We have invested in an extensive patent portfolio and we rely substantially on the protection of our intellectual property through our ownership or control of issued patents and patent applications. The degree of patent protection that will ultimately be afforded to us in the U.S. and in other important markets remains uncertain and is dependent upon the scope of protection decided upon by the patent offices, courts and lawmakers in these countries. If we cannot prevent others from exploiting claims in our patent portfolio, we will not derive the benefit from it that we currently expect. Further, we may incur substantial expense from litigation to protect our patent portfolio.

The validity, enforceability and scope of our core patents covering NUEDEXTA are currently being challenged as a result of recent abbreviated new drug application (ANDA) filings from generic drug companies. An adverse outcome in the current or any future challenges to the validity, enforceability or scope of our patent portfolio could significantly reduce revenues from NUEDEXTA and any future products. More broadly, investors should be aware that the pharmaceutical industry is highly competitive. Our ability to compete in this space involves various risks relating to our intellectual property, including:

- our patents covering NUEDEXTA may be found to be invalid and unenforceable or insufficiently broad to block the introduction of a generic form of NUEDEXTA;
- the claims in any of our pending patent applications may not be allowed and our patent applications may not be granted;
- competitors may develop similar or superior technologies independently, duplicate our technologies, or design around the patented aspects of our technologies;
- any of our issued patents may not provide us with significant competitive advantages; and
- we may not be able to secure additional worldwide intellectual property protection for our NUEDEXTA patent portfolio.

An adverse outcome with respect to any of these risks could adversely affect our ability to generate significant product revenue or become profitable.

We have received notice of five ANDA filings for NUEDEXTA submitted by generic drug companies. These ANDA filings assert that a generic form of NUEDEXTA would not infringe our issued patents. As a result of these filings, we have commenced litigation to defend our patent rights, which is expected to be costly and time-consuming and, depending on the outcome of the litigation, we may face competition from lower cost generic or follow-on products in the near term.

NUEDEXTA is approved under the provisions of the Federal Food, Drug and Cosmetic Act (FDCA), which renders it susceptible to potential competition from generic manufacturers via the Hatch-Waxman Act and ANDA process. Generic manufacturers pursuing ANDA approval are not required to conduct costly and time-consuming

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clinical trials to establish the safety and efficacy of their products; rather, they are permitted to rely on the innovator s data regarding safety and efficacy. Additionally, generic drug companies generally do not expend significant sums on sales and marketing activities, instead relying on physicians or payers to substitute the generic form of a drug for the branded form. Thus, generic manufacturers can sell their products at prices much lower than those charged by the innovative pharmaceutical or biotechnology companies who have incurred substantial expenses associated with the research and development of the drug product and who must spend significant sums marketing a new drug.

The ANDA procedure includes provisions allowing generic manufacturers to challenge the innovator s patent protection by submitting Paragraph IV certifications to the FDA in which the generic manufacturer claims that the innovator s patent is invalid, unenforceable and/or will not be infringed by the manufacture, use, or sale of the generic product. A patent owner who receives a Paragraph IV certification may choose to sue the generic applicant for patent infringement. In recent years, generic manufacturers have used Paragraph IV certifications extensively to challenge the applicability of patents listed in the FDA s Approved Drug Products List with Therapeutic Equivalence Evaluations, commonly referred to as the Orange Book, on a wide array of innovative therapeutic products. We expect this trend to continue and to affect drug products with even relatively modest revenues.

We have received Paragraph IV certification notices from five separate companies contending that our patents listed in the Orange Book (U.S. Patents 7,659,282 and RE 38,115, which expire in August 2026 and January 2016, respectively) are invalid, unenforceable and/or will not be infringed by the manufacture, use, or sale of a generic form of NUEDEXTA. In response to these notices, we have filed suit against all of the generic drug companies to defend our patent rights.

Pursuant to the provisions of the Hatch-Waxman Act, FDA final approval of the ANDAs submitted by the Defendants can occur no earlier than October 29, 2013. Further, as a result of the 30-month stay associated with the filing of the ANDA actions, the FDA cannot grant final approval to any ANDA before December 30, 2013, unless there is an earlier court decision holding that the 282 and 115 patents are not infringed and/or are invalid.

Although we intend to vigorously enforce our intellectual property rights relating to NUEDEXTA, there can be no assurance that we will prevail in our defense of our patent rights. Our existing patents could be invalidated, found unenforceable or found not to cover a generic form of NUEDEXTA. If an ANDA filer were to receive approval to sell a generic version of NUEDEXTA and/or prevail in any patent litigation, NUEDEXTA would become subject to increased competition and our revenue would be adversely affected.

PBA is a new market and estimates vary significantly over the potential market size and our anticipated revenues over the near and long term.

NUEDEXTA is being made available to patients to treat PBA, an indication for which there was no previously established pharmaceutical market. Industry sources and equity research analysts have a wide divergence of estimates for the near- and long-term market potential of our product. A variety of assumptions directly impact the estimates for our drug s market potential, including estimates of underlying neurologic condition prevalence, severity of PBA prevalence among these conditions, rates of physician adoption of our drug for treatment of PBA among these populations, health plan reimbursement rates, and patient adherence and compliance rates within each underlying neurological condition. Small differences in these assumptions can lead to widely divergent estimates of the market potential of our product. Additionally, although our approved product label is indicated to treat PBA, without regard to the underlying neurological condition, it is possible that physicians, the FDA s Office of Prescription Drug Promotion (OPDP) or others may interpret the label more narrowly than the FDA s Division of Neurology Products approval for a broad PBA label and believe that PBA secondary to certain conditions, such as Alzheimer s disease, is not an indicated use. If such misinterpretations are widespread, the actual market size may be smaller than we have estimated. Accordingly, investors are cautioned not to place undue reliance on any particular estimates of equity research analysts or industry sources.

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Significant safety or drug interaction problems could arise with respect to NUEDEXTA, which could result in restrictions in NUEDEXTA s label, recalls, withdrawal of NUEDEXTA from the market, an adverse impact on potential sales of NUEDEXTA, or cause us to alter or terminate current or future NUEDEXTA clinical development programs, any of which would adversely impact our future business prospects.

Discovery of previously unknown safety or drug interaction problems with an approved product may result in a variety of adverse regulatory actions. This risk may be increased as physicians, at their own discretion, may prescribe NUEDEXTA for off-label uses, which may result in unknown safety or drug interactions. Under the Food and Drug Administration Amendments Act of 2007, the FDA has broad authority to force drug manufacturers to take any number of actions if previously unknown safety or drug interaction problems arise, including, but not limited to: (i) requiring manufacturers to conduct post-approval clinical studies to assess known risks or signals of serious risks, or to identify unexpected serious risks; (ii) mandating labeling changes to a product based on new safety information; or (iii) requiring manufacturers to implement a Risk Evaluation Mitigation Strategy, or REMS, where necessary to assure safe use of the drug. In addition, previously unknown safety or drug interaction problems could result in product recalls, restrictions on the product s permissible uses, or withdrawal of the product from the market.

The combination of dextromethorphan and quinidine has never been marketed for the treatment of any condition until the approval of NUEDEXTA for the treatment of PBA. NUEDEXTA has only been studied in a limited number of patients in clinical trials. The data submitted to the FDA as part of our New Drug Application was obtained in controlled clinical trials of limited duration. In connection with the approval of NUEDEXTA, the FDA has required that we conduct certain post-approval studies, which include non-clinical studies. New safety or drug interaction issues may arise from these studies or as NUEDEXTA is used over longer periods of time by a wider group of patients. For example, elderly patients may be more prone to have multiple risk factors for adverse events such as certain cardiac conditions, hepatic or renal insufficiency, or multi-drug treatment regimens. In addition, as we conduct other clinical trials for AVP-923 in other indications, new safety or drug interaction problems may be identified which could negatively impact both our ability to successfully complete these studies and the use and/or regulatory status of NUEDEXTA for the treatment of PBA. New safety or drug interaction issues may result in product liability lawsuits and may require us to, among other things, provide additional warnings and/or restrictions on the NUEDEXTA prescribing information, including a boxed warning, directly alert healthcare providers of new safety information, narrow our approved indications, or alter or terminate current or planned trials for additional uses of AVP-923, any of which could have a significant adverse impact on potential sales of NUEDEXTA and our ability to achieve or maintain profitability.

In addition, if we are required to conduct additional post-approval clinical studies, implement a REMS, or take other similar actions, such requirements or restrictions could have a material adverse impact on our ability to generate revenues from sales of NUEDEXTA, and/or require us to expend significant additional funds.

We have limited capital resources and may need to raise additional funds to support our operations.

We have experienced significant operating losses due to costs associated with funding the research, development, clinical testing and commercialization of NUEDEXTA and our drug candidates. We expect to continue to incur substantial operating losses for the foreseeable future as we continue to expand our commercialization efforts for NUEDEXTA. Although we had approximately $69.0 million in cash and cash equivalents and restricted investments in marketable securities as of March 31, 2012, we currently do not have sufficient revenue from NUEDEXTA or other sources of recurring revenue or cash flow from operations to sustain our operations and it is possible that we may not be able to achieve profitability with our current capital resources.

In light of our substantial long-term capital needs, we may need to partner our rights to NUEDEXTA (either in the U.S. or outside the U.S.) or raise additional capital in the future to finance our long-term operations, until we are able to generate sufficient revenue from product sales to fund our operations. Based on our current loss rate and existing capital resources as of the date of this report, we estimate that we have sufficient funds to sustain our operations at their current and anticipated levels over the next 12 months, which includes the costs associated with the ongoing commercialization of NUEDEXTA for PBA. Although we expect to be able to raise additional capital if needed, there can be no assurance that we will be able to do so or that the available terms of any financing would be acceptable to us. If we are unable to raise additional capital to fund future operations, we may experience significant delays or cutbacks in the commercialization of NUEDEXTA and may be forced to further curtail our operations.

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If we raise additional capital, we may do so through various financing alternatives, including licensing or sales of our technologies, drugs and/or drug candidates, selling shares of common or preferred stock, through the acquisition of other companies, or through the issuance of debt securities. Each of these financing alternatives carries certain risks.

Raising capital through the issuance of common stock may depress the market price of our stock. Any such financing will dilute our existing stockholders and, if our stock price is relatively depressed at the time of any such offering, the levels of dilution would be greater.

In addition, debt financing, such as the $30 million debt facility that we recently entered into with Oxford Finance, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as encumbering our assets, making capital expenditures or entering into certain licensing transactions. In the case of our loan with Oxford Finance, we have pledged all of our assets, other than our patents and other intellectual property rights, and have agreed that we may not sell or assign rights to our patents and other intellectual property without the prior consent of Oxford. Additionally, we are required under our loan with Oxford Finance to maintain certain levels of liquidity and the introduction of a commercially available generic form of NUEDEXTA may accelerate our repayment obligations. The violation of any of these covenants may give rise to an event of default, which could accelerate our repayment obligations and provide the creditors with certain rights, including the rights to foreclose on any assets that may secure the underlying debt.

If we seek to raise capital through licensing transactions or sales of one or more of our technologies, drugs or drug candidates, as we have previously done with certain investigational compounds and docosanol 10% cream, then we will likely need to share a significant portion of future revenues from these drug candidates with our licensees. Additionally, the development of any drug candidates licensed or sold to third parties will no longer be in our control and thus we may not realize the full value of any such relationships.

We have entered into an agreement to borrow up to $30 million from Oxford Finance (Oxford) and Silicon Valley Bank (SVB). The loan agreement contains certain covenants that could adversely affect our operations and, if an event of default was to occur, we could be forced to repay the outstanding indebtedness sooner than planned and possibly at a time when we do not have sufficient capital to meet this obligation. The occurrence of any of these events could cause a significant adverse impact on our business, prospects and stock price.

Our loan agreement with Oxford and SVB (the Loan Agreement) requires us to maintain a minimum sales level relative to projected NUEDEXTA revenues, measured on a trailing three-month basis, or maintain cash and cash equivalents in accounts subject to control agreements in favor of the collateral agent equal to at least 1.5 times the outstanding amount of obligations under the Loan Agreement. The failure to satisfy both of these tests would result in an event of default, which could accelerate our repayment obligations. Additionally, the Loan Agreement contains affirmative and negative covenants that, among other things restrict our ability to:

- incur additional indebtedness or guarantees;
- incur liens;
- make investments, loans and acquisitions;
- consolidate or merge;
- sell assets, including capital stock of subsidiaries;
- alter the business of the Company;
- engage in transactions with affiliates; and

enter into agreements limiting dividends and distributions of certain subsidiaries.

The Loan Agreement also includes events of default, including, among other things, payment defaults, breaches of representations, warranties or covenants, certain bankruptcy events, the occurrence of certain material adverse changes, and a commercial, generic version of NUEDEXTA (for the treatment of PBA) becoming available. Upon the occurrence of an event of default and following any cure periods (if applicable), a default interest rate of an additional 5.0% per annum may be applied to the outstanding loan balances, and the lenders may declare all outstanding obligations immediately due and payable and take such other actions as set forth in the Loan Agreement.

These terms of the Loan Agreement could prevent us from taking certain actions without the consent of our lenders and, if an event of default should occur, we could be required to immediately repay the outstanding indebtedness. If we are unable to repay this debt, the lenders would be able to foreclose on the secured collateral, including our cash accounts, and take other remedies permitted under the security agreement. Even if we are able to repay the indebtedness on an event of default, the repayment of these sums may significantly reduce our working capital and impair our ability to operate as planned. The occurrence of any of these events could cause a significant adverse impact on our business, prospects and stock price.

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We have licensed or sold most of our non-core drug development programs and related assets and these and other possible future dispositions carry certain risks.

We have entered into agreements for the licensing or sale of our non-core assets, including FazaClo, our anthrax antibody program, and other antibodies in our infectious disease program, as well as docosanol in the U.S. and other markets worldwide. As a result, we do not currently have a diversified pipeline of product candidates and our long-term success is currently dependent on NUEDEXTA. From time to time, we have been and will continue to be engaged in discussions with potential licensing or development partners for NUEDEXTA for PBA and/or AVP-923 for other indications and we may choose to pursue a partnership or license involving NUEDEXTA, if the terms are attractive. Additionally, we may seek to acquire rights to other drugs or technologies. However, all of these transactions involve numerous risks, including:

- diversion of management s attention from normal daily operations of the business;
- disputes over earn-outs, working capital adjustments or contingent payment obligations;
- insufficient proceeds to offset expenses associated with the transactions; and
- the potential loss of key employees following such a transaction.

Transactions such as these carry significant risks where a large portion of the total consideration is contingent upon post-closing events, such as regulatory, commercialization or sales milestones. We may not have control over whether these milestones are met and, if they are not met, then a potentially large portion of the value of the transaction may not be realized. Disputes may also develop over these and other terms, such as representations and warranties, indemnities, earn-outs, and other provisions in the transaction agreements. If disputes are resolved unfavorably, our financial condition and results of operations may be adversely affected and we may not realize the anticipated benefits from the transactions.

Disputes relating to these transactions can lead to expensive and time-consuming litigation and may subject us to unanticipated liabilities or risks, disrupt our operations, divert management s attention from day-to-day operations, and increase our operating expenses. See Item 1. Legal Proceedings for further discussion relating to a lawsuit filed by Neal R. Cutler, M.D., founder of Alamo Pharmaceuticals, LLC.

The FDA s safety concerns regarding our prior formulation of NUEDEXTA, known as AVP-923, for the treatment of PBA extend to other clinical indications that we have been pursuing, including DPN pain. Due to these concerns, any future development of AVP-923 for other indications, including central neuropathic pain in patients with MS, is expected to use an alternative lower-dose quinidine formulation, which may negatively affect efficacy.

We have completed a single Phase III trial for AVP-923 in the treatment of DPN pain. In communications regarding the continued development of AVP-923 for this indication, the FDA has stated that certain safety concerns and questions raised in the PBA approvable letter issued in 2006 necessitate the testing of a low-dose quinidine formulation for the DPN pain indication. Additionally, based on feedback we have received from the FDA on the proposed continued development of AVP-923 for DPN pain, we believe it is likely that two large well-controlled Phase III trials would be needed to support a supplemental NDA filing for this indication. Due to our limited capital resources, we do not expect that we will be able to conduct the trials needed for this indication without additional capital, a development partner for AVN-923 for DPN pain, or a commercialization partner for NUEDEXTA. Moreover, although we achieved positive results in our initial Phase III trial, an alternative low-dose quinidine formulation may not yield the same levels of efficacy as seen in the earlier trials or as predicted based on our subsequent pharmacokinetic study. Any decrease in efficacy may be so great that the drug does not demonstrate a statistically significant improvement over placebo or an active comparator. Additionally, any alternative low-dose quinidine formulation that we develop may not sufficiently satisfy the FDA s safety concerns. If this were to happen, we may not be able to pursue the development of AVP-923 for DPN pain or other indications, including central neuropathic pain in patients with MS and symptoms of agitation in patients with Alzheimer s disease, or may need to undertake significant additional clinical trials, which would be costly and cause potentially substantial delays.

If our products infringe the intellectual property rights of others, we may incur damages and be required to incur the expense of obtaining a license.

Even if we successfully secure our intellectual property rights, third parties, including other biotechnology or pharmaceutical companies, may allege that our technology infringes on their rights. Intellectual property litigation is costly, and even if we were to prevail in such a dispute, the cost of litigation could adversely affect our business, financial condition, and results of operations. Litigation is also time consuming and could divert management s attention and resources away from our operations and other activities. If we were to lose any litigation, in addition to any damages we would have to pay, we could be required to stop the infringing activity or obtain a license. Any required license might not be available to us on acceptable terms, or at all. Some licenses might be non-exclusive, and our competitors could have access to the same technology licensed to us. If we were to fail to obtain a required license or were unable to design around a competitor s patent, we would be unable to sell or continue to develop some of our products, which would have a material adverse effect on our business, financial condition and results of operations.

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We rely on market research to evaluate the potential commercial acceptance of NUEDEXTA.

Based on the results of our market research, we believe that physicians are likely to continue to support the use and adoption of NUEDEXTA for the treatment of PBA. We conduct market research in accordance with Good Marketing Research Practices; however, research findings may not be indicative of the response we might receive from a broader sample of physicians. Moreover, these results are based on physicians impressions formed from a description of the product, and not actual experience from having prescribed the product, which could result in different responses from those same or other physicians. If the actual use and adoption rates of NUEDEXTA are significantly lower than expected, our financial condition and results of operations could be adversely affected.

It is unclear whether we would be eligible for patent-term restoration in the U.S. under applicable law and we therefore do not know whether our patent-term can be extended.

Some of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments. Due to receipt of approval for NUEDEXTA, the Hatch-Waxman Amendments permit a patent restoration term of up to five years for one of our patents covering NUEDEXTA as compensation for the patent term lost during product development and the regulatory review process. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of an NDA, plus the time between the submission date of an NDA and the approval of that application with a maximum of five years. In addition, the patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years after the product s approval date. In December 2011, the U.S. Patent and Trademark Office (USPTO) denied our application for patent term extension on one of our patents and that denial was confirmed in March 2012 by the District Court for the Eastern Division of Virginia.

Market exclusivity provisions under the FDCA, may also delay the submission or the approval of certain applications for competing product candidates. The FDCA provides three years of non-patent marketing exclusivity for an NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application. This three-year exclusivity covers only the conditions associated with the new clinical investigations and does not prohibit the FDA from approving abbreviated NDAs (ANDA) for drugs containing the original active agent.

Once the three-year FDCA exclusivity period has passed and after the patents (including the patent restoration term, if any) that cover NUEDEXTA expire or have been invalidated, generic drug companies would be able to introduce competing versions of the drug. If we are unsuccessful in defending our patents against generic competition, our long-term revenues from NUEDEXTA sales may be significantly less than expected, we may have greater difficulty finding a development partner or licensee for NUEDEXTA and the costs to defend the patents would be significant.

We may be unable to protect our unpatented proprietary technology and information.

In addition to our patented intellectual property, we also rely on trade secrets and confidential information. We may be unable to effectively protect our rights to such proprietary technology or information. Other parties may independently develop or gain access to equivalent technologies or information and disclose it for others to use. Disputes may arise about inventorship and corresponding rights to know-how and inventions resulting from the joint creation or use of intellectual property by us and our corporate partners, licensees, scientific and academic collaborators and consultants. In addition, confidentiality agreements and material transfer agreements we have entered into with these parties and with employees and advisors may not provide effective protection of our proprietary technology or information or, in the event of unauthorized use or disclosure, may not provide adequate remedies. If we fail to protect our trade secrets and confidential information, our business and results of operations could be adversely affected.

If we fail to obtain regulatory approval in foreign jurisdictions, we would not be able to market our products abroad and our revenue prospects would be limited.

We are seeking to have our products or product candidates, including NUEDEXTA, marketed outside the United States. In order to market our products in the European Union and many other foreign jurisdictions, we must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and jurisdictions and can involve additional testing. The time required to obtain approval may differ from that required to obtain FDA approval. The foreign regulatory approval processes may include all of the risks associated with obtaining FDA approval. We may not obtain foreign regulatory approvals on a timely basis, if at all, and may not qualify or be accepted for accelerated review in foreign countries. For example, our development partner in Japan encountered significant difficulty in seeking approval of docosanol in that country and was forced to abandon efforts to seek approval in that country. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or jurisdictions or by the FDA. We may not be able to file for regulatory

approvals and may not receive necessary approvals to commercialize our products in any market. The failure to obtain these approvals could materially adversely affect our business, financial condition and results of operations.

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We face challenges recruiting and retaining members of management and other key personnel.

The industry in which we compete has a high level of employee mobility and aggressive recruiting of skilled employees. This type of environment creates intense competition for qualified personnel, particularly in commercial, clinical and regulatory affairs, research and development and accounting and finance. Because we have a relatively small management team, the loss of any executive officers, including the Chief Executive Officer, key members of senior management or other key employees, could adversely affect our operations.

Future business development activity could disrupt our business and harm our financial condition.

In order to augment our product pipeline or otherwise strengthen our business, we may decide to acquire additional businesses, products and technologies. As we have limited experience in evaluating and completing acquisitions, our ability as an organization to make such acquisitions is unproven. Acquisitions could require significant capital infusions and could involve many risks, including, but not limited to, the following:

- we may have to issue debt or equity securities to complete business development activities, which would dilute our stockholders and could adversely affect the market price of our common stock, and we may issue securities or rights with contingent payment obligations, which could have variable accounting treatment and negative accounting consequences;
- business development activity may negatively impact our results of operations because it may require us to amortize or write down amounts related to goodwill and other intangible assets, or incur or assume substantial debt or liabilities, or it may cause adverse tax or accounting consequences, substantial depreciation or deferred compensation charges;
- we may encounter difficulties in assimilating and integrating the business, products, technologies, personnel or operations of companies that we acquire;
- certain business development activities may impact our relationship with existing or potential partners who are competitive with the acquired business, products or technologies;
- business development activities may require significant capital infusions and the acquired businesses, products or technologies may not generate sufficient value to justify acquisition costs;
- business development activity may disrupt our ongoing business, divert resources, increase our expenses and distract our management;
- business development activities may involve the entry into a geographic or business market in which we have little or no prior experience; and
- key personnel of an acquired company may decide not to work for us.

If any of these risks occurred, it could adversely affect our business, financial condition and operating results. We cannot assure you that we will be able to identify or consummate any future acquisitions on acceptable terms, or at all. If we do pursue any acquisitions, it is possible that we may not realize the anticipated benefits from such acquisitions or that the market may view such acquisitions negatively.

Our operations might be interrupted by the occurrence of a natural disaster or other catastrophic event.

Our principal operations are located in Aliso Viejo, California. We depend on our facilities and on our partners, contractors and vendors for the continued operation of our business. Natural disasters or other catastrophic events, interruptions in the supply of natural resources, political and governmental changes, wildfires and other fires, floods,

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explosions, actions of animal rights activists, earthquakes and civil unrest could disrupt our operations or those of our partners, contractors and vendors. Even though we believe we carry commercially reasonable business interruption and liability insurance, and our contractors may carry liability insurance that protect us in certain events, we might suffer losses as a result of business interruptions that exceed the coverage available under our and our contractors insurance policies or for which we or our contractors do not have coverage. Any natural disaster or catastrophic event could have a significant negative impact on our operations and financial results. However, we have a disaster recovery plan in place for our information technology infrastructure that generally allows us to have our systems operational in as little as four hours of triggering the disaster recovery plan, depending on the severity of the disaster. Moreover, any such event could adversely impact the commercialization of NUEDEXTA and our research and development programs.

Risks Relating to Our Industry

The pharmaceutical industry is highly competitive and most of our competitors have larger operations and have greater resources. As a result, we face significant competitive hurdles.

The pharmaceutical and biotechnology industries are highly competitive and subject to significant and rapid technological change. We compete with hundreds of companies that develop and market products and technologies in areas similar to those in which we are performing our research. For example, we expect that NUEDEXTA may face competition from off-label use of other agents in the treatment of PBA, none of which have proven to be safe and effective for the treatment of PBA. Additionally, NUEDEXTA may face direct competition from a generic form of NUEDEXTA, if approved, as described above.

Our competitors may have specific expertise and development technologies that are better than ours and many of these companies, which include large pharmaceutical companies, either alone or together with their research partners, have substantially greater financial resources, larger research and development capabilities and substantially greater experience than we do. Accordingly, our competitors may successfully develop competing products. We are also competing with other companies and their products with respect to manufacturing efficiencies and marketing capabilities, areas where we have limited or no direct experience.

If we fail to comply with regulatory requirements, regulatory agencies may take action against us, which could significantly harm our business.

Marketed products, along with the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for these products, are subject to continual requirements and review by the FDA and other regulatory bodies. In addition, regulatory authorities subject a marketed product, its manufacturer and the manufacturing facilities to ongoing review and periodic inspections. We are subject to ongoing FDA requirements, including required submissions of safety and other post-market information and reports, registration requirements, current Good Manufacturing Practices (cGMP) regulations, requirements regarding the distribution of samples to physicians and recordkeeping requirements.

The cGMP regulations also include requirements relating to quality control and quality assurance, as well as the corresponding maintenance of records and documentation. We rely on the compliance by our contract manufacturers with cGMP regulations and other regulatory requirements relating to the manufacture of products. We are also subject to state laws and registration requirements covering the distribution of our products. Regulatory agencies may change existing requirements or adopt new requirements or policies. We may be slow to adapt or may not be able to adapt to these changes or new requirements.

We face uncertainty related to healthcare reform, pricing and reimbursement, which could reduce our revenue.

In the United States, President Obama signed in March 2010 the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (collectively, PPACA), which is expected to substantially change the way health care is financed by both governmental and private payers. PPACA provides for changes to extend medical benefits to those who currently lack insurance coverage, encourages improvements in the quality of health care items and services, and significantly impacts the U.S. pharmaceutical industry in a number of ways, further listed below. By extending coverage to a larger population, PPACA may

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substantially change the structure of the health insurance system and the methodology for reimbursing medical services, drugs and devices. These structural changes, as well as other changes that may be made as part of deficit and debt reduction efforts in Congress, could entail modifications to the existing system of private payers and government programs, such as Medicare, Medicaid and State Children s Health Insurance Program, as well as the creation of a government-sponsored healthcare insurance source, or some combination of both. Such restructuring of the coverage of medical care in the United States could impact the extent of reimbursement for prescribed drugs, including our product candidates, biopharmaceuticals, and medical devices. Some of the specific PPACA provisions, among other things:

- Establish annual, non-deductible fees on any entity that manufactures or imports certain branded prescription drugs and biologics;
- Increase minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program;
- Extend manufacturers Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations or extension of statutory rebates to a broader patient population;
- Establish a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research;
- Require manufacturers to participate in a coverage gap discount program, under which they must agree to offer 50 percent point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer s outpatient drugs to be covered under Medicare Part D; and
- Increase the number of entities eligible for discounts under the Public Health Service pharmaceutical pricing program.

If future reimbursement for NUEDEXTA or any other approved product candidates, if any, is substantially less than we project, or rebate obligations associated with them are substantially increased, our business could be materially and adversely impacted.

Sales of NUEDEXTA for treatment of patients with PBA will depend in part on the availability of coverage and reimbursement from third-party payers such as government insurance programs, including Medicare and Medicaid, private health insurers, health maintenance organizations and other health care related organizations. Accordingly, coverage and reimbursement may be uncertain. Adoption of NUEDEXTA by the medical community may be limited if third-party payers will not offer coverage. Cost control initiatives may decrease coverage and payment levels for NUEDEXTA and, in turn, the price that we will be able to charge. We are unable to predict all changes to the coverage or reimbursement methodologies that will be applied by private or government payers to NUEDEXTA. Any denial of private or government payer coverage of NUEDEXTA could harm our business and reduce our revenue.

In addition, both the federal and state governments in the United States and foreign governments continue to propose and pass new legislation affecting coverage and reimbursement policies, which are designed to contain or reduce the cost of health care, as well as hold public hearings on these matters, which has resulted in certain private companies dropping the prices of their drugs. Further federal and state proposals and healthcare reforms are likely, which could limit the prices that can be charged for the product candidates that we develop and may further limit our commercial opportunity. There may be future changes that result in reductions in current coverage and reimbursement levels for our products, if commercialized, and we cannot predict the scope of any future changes or the impact that those changes would have on our operations.

We rely on insurance companies to mitigate our exposure for business activities, including developing and marketing pharmaceutical products for human use.

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The conduct of our business, including the testing, marketing and sale of pharmaceutical products, involves the risk of liability claims by consumers, stockholders, and other third parties. Although we maintain various types of insurance, including product liability and director and officer liability, claims can be high and our insurance may not sufficiently cover our actual liabilities. If liability claims were made against us, it is possible that our insurance carriers may deny, or attempt to deny, coverage in certain instances. If a lawsuit against us is successful, then the lack or insufficiency of insurance coverage could materially and adversely affect our business and financial condition. Furthermore, various distributors of pharmaceutical products require minimum product liability insurance coverage before their purchase or acceptance of products for distribution. Failure to satisfy these insurance requirements could impede our ability to achieve broad distribution of our products and the imposition of higher insurance requirements could impose additional costs on us. Additionally, we are potentially at risk if our insurance carriers become insolvent. Although we have historically obtained coverage through highly rated and capitalized firms, there can be no assurance that we will be able to maintain coverage under existing policies at the current rates or purchase insurance under new policies at reasonable rates.

If we market products in a manner that violates health care fraud and abuse laws, we may be subject to civil and criminal penalties.

We are subject to healthcare fraud and abuse regulation and enforcement by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include:

- the federal healthcare programs Anti-Kickback Law, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;

- federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payers that are false or fraudulent;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters; and

- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payer, including commercial insurers.

If our operations are found to be in violation of any of the laws described above or any other domestic or foreign laws or governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from governmental health care programs, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results. The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Further, the recently enacted PPACA, among other things, amends the intent requirement of the federal anti-kickback and criminal health care fraud statutes. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, the PPACA provides that the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the false claims statutes. Moreover, some states, such as California, Massachusetts and Vermont, mandate implementation of commercial compliance programs to ensure compliance with these laws. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management s attention from the operation of our business.

In addition, there has been a recent trend of increased federal and state regulation of payments made to physicians for marketing, including the tracking and reporting of gifts, compensation, and other remuneration to physicians. The shifting commercial compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance and/or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements.

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The PPACA also imposes new reporting and disclosure requirements on drug manufacturers for any transfer of value made or distributed to prescribers and other healthcare providers, effective March 31, 2013. Such information will be made publicly available in a searchable format beginning September 30, 2013. In addition, drug manufacturers will also be required to report and disclose any investment interests held by physicians and their immediate family members during the preceding calendar year. Failure to submit required information may result in civil monetary penalties of up to an aggregate of $150,000 per year (and up to an aggregate of $1 million per year for knowing failures), for all payments, transfers of value or ownership or investment interests not reported in an annual submission. Finally, under PPACA, effective April 1, 2012, pharmaceutical manufacturers and distributors must provide the U.S. Department of Health and Human Services with an annual report on the drug samples they provide to physicians.

We may incur significant liability if it is determined that we are promoting the off-label use of drugs.

The Company has taken numerous steps to ensure compliance is a high priority throughout the organization and we believe that all of our communications regarding all of our products are in compliance with the relevant regulatory requirements, however, the FDA or another regulatory authority may disagree, and we may be subject to significant liability, including civil and administrative remedies, as well as criminal sanctions. In addition, management s attention could be diverted from our business operations and our reputation could be damaged. Our distribution and contracting partners may also be the subject of regulatory investigations involving, or remedies or sanctions for, off-label promotion of products we have licensed to them, or for which they provide vendor support services, which may have an adverse impact on sales of such licensed products, or indemnification obligations. which may, in turn, have a material adverse effect on our business, financial condition and results of operations and could cause the market value of our common shares to decline.

Companies may not promote drugs for off-label uses that is, uses that are not described in the product s labeling and that differ from those approved by the FDA or other applicable regulatory agencies. Physicians may prescribe drug products for off-label uses, and such off-label uses are common across medical specialties. Although the FDA and other regulatory agencies do not regulate a physician s choice of treatments, the FDA and other regulatory agencies do restrict communications by pharmaceutical companies and their sales representatives regarding dissemination of information concerning off-label use. The FDA and other regulatory agencies actively enforce regulations prohibiting promotion of product for off-label uses and the promotion of products for which marketing authorization has not been obtained. A company that is found to have promoted product for off-label uses may be subject to significant liability, including civil and administrative remedies as well as criminal sanctions. Notwithstanding the regulatory restrictions on off-label promotion, the FDA and other regulatory authorities allow companies to engage in truthful, non-misleading, and non-promotional scientific exchange concerning their products.

There are a number of difficulties and risks associated with clinical trials and our trials may not yield the expected results.

There are a number of difficulties and risks associated with conducting clinical trials. For instance, we may discover that a product candidate does not exhibit the expected therapeutic results, may cause harmful side effects or have other unexpected characteristics that may delay or preclude regulatory approval or limit commercial use if approved. It typically takes several years to complete a late-stage clinical trial and a clinical trial can fail at any stage of testing. If clinical trial difficulties or failures arise, our product candidates may never be approved for sale or become commercially viable.

In addition, the possibility exists that:

- the results from earlier clinical trials may not be predictive of results that will be obtained from subsequent clinical trials, particularly larger trials;

- institutional review boards or regulators, including the FDA, may hold, suspend or terminate our clinical research or the clinical trials of our product candidates for various reasons, including noncompliance with regulatory requirements or if, in their opinion, the participating subjects are being exposed to unacceptable health risks;

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subjects may drop out of our clinical trials;

our preclinical studies or clinical trials may produce negative, inconsistent or inconclusive results, and we may decide, or regulators may require us, to conduct additional preclinical studies or clinical trials;

trial results derived from top-line data, which is based on a preliminary analysis of efficacy and safety data related to primary and secondary endpoints, may change following a more comprehensive review of the complete data set derived from a particular clinical trial or may change due to FDA requests to analyze the data differently; and

the cost of our clinical trials may be greater than we currently anticipate.

It is possible that earlier clinical and pre-clinical trial results may not be predictive of the results of subsequent clinical trials. If earlier clinical and/or pre-clinical trial results cannot be replicated or are inconsistent with subsequent results, our development programs may be cancelled or deferred. In addition, the results of these prior clinical trials may not be acceptable to the FDA or similar foreign regulatory authorities because the data may be incomplete, outdated or not otherwise acceptable for inclusion in our submissions for regulatory approval.

Additionally, the FDA has substantial discretion in the approval process and may reject our data, disagree with our interpretations of regulations, draw different conclusions from our clinical trial data or ask for additional information at any time during their review.

Although we would work to be able to fully address any such FDA concerns, we may not be able to resolve all such matters favorably, if at all. Disputes that are not resolved favorably could result in one or more of the following:

delays in our ability to submit an NDA;

the refusal by the FDA to accept for filing any NDA we may submit;

requests for additional studies or data;

delays in obtaining an approval;

the rejection of an application; or

the approval of the drug, but with adverse labeling claims that could adversely affect the commercial market.

If we do not receive regulatory approval to sell our product candidates or cannot successfully commercialize our product candidates, we may not be able to generate sufficient revenues or achieve or maintain profitability.

We have acquired rights to a potential second-generation formulation of AVP-923, utilizing a deuterated form of dextromethorphan (d-DM). It is possible that studies of d-DM may not produce favorable results, and even if studies do produce favorable data, we may not be able to rely on prior pre-clinical and clinical data from the development of AVP-923 to shorten the development timing or lessen our development costs.

We have licensed from Concert exclusive, worldwide rights to develop and commercialize Concert s deuterium-modified dextromethorphan (d-DM) compounds for the potential treatment of neurologic and psychiatric disorders, as well as certain rights to other deuterium-modified dextromethorphan compounds. The goal of the d-DM program is to provide therapeutically effective levels of dextromethorphan, similar to those observed with AVP-923, without the need for an enzyme inhibitor such as quinidine. Although we believe that a d-DM formulation with

lower levels of quinidine has the potential of having a similar pharmacokinetic and pharmocodynamic (PK/PD) profile to AVP-923, it is possible that we will not be able to significantly reduce the levels of quinidine in a d-DM formulation in order to maintain the necessary therapeutic effect of DM.

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The d-DM formulation would have the same pharmacology as AVP-923 and may have a similar PK/PD profile, and therefore, may have an expedited regulatory path. However, there is no assurance that we would be able to rely on prior AVP-923 pre-clinical or clinical data as we pursue the development of a potential d-DM formulation. Consequently, we may be required to pursue a full development program, including conducting pre-clinical and clinical studies necessary to establish the safety and efficacy of a d-DM formulation. These development activities would significantly increase the cost of development and length of time required before we could seek regulatory approval of a d-DM product.

Additionally, we will be dependent on Concert for the transfer and development of certain technology necessary for the manufacture of d-DM. Concert is a new development partner for us; accordingly, we do not have established channels for technology transfer, and developing these channels may take longer or be more costly than we anticipate. Further, we have agreed with Concert to establish a joint steering committee to facilitate the development of products, which will give Concert input on the development process for a period of time. As a result, our success depends partially on the success of Concert in performing its responsibilities.

Risks Related to Reliance on Third Parties

We depend on third parties to manufacture, package and distribute compounds for our drugs and drug candidates. The failure of these third parties to perform successfully could harm our business.

We have utilized, and intend to continue utilizing, third parties to manufacture, package and distribute NUEDEXTA and the active pharmaceutical ingredient (API) for docosanol 10% cream and to provide clinical supplies of our drug candidates. We have no experience in manufacturing and do not have any manufacturing facilities. Currently, we have sole suppliers for the API for docosanol and NUEDEXTA, and a sole manufacturer for the finished form of NUEDEXTA. In addition, these materials are custom and available from only a limited number of sources. In particular, there may be a limited supply source for APIs in NUEDEXTA. Although we maintain a significant supply of APIs on hand, any sustained disruption in this supply could adversely affect our operations and revenues. Any material disruption in manufacturing could cause a delay in shipments and possible loss of sales. We do not have any long-term agreements in place with our current docosanol supplier or NUEDEXTA API suppliers. If we are required to change manufacturers, we may experience delays associated with finding an alternate manufacturer that is properly qualified to produce supplies of our products and product candidates in accordance with FDA requirements and our specifications. Any delays or difficulties in obtaining APIs or in manufacturing, packaging or distributing NUEDEXTA could negatively affect our sales revenues, as well as delay our clinical trials of AVP-923 for DPN pain, MS-related pain or other potential indications. The third parties we rely on for manufacturing and packaging are also subject to regulatory review, and any regulatory compliance problems with these third parties could significantly delay or disrupt our commercialization activities. Additionally, macro-economic conditions may adversely affect these third parties, causing them to suffer liquidity or operational problems. If a key third party vendor becomes insolvent or is forced to lay off workers assisting with our projects, our results and development timing could suffer.

Because we depend on clinical research centers and other contractors for clinical testing and for certain research and development activities, the results of our clinical trials and such research activities are, to a certain extent, beyond our control.

The nature of clinical trials and our business strategy of outsourcing a substantial portion of our research require that we rely on clinical research centers and other contractors to assist us with research and development, clinical testing activities, patient enrollment and regulatory submissions to the FDA. As a result, our success depends partially on the success of these third parties in performing their responsibilities. Although we pre-qualify our contractors and we believe that they are fully capable of performing their contractual obligations, we cannot directly control the adequacy and timeliness of the resources and expertise that they apply to these activities. Additionally, macro-economic conditions may affect our development partners and vendors, which could adversely affect their ability to timely perform their tasks. If our contractors do not perform their obligations in an adequate and timely manner, the pace of clinical development, regulatory approval and commercialization of our drug candidates could be significantly delayed and our prospects could be adversely affected.

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We generally do not control the development of compounds licensed to third parties and, as a result, we may not realize a significant portion of the potential value of any such license arrangements.

Under our typical license arrangement we have no direct control over the development of drug candidates and have only limited, if any, input on the direction of development efforts. These development efforts are made by our licensing partner, and if the results of their development efforts are negative or inconclusive, it is possible that our licensing partner could elect to defer or abandon further development of these programs. We similarly rely on licensing partners to obtain regulatory approval for docosanol in foreign jurisdictions. Because much of the potential value of these license arrangements is contingent upon the successful development and commercialization of the licensed technology, the ultimate value of these licenses will depend on the efforts of licensing partners. If our licensing partners do not succeed in developing the licensed technology for whatever reason, or elect to discontinue the development of these programs, we may be unable to realize the potential value of these arrangements. If we were to license NUEDEXTA to a third party or a development partner, it is likely that much of the long-term success of that drug will similarly depend on the efforts of the licensee.

We expect to rely entirely on third parties for international registration, sales and marketing efforts.

In the event that we attempt to enter into international markets, in some instances we expect to rely on collaborative partners to obtain regulatory approvals and to market and sell our product(s) in those markets. We have not yet entered into any collaborative arrangement with respect to marketing or selling NUEDEXTA, with the exception of one such agreement relating to Israel. We may be unable to enter into any other arrangements on terms favorable to us, or at all, and even if we are able to enter into sales and marketing arrangements with collaborative partners, we cannot assure you that their sales and marketing efforts will be successful. If we are unable to enter into favorable collaborative arrangements with respect to marketing or selling NUEDEXTA in international markets, or if our collaborators efforts are unsuccessful, our ability to generate revenues from international product sales will suffer.

Risks Relating to Our Stock

Our stock price has historically been volatile and we expect that this volatility will continue for the foreseeable future.

The market price of our common stock has been, and is likely to continue to be, highly volatile. This volatility can be attributed to many factors independent of our operating results, including the following:

- comments made by securities analysts, including changes in their recommendations;
- short selling activity by certain investors, including any failures to timely settle short sale transactions;
- announcements by us of financing transactions and/or future sales of equity or debt securities;
- sales of our common stock by our directors, officers or significant stockholders, including sales effected pursuant to predetermined trading plans adopted under the safe-harbor afforded by Rule 10b5-1;
- regulatory developments in the U.S. and foreign countries, including the passage of laws, rules or regulations relating to healthcare and reimbursement or the public announcement of inquiries relating to these subjects;
- lack of volume of stock trading leading to low liquidity; and
- market and economic conditions.

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If a substantial number of shares are sold into the market at any given time, particularly following any significant announcements or large swings in our stock price (whether sales are under our existing shelf registration statements, from an existing stockholder, or the result of warrant or stock options exercised), there may not be sufficient demand in the market to purchase the shares without a decline in the market price for our common stock. Moreover, continuous sales into the market of a number of shares in excess of the typical trading volume for our common stock, or even the availability of such a large number of shares, could depress the trading market for our common stock over an extended period of time.

Additionally, our stock price has been volatile as a result of announcements of regulatory actions and decisions relating to NUEDEXTA, and periodic variations in our operating results. We expect that our operating results will continue to vary from quarter to quarter, particularly as we continue to market NUEDEXTA and report sales results. Our operating results and prospects may also vary depending on the status of our partnering arrangements.

As a result of these factors, we expect that our stock price may continue to be volatile and investors may be unable to sell their shares at a price equal to, or above, the price paid. Additionally, any significant drops in our stock price could give rise to stockholder lawsuits, which are costly and time consuming to defend against and which may adversely affect our ability to raise capital while the suits are pending, even if the suits are ultimately resolved in favor of the Company. We have, from time to time, been a party to such suits and although none have been material to date, there can be no assurance that any such suit will not have an adverse effect on the Company.

If our internal controls over financial reporting are not considered effective, our business and stock price could be adversely affected.

Section 404 of the Sarbanes-Oxley Act of 2002 requires us to evaluate the effectiveness of our internal controls over financial reporting as of the end of each fiscal year, and to include a management report assessing the effectiveness of our internal controls over financial reporting in our annual report on Form 10-K for that fiscal year. Section 404 also requires our independent registered public accounting firm to attest to, and report on, management s assessment of our internal controls over financial reporting, and we again became subject to these requirements starting with the year ended September 30, 2010.

Our management, including our chief executive officer and principal financial officer, does not expect that our internal controls over financial reporting will prevent all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system s objectives will be met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud involving a company have been, or will be, detected. The design of any system of controls is based in part on certain assumptions about the likelihood of future events, and we cannot assure you that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become ineffective because of changes in conditions or deterioration in the degree of compliance with policies or procedures. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected. We cannot assure you that we or our independent registered public accounting firm will not identify a material weakness in our internal controls in the future. A material weakness in our internal controls over financial reporting would require management and our independent registered public accounting firm to consider our internal controls as ineffective. If our internal controls over financial reporting are not considered effective, we may experience a loss of public confidence, which could have an adverse effect on our business and on the market price of our common stock.

Because we do not expect to pay dividends in the foreseeable future, you must rely on stock appreciation for any return on your investment.

We have paid no cash dividends on our common stock to date, and we currently intend to retain our future earnings, if any, to fund the development and growth of our business. As a result, we do not expect to pay any cash dividends in the foreseeable future, and payment of cash dividends, if any, will also depend on our financial condition, results of operations, capital requirements and other factors and will be at the discretion of our board of directors. Furthermore, we may in the future become subject to contractual restrictions on, or prohibitions against, the payment of dividends. Accordingly, the success of your investment in our common stock will likely depend entirely upon any future appreciation. There is no guarantee that our common stock will appreciate in value or even maintain the price at which you purchased your shares, and you may not realize a return on your investment in our common stock.

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Our corporate governance documents, rights agreement and Delaware law may delay or prevent an acquisition of us that stockholders may consider favorable, which could decrease the value of our common stock.

Our certificate of incorporation and bylaws and Delaware law contain provisions that could make it more difficult for a third party to acquire us without the consent of our board of directors. These provisions include restrictions on the ability of our stockholders to remove directors and supermajority voting requirements for stockholders to amend our organizational documents and a classified board of directors. In addition, our board of directors has the right to issue preferred stock without stockholder approval, which could be used to dilute the stock ownership of a potential hostile acquirer. Delaware law, for instance, also imposes some restrictions on mergers and other business combinations between any holder of 15% or more of our outstanding common stock and us. Although we believe these provisions protect our stockholders from coercive or otherwise unfair takeover tactics and thereby provide for an opportunity to receive a higher bid by requiring potential acquirers to negotiate with our board of directors, these provisions apply even if the offer may be considered beneficial by some stockholders. We have also adopted a stockholder rights agreement intended to deter hostile or coercive attempts to acquire us. Under the agreement, if a person becomes an acquiring person, each holder of a right (other than the acquiring person) will be entitled to purchase, at the then-current exercise price, such number of shares of our preferred stock which are equivalent to shares of common stock having twice the exercise price of the right. If we are acquired in a merger or other business combination transaction after any such event, each holder of a right will then be entitled to purchase, at the then-current exercise price, shares of the acquiring company s common stock having a value of twice the exercise price of the right. Our stockholder rights agreement could make it more difficult for a third party to acquire, or could discourage a third party from acquiring, us or a large block of our common stock without the support of our board of directors. Therefore, the agreement makes an acquisition much more costly to a potential acquirer.

Item 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Not applicable.

Item 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

Item 5. OTHER INFORMATION

None.

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Item 6. EXHIBITS

Exhibits

10.1	Form of Indemnification Agreement with certain Directors and Executive Officers of the Registrant
31.1	Certification of Principal Executive Officer Required Under Rule 13a-14(a) of the Securities Exchange Act of 1934, as amended.
31.2	Certification of Principal Financial Officer Required Under Rule 13a-14(a) of the Securities Exchange Act of 1934, as amended.
32.1	Certification of Principal Executive Officer and Principal Financial Officer Required Under Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. 1350.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Calculation Linkbase Document
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

The XBRL information is deemed furnished and not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities and Exchange Act of 1933, as amended, is deemed not filed for purposes of Section 18 of the Securities and Exchange Act of 1934, as amended, and otherwise is not subject to liability under these Sections.

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SIGNATURES

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

Signature	Title	Date
/s/ *KEITH A. KATKIN*	President and Chief Executive Officer	May 9, 2012
Keith A. Katkin	(Principal Executive Officer)	
/s/ *CHRISTINE G. OCAMPO*	Vice President, Finance	May 9, 2012
Christine G. Ocampo	(Principal Financial Officer and Principal Accounting Officer)	