ZOGENIX, INC.
Form 424B4
November 23, 2010

Filed Pursuant to Rule 424(b)(4)
Registration No. 333-169210

PROSPECTUS

14,000,000 Shares

Common Stock

This is an initial public offering of Zogenix, Inc. We are offering 14,000,000 shares of our common stock. The initial public offering price of our common stock is $4.00 per share.

Prior to this offering there has been no public market for our common stock. Our common stock has been approved for listing on The NASDAQ Global Market under the symbol ZGNX.

Investing in our common stock involves risks. See Risk Factors beginning on page 10.

	Per Share	Total
Initial price to public	$ 4.00	$ 56,000,000
Underwriting discounts and commissions from shares offered to certain of our current stockholders(1)	$ 0.0981	$ 700,326
Proceeds, before expenses, to Zogenix, Inc. from shares offered to certain of our current stockholders(1)	$ 3.9019	$ 27,855,254
Underwriting discounts and commissions from shares offered to the public(1)	$ 0.28	$ 1,921,109
Proceeds, before expenses, to Zogenix, Inc. from shares offered to the public(1)	$ 3.72	$ 25,523,311

(1) Assumes that certain of our current stockholders purchase an aggregate of 7,138,895 shares of our common stock in this offering as described below.

We have granted the underwriters an option to purchase up to 2,100,000 additional shares of our common stock to cover over-allotments, if any, exercisable at any time until 30 days after the date of this prospectus.

Certain of our current stockholders have indicated an interest in purchasing an aggregate of 7,138,895 shares of our common stock in this offering at the initial public offering price. Although we anticipate that these current stockholders will purchase, and that the underwriters will sell to these current stockholders, all of these shares, indications of interest are not binding agreements or commitments to purchase and these current stockholders may determine to purchase less or no shares in this offering and the underwriters may determine to sell less or no shares in this offering to these current stockholders.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

The underwriters expect to deliver the shares on or about November 29, 2010.

Wells Fargo Securities **Leerink Swann**

Oppenheimer & Co. **Stifel Nicolaus Weisel**

Prospectus dated November 22, 2010.

We launched our first product, Sumavel DosePro , using our proprietary DosePro technology in January 2010.

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You should rely only on the information contained in this prospectus and in any free writing prospectus that we may provide to you in connection with this offering. Neither we nor any of the underwriters has authorized anyone to provide you with information different from, or in addition to, that contained in this prospectus or any such free writing prospectus. If anyone provides you with different or inconsistent information, you should not rely on it. Neither we nor any of the underwriters is making an offer to sell or seeking offers to buy these securities in any jurisdiction where or to any person to whom the offer or sale is not permitted. The information in this prospectus is accurate only as of the date on the front cover of this prospectus and the information in any free writing prospectus that we may provide you in connection with this offering is accurate only as of the date of that free writing prospectus. Our business, financial condition, results of operations and prospects may have changed since those dates.

For investors outside the United States: Neither we nor any of the underwriters has done anything that would permit this offering or possession or distribution of this prospectus or any free writing prospectus we may provide to you in connection with this offering in any jurisdiction where action for that purpose is required, other than in the United States. You are required to inform yourselves about and to observe any restrictions relating to this offering and the distribution of this prospectus and any such free writing prospectus outside of the United States.

PROSPECTUS SUMMARY

This summary does not contain all of the information you should consider before buying shares of our common stock. You should read the entire prospectus carefully, especially the Risk Factors section and our financial statements and the related notes appearing at the end of this prospectus, before deciding to invest in shares of our common stock. Unless the context requires otherwise, references in this prospectus to Zogenix, we, us and our refer to Zogenix, Inc., including, as of June 7, 2010, its consolidated subsidiary.

Overview

We are a pharmaceutical company commercializing and developing products for the treatment of central nervous system disorders and pain. Our first commercial product, Sumavel DosePro (*sumatriptan* injection) Needle-free Delivery System, was launched in January 2010. Sumavel DosePro offers fast-acting, easy-to-use, needle-free subcutaneous administration of *sumatriptan* for the acute treatment of migraine and cluster headache in a pre-filled, single-use delivery system. Sumavel DosePro is the first drug product approved by the U.S. Food and Drug Administration, or FDA, that allows for the needle-free, subcutaneous delivery of medication. Our lead product candidate, ZX002, is a novel, oral, single-entity controlled-release formulation of *hydrocodone* currently in Phase 3 clinical trials for the treatment of moderate to severe chronic pain in patients requiring around-the-clock opioid therapy. Sumavel DosePro and ZX002 each has the potential to address significant unmet medical needs and become important and widely-used additions to the treatment options available to patients and physicians in the United States multi-billion dollar migraine and chronic pain markets, respectively.

Sumavel DosePro may offer a faster-acting and more efficacious treatment alternative to oral and nasal triptans and simple, convenient administration when compared to traditional, needle-based *sumatriptan* injection. According to its Prescribing Information, Sumavel DosePro can provide onset of migraine pain relief in as little as ten minutes for some patients. As a result, we believe that Sumavel DosePro has the potential to be prescribed by a broad physician audience, especially for difficult to treat migraine episodes.

Migraine is a syndrome that affects approximately 30 million people in the United States, according to a 2010 National Headache Foundation press release. Triptans are the class of drugs most often prescribed for treating migraines. In the United States in the 12 months ended June 2010, triptans generated sales of approximately $3.45 billion and s*umatriptan*, including branded and generic forms, represented the biggest market share of the seven approved triptans, with sales of approximately $1.97 billion, according to Wolters Kluwer Pharma Solutions (Source® PHAST Institution/Retail).

We launched the commercial sale of Sumavel DosePro in the United States in January 2010 with our co-promotion partner, Astellas Pharma US, Inc., or Astellas. Our sales and marketing organization is comprised of approximately 100 professionals. Our field sales force of approximately 80 representatives is promoting Sumavel DosePro primarily to neurologists and other key prescribers of migraine medications, including headache clinics and headache specialists. Our promotional efforts are complemented by our collaboration with Astellas and approximately 400 of its sales representatives, who are promoting Sumavel DosePro primarily to primary care physicians, OB/GYNs, emergency medicine physicians and urologists in the United States. We also have entered into a partnership for Sumavel DosePro with Desitin Arzneimittel GmbH to accelerate development and regulatory approvals in Europe and further enhance the global commercial potential of Sumavel DosePro.

Sumavel DosePro has demonstrated consistent monthly growth in total prescriptions since its launch in January 2010. The product continues to add new and repeat prescribers in both the neurology and primary care settings, including a significant number of prescribers who had not prescribed needle-based *sumatriptan* injection in the prior 12 months. The product is gaining use from a range of

patient segments, including new triptan users, patients being converted to the product from other migraine drugs and patients who have been prescribed Sumavel DosePro and also have other triptan prescriptions. This experience is consistent with our belief that many patients will selectively use Sumavel DosePro for their more challenging migraine episodes, while continuing to use oral triptans to treat their less severe migraine episodes. Through our ongoing efforts with the largest commercial health plans, Sumavel DosePro is achieving broad coverage in the United States, with a reimbursement claims approval rate of approximately 78% since launch (Source® Dynamic Claims January 2010 August 2010). Total gross sales of Sumavel DosePro through September 30, 2010 were $16.4 million. For the same period, we recognized $11.8 million in net product revenue from these sales, represented by more than 21,800 aggregate dispensed prescriptions. Weekly prescribing data shows that more than 5,600 physicians have prescribed Sumavel DosePro. (Source® PHAST Retail January 2010 September 2010 and Source® LaunchTrac week ended January 15, 2010 week ended October 1, 2010)

Our lead product candidate, ZX002, is a novel, oral, single-entity controlled-release formulation of *hydrocodone* currently in Phase 3 clinical trials for the treatment of moderate to severe chronic pain in patients requiring around-the-clock opioid therapy. ZX002 utilizes Elan Pharma International Limited s, or Elan s, proprietary Spheroidal Oral Drug Absorption System, or SODAS® technology, which serves to enhance the release profile of *hydrocodone* to provide consistent 12-hour pain relief relative to existing immediate-release combination formulations. Most marketed *hydrocodone* products contain the analgesic combination ingredient *acetaminophen,* which if taken in high quantities over time can cause liver toxicity. In June 2009, the FDA organized a joint advisory committee meeting that highlighted the public health problem of liver injury related to the use of *acetaminophen* in both over-the-counter and prescription products. ZX002, if approved, may represent the first available controlled-release version of *hydrocodone* and also the first *hydrocodone* product that is not combined with another analgesic. As a result, we believe ZX002 could generate sales from both patients who are using immediate-release opioid products on a chronic basis and patients already using extended-release opioids. We initiated the Phase 3 clinical development program for ZX002 in March 2010 and, if successful, expect to submit a New Drug Application with the FDA by early 2012. We in-licensed exclusive U.S. rights to ZX002 from Elan in 2007.

The American Pain Society estimated in 1999 that 9% of the U.S. adult population suffers from moderate to severe non-cancer related chronic pain. Chronic pain can be treated with both immediate-release and extended-release opioids. We define our target market for ZX002 as prescription, non-injectable *codeine*-based and extended-release *morphine*-based pain products. This market generated U.S. sales of approximately $13.0 billion for the 12 months ended June 2010, based on average wholesale price, on approximately 202 million prescriptions. During the same period, existing *hydrocodone* products, the most commonly prescribed pharmaceutical products in the United States, generated $3.1 billion in sales on approximately 126 million prescriptions. (Source® PHAST Retail). We believe ZX002 has the potential to be an important therapeutic alternative to existing *hydrocodone* products, including the branded product Vicodin and its generic equivalents.

Our DosePro technology is a novel, patent-protected, needle-free drug delivery system designed for self-administration of a pre-filled, single dose of liquid drug. We believe the FDA s approval of Sumavel DosePro represents an important validation of the technology. Results from our pre-clinical and clinical studies demonstrate that DosePro can be used successfully with small molecules and biological products, including protein therapeutics and monoclonal antibodies. We are building our internal product pipeline by investigating proven drugs that can be paired with DosePro to enhance their benefits and commercial attractiveness. Specifically, we have initiated pre-clinical development on a proprietary long-acting formulation of an injectable central nervous system, or CNS, drug product and are also evaluating the market potential, formulation requirements and clinical development pathway of an additional CNS compound that could be paired with DosePro to enhance its commercial

attractiveness. If these efforts are successful, we may be able to submit an Investigational New Drug Application for one or both product candidates in 2011. We are also seeking to capitalize on our DosePro technology by out-licensing it to potential partners enabling them to enhance, differentiate or extend the life cycle of their proprietary injectable products. We acquired the DosePro technology and related intellectual property from Aradigm Corporation in August 2006.

Our management team has a proven clinical, regulatory, business development and commercialization track record at Zogenix and prior organizations, as well as significant expertise in CNS disorders and pain. Since our inception in 2006, our management team has successfully acquired, developed, obtained regulatory approval for and launched the commercial sale of Sumavel DosePro and completed a significant primary care co-promotion agreement in the United States and secured a European partnership for the product. We also completed an in-licensing transaction and initiated Phase 3 development for our ZX002 product candidate.

Sumavel DosePro Market Experience to Date

Selected market highlights since we launched Sumavel DosePro in January 2010 include:

Prescription Trends. Monthly prescription data shows that more than 21,800 aggregate prescriptions of Sumavel DosePro have been dispensed and that monthly total prescriptions have increased in each month since launch. In September 2010, more than 3,500 total prescriptions were dispensed and nearly 31% of total prescriptions were classified as refill prescriptions. (Source® PHAST Retail January 2010 September 2010)

Prescriber Base. Weekly prescribing data shows that more than 5,600 physicians have prescribed Sumavel DosePro, of whom a growing proportion are now repeat prescribers (Source LaunchTrac week ended January 15, 2010 week ended October 1, 2010). In addition, 32% of Sumavel DosePro prescribers had not written a prescription for needle-based *sumatriptan* injection in the previous 12 months and an additional 35% of prescribers had written, on average, less than one prescription per month for needle-based *sumatriptan* injection. (Source® LaunchTrac week ended January 15, 2010 week ended July 30, 2010)

Patient Dynamics. Analysis of patient data indicates that approximately 34% of patients filling a Sumavel DosePro prescription were new to the triptan market (i.e., had not filled a triptan prescription in the prior 18 months), approximately 34% had active prescriptions for Sumavel DosePro and at least one additional triptan and approximately 16% of patients had converted to Sumavel DosePro from another triptan. The remaining approximately 16% of patients were continuing users of Sumavel DosePro. Importantly, of the patients who converted from another triptan, 77% converted from oral triptans, including tablets and melt formulations. (Source® Lx PTA January 2010 August 2010)

Patients Experience. Patients experience with Sumavel DosePro has been positive based on feedback provided via the Connects Program from Infomedics. This internet-based program invites patients that received a Sumavel DosePro prescription to register online at the time of their prescription and then provide feedback after they have used the product to treat a migraine episode. Through September 11, 2010, 1,071 patient respondents who had used Sumavel DosePro have rated their satisfaction with Sumavel DosePro at an average score of 7.1 versus 5.5 for their prior migraine medication (9-point satisfaction scale, with 9 being very satisfied).

Investment Highlights

We believe we are differentiated by the unique characteristics of our marketed product and late stage product candidate, each of which addresses large market opportunities, as well as our established commercial infrastructure, our innovative technology and the depth of experience of our management team. The following represents the key attributes that help differentiate our company:

- Fully-integrated pharmaceutical company with established commercial infrastructure.
- Sumavel DosePro, a differentiated new entrant in the migraine market that has demonstrated consistent monthly prescription growth since its launch.
- ZX002, a novel, controlled-release chronic pain therapy in Phase 3 clinical development.
- Validated, proprietary DosePro technology with broad range of potential applications.
- Experienced management team with unique commercial and development expertise, including CNS sales and marketing experience.

Our Strategy

Our core strategy is to commercialize and develop differentiated CNS and pain therapeutics that can address significant unmet medical needs and overcome limitations of existing products. Key elements of our strategy include:

- Increasing sales and continuing to drive patient and physician adoption of Sumavel DosePro in the United States.
- Developing and commercializing ZX002 for the treatment of moderate to severe chronic pain.
- Expanding our product pipeline in CNS disorders and/or pain.
- Obtaining regulatory approvals for Sumavel DosePro outside of the United States.
- Out-licensing our proprietary DosePro technology.
- Securing rights to complementary products and product candidates that address CNS disorders and/or pain.

Our Risks

Our business and our ability to execute our business strategy are subject to a number of risks that you should be aware of before you decide to buy our common stock. In particular, you should consider the following risks, which are discussed more fully in Risk Factors :

- We are largely dependent on the commercial success of Sumavel DosePro. Through September 30, 2010, we have only recognized $11.8 million in net product revenue from sales of Sumavel DosePro, and we may never significantly increase these sales or become

profitable.

We are at an early stage of commercialization and have incurred significant net losses since our inception and anticipate that we will incur continued net losses for at least the next several years. Our net loss applicable to common stockholders was $46.0 million in 2007, $45.6 million in 2008, $45.9 million in 2009 and $71.4 million for the nine months ended September 30, 2010.

We may not be successful in executing our sales and marketing strategy for the commercialization of Sumavel DosePro. As part of this strategy, we are dependent on our collaboration with Astellas to promote Sumavel DosePro primarily to primary care physicians, OB/GYNs, emergency medicine physicians and urologists. If we are unable to successfully execute such strategy, we may not be able to generate significant revenue.

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

We are dependent on numerous third parties in our supply chain, all of which are currently single source suppliers, for the commercial supply of Sumavel DosePro and a sole source supplier for the clinical supply of ZX002, and if we experience problems with any of these suppliers, the manufacturing of Sumavel DosePro and ZX002 could be delayed.

ZX002 is subject to extensive regulation, and we cannot give any assurance that it or any of our other product candidates will receive regulatory approval or be successfully commercialized.

Our clinical trials may fail to demonstrate acceptable levels of safety and efficacy of ZX002 or any of our other product candidates, which could prevent or significantly delay their regulatory approval.

Delays in the commencement or completion of clinical testing for ZX002 or pre-clinical or clinical testing for our other product candidates could result in increased costs to us and delay or limit our ability to pursue regulatory approval for, or generate additional revenues from, such product candidates.

Our success depends in part on our ability to protect our intellectual property. It may be difficult and costly to protect our proprietary rights and technology, and we may not be able to ensure their protection.

We may encounter unexpected safety, manufacturing, supply, regulatory or other issues relating to Sumavel DosePro, which may limit its commercial sales or regulatory acceptance.

Company Information

We were formed as a Delaware corporation on May 11, 2006 as SJ2 Therapeutics, Inc. We commenced our operations on August 25, 2006 and changed our name to Zogenix, Inc. on August 28, 2006. Our principal executive offices are located at 12671 High Bluff Drive, Suite 200, San Diego, CA 92130, and our telephone number is 1-866-ZOGENIX (1-866-964-3649). We formed a wholly-owned subsidiary, Zogenix Europe Limited, in June 2010, a company organized under the laws of England and Wales and which is located in the United Kingdom, and whose principal operations are to support the manufacture of the DosePro technology. Our website address is www.zogenix.com. The information on, or accessible through, our website is not part of this prospectus.

Sumavel®, DosePro®, Intrajet®, and Zogenix® are our trademarks. This prospectus also contains trademarks of other companies including Amerge®, Axert®, BOTOX®, Cambia®, Frova®, Imigran®, Imitrex®, Imitrex STATdose System®, Lortab®, Maxalt®, Neurontin®, Relpax®, SODAS®, Treximet®, Vicodin®, Vicoprofen®, Voltaren® and Zomig®. Unless otherwise specified, all prescription, prescriber and patient data in this prospectus is from Wolters Kluwer Pharma Solutions, Source® Pharmaceutical Audit Suite (PHAST), Institutional/Retail, Source® PHAST Retail, Source® Prescriber, Source® LaunchTrac, Source® Dynamic Claims or Source® Lx PTA.

The Offering

Common stock offered	14,000,000 shares (or 16,100,000 shares if the underwriters over-allotment option is exercised in full)
Common stock to be outstanding after this offering	33,563,802 shares (or 35,663,802 shares if the underwriters over-allotment option is exercised in full)
Use of proceeds	We intend to use the net proceeds from this offering to fund Phase 3 clinical trials and related development activities for ZX002, to fund the ongoing commercialization of Sumavel DosePro and for working capital and other general corporate purposes.
Risk factors	You should read the Risk Factors section of this prospectus for a discussion of the factors to consider carefully before deciding to purchase any shares of our common stock.
Nasdaq Global Market symbol	ZGNX

The number of shares of common stock to be outstanding after this offering set forth above includes:

- 15,690,046 shares outstanding as of September 30, 2010, after giving effect to the conversion of all outstanding shares of our convertible preferred stock into 14,239,797 shares of common stock upon completion of this offering; and
- the issuance of 3,873,756 shares of our common stock upon completion of this offering as a result of the automatic conversion of the $15.0 million in aggregate principal amount of convertible promissory notes we issued in July 2010, or the 2010 Notes (including accrued interest thereon), based on the initial public offering price of $4.00 per share and assuming the conversion occurs on November 29, 2010 (the expected closing date of this offering).

The number of shares of common stock to be outstanding after this offering set forth above excludes:

- 256,816 shares of common stock issuable upon the exercise of warrants outstanding as of September 30, 2010, at a weighted average exercise price of $10.92 per share, which warrants are expected to remain outstanding upon completion of this offering;
- 1,482,780 shares of common stock issuable upon the exercise of options outstanding as of September 30, 2010, at a weighted average exercise price of $3.36 per share;

2,000,000 additional shares of common stock reserved for future issuance under our 2010 Equity Incentive Award Plan, or the 2010 Plan, which will become effective immediately prior to the completion of this offering, plus 233,689 shares of common stock reserved for future grant or issuance under our 2006 Equity Incentive Plan, or the 2006 Plan, as of September 30, 2010, which shares will be added to the shares to be reserved under our 2010 Plan upon the effectiveness of the 2010 Plan, plus any annual increases in the number of shares of common stock reserved for future issuance under the 2010 Plan pursuant to an evergreen provision and any other shares that may become issuable under the 2010 Plan pursuant to its terms, as more fully described in Compensation Discussion and Analysis Employee Equity Incentive Plans 2010 Equity Incentive Award Plan; and

500,000 shares of common stock reserved for issuance under our 2010 Employee Stock Purchase Plan, or the Purchase Plan, which will become effective following the completion of this offering, plus any annual increases in the number of shares of common stock reserved for issuance under the Purchase Plan pursuant to an evergreen provision, as more fully described in Compensation Discussion and Analysis Employee Equity Incentive Plans 2010 Employee Stock Purchase Plan.

Except as otherwise indicated, all information in this prospectus assumes or gives effect to:

no exercise by the underwriters of their option to purchase up to an additional 2,100,000 shares of common stock to cover over-allotments, if any;

the purchase of an aggregate of 7,138,895 shares of our common stock in this offering by certain of our current stockholders as described below;

the filing of our amended and restated certificate of incorporation and adoption of our amended and restated bylaws upon completion of this offering;

the conversion of all outstanding shares of our convertible preferred stock into 14,239,797 shares of common stock upon completion of this offering;

the termination of outstanding warrants exercisable for an aggregate of 1,290,887 shares of our common stock, or the Series B Warrants, without having been exercised (the Series B Warrants will terminate automatically upon completion of this offering and we have assumed that these warrants will terminate without having been exercised because the exercise price exceeds the initial public offering price of our common stock in this offering);

no exercise of outstanding options or warrants since September 30, 2010; and

a one-for-ten reverse stock split of our common stock effected in November 2010.

Abingworth Bioventures, Chicago Growth Partners II, L.P., Clarus Lifesciences I, L.P., Domain Associates, L.L.C., Scale Venture Partners II, LP, Thomas, McNerney & Partners, L.P. and Cam L. Garner, or funds affiliated with them, each of which is a current stockholder and which we refer to collectively as the Current Stockholders, have indicated an interest in purchasing an aggregate of 7,138,895 shares of our common stock in this offering at the initial public offering price. Although we anticipate that the Current Stockholders will purchase, and that the underwriters will sell to the Current Stockholders, all of these shares, indications of interest are not binding agreements or commitments to purchase and the Current Stockholders may determine to purchase less or no shares in this offering and the underwriters may determine to sell less or no shares in this offering to the Current Stockholders. The underwriters will receive underwriting discounts and commissions of $0.0981 per share on any shares sold to the Current Stockholders.

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Summary Financial Data

The following table summarizes certain of our financial data. The summary statement of operations data for the years ended December 31, 2007, 2008 and 2009 are derived from our audited financial statements included elsewhere in this prospectus. The summary statement of operations data for the nine months ended September 30, 2009 and 2010 and the balance sheet data as of September 30, 2010 have been derived from our unaudited interim financial statements, which are included elsewhere in this prospectus. The unaudited interim financial statements have been prepared on the same basis as the audited financial statements and, in the opinion of management, reflect all adjustments, consisting primarily of normal recurring adjustments, necessary to fairly present our financial position as of September 30, 2010 and results of operations for the nine months ended September 30, 2009 and 2010. Our historical results of operations and financial condition are not necessarily indicative of the results or financial condition that may be expected in the future. The summary financial data set forth below should be read together with our financial statements and related notes, Selected Financial Data and Management s Discussion and Analysis of Financial Condition and Results of Operations included elsewhere in this prospectus.

	Year Ended December 31,			Nine Months Ended September 30,	
	2007	2008	2009	2009	2010
	(In Thousands, Except Per Share Amounts)				
Statement of Operations Data					
Revenue:					
Net product revenue	$	$	$	$	$ 11,828
Contract revenue					2,810
Total revenue					14,638
Operating expenses:					
Cost of sales					9,403
Royalty expense					598
Research and development	24,329	33,910	21,438	22,305	19,394
Selling, general and administrative	4,725	11,820	14,102	8,027	36,792
Total operating expenses	29,054	45,730	35,540	30,332	66,187
Loss from operations	(29,054)	(45,730)	(35,540)	(30,332)	(51,549)
Other income (expense):					
Interest income	927	696	10	7	4
Interest expense	(377)	(1,718)	(9,188)	(8,563)	(6,938)
Change in fair value of warrant liability	(107)	1,119	(755)	(505)	(12,833)
Other financing income	906				
Other income (expense)	25	63	(416)	(350)	(113)
Total other income (expense)	1,374	160	(10,349)	(9,411)	(19,880)
Net loss	(27,680)	(45,570)	(45,889)	(39,743)	(71,429)
Deemed dividend for the beneficial conversion on Series A-1 and Series A-2 convertible preferred stock	(18,360)				
Net loss applicable to common stockholders	$ (46,040)	$ (45,570)	$ (45,889)	$ (39,743)	$ (71,429)
Net loss per share, basic and diluted	$ (80.77)	$ (52.68)	$ (40.97)	$ (36.43)	$ (53.31)
Weighted-average shares outstanding, basic and diluted	570	865	1,120	1,091	1,340
Pro forma net loss per share, basic and diluted (unaudited)(1)			$ (4.49)		$ (3.47)
Weighted-average pro forma shares outstanding, basic and diluted (unaudited)(1)			10,057		16,810

(1) See Note 2 of Notes to Financial Statements for an explanation of the method used to calculate net loss per share and the number of shares used in the computation of the per share amounts.

	As of September 30, 2010	
	Actual	Pro Forma As Adjusted
	(In Thousands)	
Balance Sheet Data:		
Cash and cash equivalents	$ 11,673	$ 62,403
Working capital (deficit)	(920)	61,000
Total assets	55,034	104,258
Long-term debt, less current portion	22,390	22,390
Convertible preferred stock warrant liability	20,301	
Convertible preferred stock	149,312	
Accumulated deficit	(195,967)	(195,967)
Total stockholders equity (deficit)	(183,780)	46,247

The summary pro forma as adjusted balance sheet data above gives effect to the following transactions as if they had occurred as of September 30, 2010:

(1) the sale of 14,000,000 shares of common stock in this offering and our receipt of the estimated net proceeds therefrom, based on the initial public offering price of $4.00 per share and after deducting the underwriting discounts and commissions and estimated offering costs payable by us and assuming that the Current Stockholders purchase all of the 7,138,895 shares that they have indicated an interest in purchasing as described above;

(2) the conversion of all outstanding shares of our convertible preferred stock into 14,239,797 shares of our common stock upon the completion of this offering and the resultant reclassification of our convertible preferred stock warrant liability to stockholders equity (deficit) in connection with such conversion;

(3) the termination of all of the Series B Warrants upon completion of this offering without those warrants having been exercised;

(4) the issuance of 3,873,756 shares of our common stock upon completion of this offering as a result of the automatic conversion of the 2010 Notes (including accrued interest thereon), based on the initial public offering price of $4.00 per share and assuming the conversion occurs on November 29, 2010 (the expected closing date of this offering); and

(5) the conversion of our remaining warrants to purchase convertible preferred stock, which warrants are expected to remain outstanding upon the completion of this offering, into warrants to purchase our common stock.

RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the following risk factors, as well as the other information in this prospectus, before deciding whether to invest in shares of our common stock. The occurrence of any of the following risks could have a material adverse effect on our business, financial condition, results of operations and prospects. In that case, the trading price of our common stock could decline, and you may lose all or part of your investment.

Risks Related to Our Business and Industry

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

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

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

We cannot be certain that our continued marketing of Sumavel DosePro will result in increased demand for, and sales of, the product. If we fail to successfully increase sales of Sumavel DosePro, we may be unable to generate sufficient revenues to grow or sustain our business and we may never become profitable, and our business, financial condition and results of operations will be materially adversely affected.

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

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

We have generated substantial net losses and negative cash flow from operations since our inception in 2006. For example, for 2007, 2008 and 2009 and the nine months ended September 30, 2010, we incurred net losses of $27.7 million, $45.6 million, $45.9 million and $71.4 million, respectively, our net cash used in operating activities was $26.8 million, $41.3 million, $32.4 million and $58.5 million,

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respectively, and, at September 30, 2010, our accumulated deficit was $196.0 million. We expect our losses and negative cash flow to continue for at least the next several years as a result of the increasing development expenses in connection with our ongoing clinical development for ZX002 and the cost of the sales and marketing expense associated with Sumavel DosePro. Our ability to generate revenues from Sumavel DosePro or any of our product candidates will depend on a number of factors, including, in the case of Sumavel DosePro, the factors described in the following two risk factors and, in the case of our product candidates, our ability to successfully complete clinical trials, obtain necessary regulatory approvals and negotiate arrangements with third parties to help finance the development of, and market and distribute, any product candidates that receive regulatory approval. In addition, we will be subject to the risk that the marketplace will not accept our products.

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

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

Prior to the launch of Sumavel DosePro in January 2010, we built a commercial sales and marketing organization including sales, marketing, communications, managed markets, trade and distribution functions, which is now focused exclusively on marketing and selling Sumavel DosePro primarily to physicians, nurses and other healthcare professionals in the United States. Our field sales force includes approximately 80 sales representatives who are promoting Sumavel DosePro primarily to neurologists and other key prescribers of migraine medications, including headache clinics and headache specialists in the United States. Although we believe we have adequately sized our sales force in order to reach this targeted audience, we may either increase or decrease the size of our sales force in the future based upon market conditions and actual sales performance. In addition, we could lose sales personnel or the performance of our sales personnel as measured by actual sales may be disappointing. Many of our competitors have significantly larger sales and marketing organizations, and significantly greater experience than we do in selling, marketing and distributing pharmaceuticals, and we may not be able to compete successfully with them with the commercial infrastructure we have developed.

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

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

- Astellas could fail to devote sufficient resources to the promotion of Sumavel DosePro, including by failing to develop, deploy or expand its sales force as necessary;

Astellas could terminate the co-promotion agreement for any or no cause upon 180-days written notice at any time, which may negatively impact our ability to generate, or prevent us from generating, sufficient revenue;

Astellas could fail to comply with applicable regulatory guidelines with respect to the promotion of Sumavel DosePro, which could result in administrative or judicially imposed sanctions, including warning letters, civil and criminal penalties, and injunctions; and

disputes regarding the co-promotion agreement that negatively impact or terminate the commercialization efforts of Astellas may negatively impact or prevent the generation of sufficient revenue or result in significant litigation or arbitration.

Furthermore, Astellas may terminate the co-promotion agreement in the event we undergo a change of control (as defined in the agreement), if a governmental authority takes action that prevents or makes it unlawful for Astellas to perform its obligations under the agreement, in the event of our inability to supply commercial product, under certain circumstances where a third party asserts that the making or selling of Sumavel DosePro infringes the intellectual property rights of a third party, if we materially breach our minimum sales effort obligations and do not cure that breach within a specified period, upon the occurrence of a large scale recall or market withdrawal of Sumavel DosePro, upon a failure of the Sumavel DosePro brand to achieve certain minimum sales levels in 2010 or 2011, upon a material uncured breach by us or in the event of our insolvency or bankruptcy or other event which affects our ability to perform our obligations under the agreement. Accordingly, we cannot assure you that Astellas will not terminate the agreement under these circumstances. As an alternative to termination, we and Astellas could agree to amend or otherwise restructure the current co-promotion agreement. Such amendment or restructuring could change the financial terms of our agreement, change our respective minimum sales force requirements, or otherwise materially alter our co-promotion relationship. Such an amendment or restructuring could require us to expand our sales force or otherwise invest significant additional financial resources in order to adequately support the successful sales and marketing of Sumavel DosePro.

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

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

If Sumavel DosePro, ZX002, if approved, or any other product candidate for which we receive regulatory approval does not achieve broad market acceptance or coverage by third-party payors, the revenues that we generate will be limited.

The commercial success of Sumavel DosePro, ZX002, if approved, and any product candidates for which we obtain marketing approval from the U.S. Food and Drug Administration, or FDA, or other regulatory authorities will depend upon the acceptance of these products by physicians, patients, healthcare payors and the medical community. Coverage and reimbursement of our approved product by third-party payors is also necessary for commercial success. The degree of market acceptance of Sumavel DosePro and any other product candidates for which we may receive regulatory approval will depend on a number of factors, including:

our ability to provide acceptable evidence of safety and efficacy;

acceptance by physicians and patients of the product as a safe and effective treatment;

the relative convenience and ease of administration;

the prevalence and severity of adverse side effects;

limitations or warnings contained in a product s FDA-approved labeling;

the clinical indications for which the product is approved;

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

availability and perceived advantages of alternative treatments;

any negative publicity related to our or our competitors products;

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

pricing and cost effectiveness;

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

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

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

In addition, products used to treat and manage pain, especially in the case of opioids, are from time to time subject to negative publicity, including illegal use, overdoses, abuse, diversion, serious injury and death. These events have led to heightened regulatory scrutiny. Controlled substances are classified by the DEA as Schedule I through V substances, with Schedule I substances being prohibited for sale in the United States, Schedule II substances considered to present the highest risk of abuse and Schedule V substances being considered to present the lowest relative risk of abuse. ZX002 contains *hydrocodone*, and we anticipate it will be regulated as a Schedule II controlled substance, and despite the strict regulations on the marketing, prescribing and dispensing of such substances, illicit use and abuse of *hydrocodone* is well-documented. Thus, the regulatory approval process and the marketing of ZX002 may generate public controversy that may adversely affect regulatory approval and market acceptance of ZX002.

Our efforts to educate the medical community and third-party payors on the benefits of Sumavel DosePro, ZX002, if approved, and any of our product candidates for which we obtain marketing approval from the FDA or other regulatory authorities and gain broad market acceptance may require

significant resources and may never be successful. If our products do not achieve an adequate level of acceptance by physicians, third-party payors and patients, we may not generate sufficient revenue from these products to become or remain profitable.

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

We commenced our operations on August 25, 2006. Our operations to date have been limited to organizing and staffing our company, scaling up manufacturing operations with our third-party contract manufacturers, building a sales and marketing organization, conducting product development activities for our product and product candidates, in-licensing rights to ZX002, and commercializing Sumavel DosePro. Moreover, Sumavel DosePro is our only product that is approved for sale. Consequently, any predictions about our future performance may not be as accurate as they could be if we had a history of successfully developing and commercializing pharmaceutical products.

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

The majority of our sales of Sumavel DosePro are to wholesale pharmaceutical distributors who, in turn, sell the products to pharmacies, hospitals and other customers. Three wholesale pharmaceutical distributors, Cardinal Health, Inc., McKesson Corporation and AmerisourceBergen Corporation, individually comprised 48.2%, 37.2% and 10.2%, respectively, of our total gross sales of Sumavel DosePro for the nine months ended September 30, 2010, which may result in substantial fluctuations in our results of operations from period to period. The loss of any of these wholesale pharmaceutical distributors accounts or a material reduction in their purchases could have a material adverse effect on our business, results of operations, financial condition and prospects.

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

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

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

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

If approved for the treatment of moderate to severe chronic pain, we anticipate that ZX002 would compete against other marketed branded and generic pain therapeutics. Opioid therapeutics generally fall into two classes: *codeines*, which include *oxycodones* and *hydrocodones,* and *morphines*. ZX002 is a *hydrocodone*, the most commonly prescribed opioid in the United States, and we expect ZX002 will compete with therapeutics within both the *codeine* and *morphine* classes. These therapeutics include both Schedule II and Schedule III products being marketed by companies such as Endo Pharmaceuticals Holdings Inc., Johnson & Johnson, King Pharmaceuticals, Inc., Mallinckrodt Inc., Purdue Pharma L.P., Teva Pharmaceutical Industries Limited and Watson Pharmaceuticals, Inc.

In addition to already marketed therapeutics, we also face competition from product candidates that are or could be under development by many of the above-mentioned entities and others. For example, there are several products for the treatment of migraine under development by large pharmaceutical companies such as GSK and Merck & Co., Inc., and other smaller companies such as NuPathe, Inc. and MAP Pharmaceuticals, Inc. If approved, ZX002 may also compete with at least fifteen opioid product candidates under development, including abuse and diversion resistant formulations of currently available opioids, novel opioids and alternative delivery forms of various opioids under development at other pharmaceutical companies, including extended-release *hydrocodone* product candidates being developed by Cephalon, Inc., Egalet A/S and King Pharmaceuticals, Inc. ZX002 may

also face competition from non-opioid product candidates including new chemical entities, as well as alternative delivery forms of non-steroidal anti-inflammatory drugs. These new opioid and non-opioid product candidates are being developed by companies such as Acura Pharmaceuticals, Inc., Altea Therapeutics Corporation, Elite Pharmaceuticals, Inc., Javelin Pharmaceuticals, Inc., Pfizer Inc. and QRxPharma Ltd.

We expect Sumavel DosePro and, if approved, ZX002 and any of our other product candidates to compete on the basis of, among other things, product efficacy and safety, time to market, price, patient reimbursement by third-party payors, extent of adverse side effects and convenience of treatment procedures. One or more of our competitors may develop needle-free injectable products, products to address chronic pain or other products that compete with ours, obtain necessary approvals for such products from the FDA, or other agencies, if required, more rapidly than us or develop alternative products or therapies that are safer, more effective and/or more cost effective than any products developed by us. If any of our product candidates receive the requisite regulatory approval and classification and are marketed, the competition which we will encounter will have, and the competition we are currently encountering with our Sumavel DosePro product has had and will continue to have, an effect on our product prices, market share and results of operations. We may not be able to differentiate any products that we are able to market from those of our competitors, successfully develop or introduce new products that are less costly or offer better results than those of our competitors, or offer purchasers of our products payment and other commercial terms as favorable as those offered by our competitors.

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

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

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

We are dependent on numerous third parties in our supply chain, all of which are currently single source suppliers, for the commercial supply of Sumavel DosePro and a sole source supplier for clinical supply of ZX002, and if we experience problems with any of these suppliers, the manufacturing of Sumavel DosePro and ZX002 could be delayed.

While we own most of the specialized equipment used to manufacture critical components of Sumavel DosePro, we do not own or operate manufacturing facilities and currently lack the in-house capability to manufacture Sumavel DosePro, ZX002 or any other products or product candidates. Our DosePro device and Sumavel DosePro are manufactured by contract manufacturers, component fabricators and secondary service providers. Final aseptic fill, finish, assembly and packaging of Sumavel DosePro are performed at Patheon UK Limited, Swindon, United Kingdom, a specialist in the aseptic fill/finish of injectables and other sterile pharmaceutical products. In addition, Nypro Limited, located in Bray, Ireland, manufactures the actuator assemblies and injection molded components for our DosePro device and MGlas AG, located in Schweinfurt, Germany, manufactures the specialized glass capsule that houses the *sumatriptan* active pharmaceutical ingredient, or API, in our DosePro device. Each of these manufacturers and each other company that supplies, fabricates or manufactures any component used in our DosePro device is currently the only qualified source of their respective components. We currently rely on Dr. Reddy s as the only supplier of *sumatriptan* API for use in Sumavel DosePro. We also outsource all manufacturing and packaging of the clinical trial materials for ZX002 to third parties. Although we plan to qualify additional manufacturers and suppliers of some of the components used in Sumavel DosePro, there can be no assurance that we will be able to do so and the current manufacturers and suppliers of these components will likely be single source suppliers to us for a significant period of time. Similarly, under our license agreement, Elan is the exclusive manufacturer of ZX002. We may never be able to establish additional sources of supply for ZX002.

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

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

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

If our contract manufacturers or suppliers fail to deliver the required commercial quantities of Sumavel DosePro and its various components, the quantities of ZX002 or any of our other product candidates required for our clinical trials and, if approved, for commercial sale, on a timely basis and at commercially reasonable prices, and we are unable to find one or more replacement manufacturers or suppliers capable of production at a substantially equivalent cost, in substantially equivalent volumes and quality, and on a timely basis, we would likely be unable to meet demand for our products and would have to delay or terminate our pre-clinical or clinical trials, and we would lose potential revenue. It may also take a significant period of time to establish an alternative source of supply for our product,

product candidates and components and to have any such new source approved by the FDA or any applicable foreign regulatory authorities. Furthermore, any of the above factors could cause the delay or suspension of initiation or completion of clinical trials, regulatory submissions or required approvals of our product candidates, cause us to incur higher costs and could prevent us from commercializing our product candidates successfully.

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

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

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

We have retained third-party service providers to perform a variety of functions related to the sale and distribution of our products, key aspects of which are out of our direct control. For example, we rely on Cardinal Health 105, Inc. (a/k/a Specialty Pharmaceutical Services) to provide key services related to logistics, warehousing and inventory management, distribution, contract administration and chargeback processing, accounts receivable management and call center management, and, as a result, most of our inventory is stored at a single warehouse maintained by the service provider. We place substantial reliance on this provider as well as other third-party providers that perform services for us, including entrusting our inventories of products to their care and handling. If these third-party service providers fail to comply with applicable laws and regulations, fail to meet expected deadlines, or otherwise do not carry out their contractual duties to us, or encounter physical damage or natural disaster at their facilities, our ability to deliver product to meet commercial demand would be significantly impaired. In addition, we utilize third parties to perform various other services for us relating to sample accountability and regulatory monitoring, including adverse event reporting, safety database management and other product maintenance services. If the quality or accuracy of the data maintained by these service providers is insufficient, our ability to continue to market our products could be jeopardized or we could be subject to regulatory sanctions. We do not currently have the internal capacity to perform these important commercial functions, and we may not be able to maintain commercial arrangements for these services on reasonable terms.

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

We believe that there is a perception among some patients, physicians and other customers that a needle-free delivery system should be pain free. While our experience indicates that some patients will

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

ZX002 is subject to extensive regulation, and we cannot give any assurance that it or any of our other product candidates will receive regulatory approval or be successfully commercialized.

We currently are developing ZX002 for the treatment of moderate to severe chronic pain. The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of opioid drug products, among other things, are subject to extensive regulation by the FDA, the DEA and other regulatory authorities in the United States. We are not permitted to market ZX002 in the United States unless and until we receive regulatory approval from the FDA. We cannot provide any assurance that we will obtain regulatory approval for ZX002 or any of our other product candidates, or that any such product candidates will be successfully commercialized.

We have not yet completed all necessary studies, nor submitted a new drug application, or NDA, or received marketing approval, for ZX002. Obtaining approval of an NDA is a lengthy, expensive and uncertain process. The FDA also has substantial discretion in the drug approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons. For example:

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

ZX002 has undergone Phase 1 pharmacokinetics studies as well as Phase 2 clinical trials. However, these studies and trials were conducted by a third party and, accordingly, we did not directly participate in their design or execution. In addition, we will also need to successfully complete Phase 3 clinical trials to establish its safety and efficacy, additional Phase 1 studies, and additional pre-clinical studies prior to our submission of an NDA to the FDA for approval. We initiated the Phase 3 clinical development program for ZX002 in March 2010. ZX002 and any of our other product candidates may fail to achieve their specified endpoints in clinical trials. Furthermore, product candidates such as ZX002 may not be approved even if they achieve their specified endpoints in clinical trials. The FDA may disagree with our trial design and our interpretation of data from clinical trials, or may change the requirements for approval even after it has reviewed and commented on the design for our clinical trials. The FDA may also approve a product candidate for fewer or more limited indications than we request, or may grant approval contingent on the performance of costly post-approval clinical trials. In addition, the FDA may not approve the labeling claims that we believe are necessary or desirable for the successful commercialization of our product candidates.

If we are unable to obtain regulatory approval for ZX002 or any other product candidates on the timeline we anticipate, we will not be able to execute our business strategy effectively and our ability to generate additional revenues beyond Sumavel DosePro will be limited, which would have a material adverse impact on our business, results of operations, financial condition and prospects.

Our clinical trials may fail to demonstrate acceptable levels of safety and efficacy of ZX002 or any of our other product candidates, which could prevent or significantly delay their regulatory approval.

Our ZX002 product candidate and our other product candidates are prone to the risks of failure inherent in drug development. Before obtaining U.S. regulatory approval for the commercial sale of ZX002 or any other product candidate, we must gather substantial evidence from well-controlled clinical trials that demonstrate to the satisfaction of the FDA that the product candidate is safe and effective, and similar regulatory approvals would be necessary to commercialize the product candidate in other countries.

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

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

With regard to ZX002, data from a Phase 2 clinical trial in osteoarthritis patients has shown what we believe is a clinically acceptable safety profile and a pharmacodynamic profile which supports further product development for the treatment of moderate to severe pain in patients requiring around-the-clock opioid therapy. In the two Phase 2 clinical trials conducted to date, patients experienced mild to moderate adverse events, including nausea, vomiting, headache, dizziness, sweating, constipation and drowsiness, which are similar to the reported side effects of opioids currently prescribed for chronic pain. However, our licensor, Elan Pharma International Ltd., or Elan, conducted these trials and we have not independently verified the data or completed any of our own Phase 2 or Phase 3 trials for this product candidate. In addition, these results may not be predictive of results obtained in our ongoing Phase 3 clinical trials or any other required future trials, and we may be unable to demonstrate sufficient safety and efficacy to obtain the requisite regulatory approvals or approvals for commercially viable uses. A number of companies in the biotechnology and pharmaceutical industries have suffered significant setbacks in advanced clinical trials, even after promising results in earlier trials. If ZX002 is not shown to be safe and effective in clinical trials, this program could be delayed or terminated, which could have a material adverse effect on our business, results of operations, financial condition and prospects.

Delays in the commencement or completion of clinical testing for ZX002 or pre-clinical or clinical testing for any of our other product candidates could result in increased costs to us and delay or limit our ability to pursue regulatory approval or generate revenues.

Clinical trials are very expensive, time consuming and difficult to design and implement. Even if the results of our clinical trials are favorable, the clinical trials of ZX002 will continue for several years and may take significantly longer than expected to complete. Delays in the commencement or completion of clinical testing for ZX002 or pre-clinical or clinical testing for any of our other product candidates could significantly affect our product development costs and business plan. In March 2010, we initiated a Phase 3 clinical development program for ZX002, including a pivotal efficacy trial. Phase 3 clinical efficacy trials, in general, are significantly more complex and time-consuming and involve more patients than the Phase 1 and 2 clinical trials that have been completed to date. We do not know whether our Phase 3 clinical trials of ZX002 or any other pre-clinical or clinical trials will begin on time or be completed on schedule, if at all. The commencement and completion of clinical trials can be delayed for a number of reasons, including delays related to:

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

We believe that we have planned and designed an adequate Phase 3 clinical trial program for ZX002, and we presented the trial design for our Phase 3 trials to the FDA at our End of Phase 2 meeting in June 2008. Although we believe the FDA has generally agreed with the design of our Phase 3 clinical trial program, the FDA could still determine that it is not satisfied with our plan or the details of our pivotal clinical trial protocols and designs. While the FDA has provided us with a written record of our discussions and responses to our questions at our End of Phase 2 meeting, such records and responses do not guarantee that the FDA will deem our trial design to be sufficient for the purpose of obtaining marketing approval for ZX002. We did not seek a Special Protocol Assessment from the FDA for our ongoing pivotal Phase 3 efficacy study for ZX002 (Study 801).

In addition, chronic pain patients have historically been difficult to keep enrolled in clinical trials. If a significant number of patients fail to stay enrolled in any of our current or future clinical trials of ZX002 and such failure is not adequately accounted for in our trial design and enrollment assumptions, our clinical development program could be delayed. Clinical trials may also be delayed or repeated as a result of ambiguous or negative interim results or unforeseen complications in testing. In addition, a clinical trial may be suspended or terminated by us, the FDA, the IRB overseeing the clinical trial at issue, any of our clinical trial sites with respect to that site, or other regulatory authorities due to a number of factors, including:

- failure to design appropriate clinical trial protocols;
- failure by us, our employees, our CROs or their employees to conduct the clinical trial in accordance with all applicable FDA, DEA or other regulatory requirements or our clinical protocols;
- inspection of the clinical trial operations or trial sites by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;
- discovery of serious or unexpected toxicities or side effects experienced by study participants or other unforeseen safety issues;
- lack of adequate funding to continue the clinical trial, including the incurrence of unforeseen costs due to enrollment delays, requirements to conduct additional trials and studies and increased expenses associated with the services of our CROs and other third parties;
- lack of effectiveness of any product candidate during clinical trials;
- slower than expected rates of subject recruitment and enrollment rates in clinical trials;
- failure of our CROs or other third-party contractors to comply with all contractual requirements or to perform their services in a timely or acceptable manner;
- inability or unwillingness of medical investigators to follow our clinical protocols;
- in the case of ZX002, regulatory concerns with opioid products generally and the potential for abuse and diversion of the drugs; and
- unfavorable results from on-going clinical trials and pre-clinical studies.

Additionally, changes in applicable regulatory requirements and guidance may occur and we may need to amend clinical trial protocols to reflect these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for reexamination, which may impact the costs, timing or successful completion of a clinical trial. If we experience delays in completion of, or if we terminate, any of our clinical trials, the commercial prospects for ZX002 and our other product candidates may be harmed, which may have a material adverse effect on our business, results of operations, financial condition and prospects.

Our competitors could receive FDA approval for an extended-release hydrocodone product before we receive FDA approval for ZX002, and thus could be granted regulatory exclusivity that could significantly delay our ability to receive approval for and commercialize ZX002 and therefore dramatically reduce its market potential. Our competitors could also pursue regulatory and other strategies to combat competition from 505(b)(2) products, which also may negatively affect the approval and commercialization of ZX002 and any of our other product

candidates.

The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Amendments, added Section 505(b)(2) to the FFDCA, or Section 505(b)(2). Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. For example, we obtained FDA marketing approval of Sumavel DosePro

under Section 505(b)(2), and we intend to submit the NDA for ZX002 under Section 505(b)(2), and as such the NDA will rely, in part, on the FDA s previous findings of safety and effectiveness for *hydrocodone*.

Certain of our competitors may file a 505(b)(2) application for extended-release *hydrocodone* either before or shortly after we submit our own NDA for ZX002. The first approved 505(b)(2) applicant for a particular condition of use, or change to a marketed product, such as a new extended-release formulation for a previously approved product, may be granted three-year Hatch-Waxman exclusivity if one or more clinical studies, other than bioavailability or bioequivalence studies, was essential to the approval of the application and was conducted/sponsored by the applicant. Three-year Hatch-Waxman exclusivity delays the FDA s approval of other 505(b)(2) applicants for the same condition of use or change to the drug product that was granted exclusivity, regardless of the date of submission of each NDA. We believe that several competitors are developing extended-release *hydrocodone* products, and if the FDA approves a competitor s 505(b)(2) application for its extended-release *hydrocodone* product before our application, and granted the competitor three-year exclusivity, the FDA would be precluded from making effective our NDA for ZX002 until after that three-year exclusivity period has run, and such delay would dramatically reduce our expected market potential for ZX002. Additionally, even if our 505(b)(2) application for extended-release *hydrocodone* is approved first, we may still be subject to competition by other *hydrocodone* products, including approved products or other 505(b)(2) applications for different conditions of use that would not be restricted by the three-year exclusivity.

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

- extending patent protection for existing products that would block Section 505(b)(2) approval of the product candidate by pursuing new patents for existing products that may be granted just before the expiration of one patent, which could extend patent protection for a number of years or otherwise delay the launch of generic, 505(b)(2) or other competing products;

- submitting Citizen Petitions to request the FDA to take adverse administrative action with respect to approval of a generic, 505(b)(2) or other competing product;

- filing patent infringement lawsuits, whether or not meritorious, to trigger up to a 30-month stay in the approval of a generic, 505(b)(2) or other competing product; and

- engaging in state-by-state initiatives to enact legislation or regulatory policies that restrict the substitution of some generic, 505(b)(2) or other competing drugs for brand-name drugs.

If any of these strategies are successful, our ability to obtain approval of and commercialize ZX002 and any of our other product candidates for which we rely on Section 505(b)(2) will be adversely affected.

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

We have agreements with third-party CROs to conduct our ongoing Phase 3 trials for ZX002, and anticipate that we may enter into other such agreements in the future regarding any of our other product candidates. We rely heavily on these parties for the execution of our clinical and pre-clinical studies, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol. We and our CROs are required to comply with current good clinical practices, or GCPs. The FDA enforces these GCP regulations through periodic inspections of trial sponsors, principal investigators and trial sites. If we or our CROs fail to comply with applicable GCP regulations, the data generated in our clinical trials may be deemed unreliable and the FDA may require us to perform additional clinical trials before approving our marketing applications. We cannot

assure you that, upon inspection, the FDA and similar foreign regulators will determine that any of our clinical trials comply or complied with GCP regulations. In addition, our clinical trials must be conducted with product produced under current good manufacturing practices, or cGMPs, regulations, and require a large number of test subjects. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

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

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

The development of a REMS for ZX002 could cause significant delays in the approval process for ZX002 and would add additional layers of regulatory requirements, including possible prescribing restrictions, requirements for post-marketing studies or restrictions on distribution and use, which could significantly impact our ability to commercialize ZX002 and dramatically reduce its market potential.

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

In February 2009, the FDA informed drug manufacturers that it will require a REMS for all sustained-release opioid drug products. The FDA has since initiated efforts to develop a new standardized REMS for these opioid medications to ensure their safe use. A controlled-release formulation of *hydrocodone*, such as ZX002, would be required to have a REMS. The FDA s authority to take this action is based on risk management and post-market safety provisions within the FDAAA. We intend to submit a REMS at the time of the NDA submission for ZX002. The development of the REMS could cause significant delays in the approval process for ZX002. In addition, as part of the REMS for ZX002, the FDA could require stringent restrictions on the prescribing, distribution, and patient use of the product, which could significantly impact our ability to commercialize ZX002 and dramatically reduce its market potential.

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

In March 2008, we entered into a licensing and distribution agreement with Desitin pursuant to which we granted Desitin the exclusive right under our intellectual property rights related to Sumavel DosePro to develop, use, distribute, sell, offer for sale, and import Sumavel DosePro and any potential modified versions of Sumavel DosePro in the European Union, Norway, Switzerland and Turkey. In that regard, Desitin is not obligated under the agreement to pursue regulatory approval or commercialization of Sumavel DosePro in any of these countries except for Germany. Since we will depend on Desitin to develop, obtain regulatory approval for and, if regulatory approval is granted, commercialize Sumavel DosePro in these countries, we will have limited control over the success of Desitin s development, regulatory approval and commercialization efforts. Desitin submitted a Marketing Authorization Application for Sumavel DosePro to the Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM)) in Germany, the reference member state, through the Decentralized Procedure in October 2009, following completion of a European pivotal bioequivalence trial comparing needle-free Sumavel DosePro to a traditional needle-based autoinjector, Imigran-Inject, the European brand of Imitrex STATdose. However, any additional clinical studies Desitin may be required to conduct as part of the regulatory approval process may not corroborate the results of the clinical studies we have conducted or may have adverse results or effects on our ability to maintain regulatory approvals in the United States or obtain them in other countries. In addition, although we believe that the U.S. market represents the largest commercial opportunity for Sumavel DosePro, Desitin may not develop Sumavel DosePro as fast or generate as large of a market as we would like or as the market may expect and Desitin may not seek to develop, obtain approval for or commercialize Sumavel DosePro in countries for which it has exclusive rights, other than in Germany, where Desitin is required to develop, seek approval for and commercialize Sumavel DosePro. Any failure by Desitin to successfully commercialize Sumavel DosePro or to successfully obtain applicable foreign regulatory approval for Sumavel DosePro would limit our opportunity to receive revenue from the territories licensed to Desitin. Furthermore, negative developments occurring in those territories controlled by Desitin could have a negative impact on physician and patient impressions of our product in the United States and elsewhere.

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

Major pharmaceutical companies usually employ groups of sales representatives numbering in the thousands to call on the large number of primary care physicians. In connection with the launch of Sumavel DosePro in January 2010 we built a sales and marketing organization to promote Sumavel DosePro in the United States, including a focused sales force of approximately 80 representatives primarily targeting neurologists and other key prescribers of migraine medications, including headache clinics and headache specialists. In addition, in July 2009, we entered into an exclusive agreement with Astellas under which Sumavel DosePro is also being marketed by Astellas in the United States and promoted primarily to primary care physicians, OB/GYNs, emergency medicine physicians, and urologists by approximately 400 Astellas sales representatives. In order to expand the market opportunity for any additional product candidates that receive regulatory approval into the broader primary care physician audiences, we will need to continue to expand our sales and marketing personnel and commercial infrastructure and/or establish partnerships with pharmaceutical companies or contract sales organizations to co-promote such product candidates. We currently, and on an ongoing basis will have to, compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain sales and marketing personnel. We also face competition in our search for collaborators and potential co-promoters. To the extent we rely on additional third parties to commercialize any product candidates that may receive regulatory approval, we are likely to receive less revenues than if

we commercialized these products ourselves. Further, by entering into strategic partnerships or similar arrangements, we may rely in part on such third parties for financial and commercialization resources. Even if we are able to identify suitable partners to assist in the commercialization of our product candidates, they may fail to devote the resources necessary to realize the full commercial potential of our products. In addition, we may lack the financial and managerial resources to increase the size of our sales and marketing organization to adequately commercialize any product candidates that may be approved, and any increase in our sales force would result in an increase in our expenses, which could be significant before we generate revenues from any newly approved product candidate. If we are unable to expand our sales and marketing infrastructure or enter into a third-party arrangement, we would not be able to successfully commercialize any approved products. Even if we are able to expand our sales and marketing personnel or successfully establish partnership arrangements, such sales force and marketing teams may not be successful in commercializing our products, which would adversely affect our ability to generate revenue for such products, which will have a material adverse effect on our business, results of operations, financial condition and prospects.

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

As part of our growth strategy we intend to seek to expand our product pipeline by exploring acquisition or in-licensing opportunities of proven drugs that can be paired with our DosePro needle-free drug delivery system. However, the current version of our DosePro drug delivery system cannot be used with drug formulation volumes greater than 0.5 mL. Many marketed and development-stage injectable products, including most biologics, have formulation volumes greater than 0.5 mL and would require reformulation, if possible, to accommodate the approved doses in smaller volumes that are compatible with DosePro. Any reformulation may increase the risk of failure during development, extend the development timelines, increase development costs and add complexity to the regulatory approval process and in some cases reformulation may not be possible. If we are not able to identify additional drug compounds that can be delivered via the current version of our DosePro technology, or if we are unable to successfully develop higher dose versions of this technology, our ability to develop additional product candidates and grow our business would be adversely affected. We will also seek opportunities to out-license the DosePro technology to partners seeking to enhance, differentiate, or extend the life-cycle of their injectable products. If we are unable to secure partnerships with companies that have compounds that can be delivered via the current version of our DosePro technology, or if we are unable to successfully develop higher dose versions of this technology, we will not be able to generate revenues from out-licensing our DosePro technology.

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

Furthermore, we intend to in-license, acquire, develop and/or market additional products and product candidates in the areas of pain and central nervous system, or CNS, disorders. Because our internal research and development capabilities are limited, we may be dependent upon pharmaceutical and biotechnology companies, academic scientists and other researchers to sell or license products or technology to us. The success of this strategy depends partly upon our ability to identify and select promising pharmaceutical product candidates and products, negotiate licensing or acquisition agreements with their current owners and finance these arrangements.

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

Further, any product candidate that we acquire may require additional development efforts prior to commercial sale, including pre-clinical or clinical testing and approval by the FDA and applicable foreign regulatory authorities. All product candidates are prone to risks of failure typical of pharmaceutical product development, including the possibility that a product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities. In addition, we cannot provide assurance that any products that we develop or approved products that we acquire will be manufactured or sold profitably or achieve market acceptance.

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

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

In a short period of time from November 2009 until January 2010, we hired approximately 80 field-based sales employees and related sales and managed markets management personnel to complete our commercial infrastructure in order to launch Sumavel DosePro. This additional hiring contributed to an increase in our full-time employees from 48 as of October 31, 2009 to 145 as of September 30, 2010. We may need to continue to expand our managerial, operational and other resources in order to grow, manage and fund our existing business. Our management and personnel, systems and facilities currently in place may not be adequate to support this recent and any future growth, and we may be unable to fund the costs and expenses required to increase our necessary headcount and infrastructure. Our need to effectively manage our operations, any future growth and various projects requires that we:

- manage our internal and external commercialization efforts for Sumavel DosePro effectively while carrying out our contractual obligations to Astellas and other third parties and complying with all applicable laws, rules and regulations;
- manage our internal development efforts for ZX002 and our other product candidates effectively while carrying out our contractual obligations to licensors, collaborators and other third parties and complying with all applicable laws, rules and regulations;
- continue to improve our operational, financial and management controls, reporting systems and procedures; and
- attract and retain sufficient numbers of talented employees.

We may be unable to successfully implement or fund these tasks on a larger scale and, accordingly, may not achieve our commercialization and development goals. In addition, our management may have to divert a disproportionate amount of its attention away from day-to-day activities and towards managing these growth-related activities. Our future financial performance and our ability to execute on our business plan will depend, in part, on our ability to effectively manage any future growth and our failure to effectively manage any growth could have a material adverse effect on our business, results of operations, financial condition and prospects.

If we are unable to attract and retain key personnel, we may not be able to manage our business effectively or develop our product candidates or commercialize our product.

Our success depends on our continued ability to attract, retain and motivate highly qualified management and key clinical development, regulatory, sales and marketing and other personnel. We are highly dependent on the development, regulatory, commercial and financial expertise of our senior management team. We may not be able to attract or retain qualified management and scientific and clinical personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses, particularly in the areas in Southern and Northern California, where we currently operate. Our industry has experienced a high rate of turnover of management personnel in recent years. If we are not able to attract, retain and motivate necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development and commercialization objectives, our ability to raise additional capital and our ability to implement our business strategy. The loss of the services of any members of our senior management team, especially our Chief Executive Officer, Roger L. Hawley, and President and Chief Operating Officer, Stephen J. Farr, Ph.D., could negatively impact the commercialization of Sumavel DosePro and could delay or prevent the development and commercialization of any other product candidates, including ZX002. In addition, under the terms of our amended and restated loan and security agreement with Oxford Finance Corporation and Silicon Valley Bank, if our Chief Executive Officer, Chief Financial Officer or President resigns, is terminated or is no longer actively involved in his or her current position and is not replaced by a person acceptable to our board of directors within 120 days, an event of default would be triggered under the agreement, and the lenders would be able to demand immediate repayment of all borrowings outstanding under the agreement. Further, if we lose any members of our senior management team, we may not be able to find suitable replacements, and our business may be harmed as a result. In addition to the competition for personnel, our locations in California in particular are characterized by a high cost of living. As such, we could have difficulty attracting experienced personnel to our company and may be required to expend significant financial resources in our employee recruitment and retention efforts.

Although we have employment agreements with each of our executive officers, these agreements are terminable by them at will at any time with or without notice and, therefore, do not provide any assurance that we will be able to retain their services. We do not maintain key man insurance policies on the lives of our senior management team or the lives of any of our other employees. In addition, we have clinical advisors who assist us in formulating our clinical strategies. These advisors are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us, or may have arrangements with other companies to assist in the development of products that may compete with ours. If we are unable to attract and retain key personnel, our business, results of operations, financial condition and prospects will be adversely affected.

We may engage in strategic transactions that could impact our liquidity, increase our expenses and present significant distractions to our management.

From time to time we may consider strategic transactions, such as acquisitions of companies, asset purchases and out-licensing or in-licensing of products, product candidates or technologies. Additional potential transactions that we may consider include a variety of different business arrangements, including spin-offs, strategic partnerships, joint ventures, restructurings, divestitures, business combinations and investments. Any such transaction may require us to incur non-recurring or other charges, may increase our near and long-term expenditures and may pose significant integration challenges or disrupt our management or business, which could adversely affect our operations and financial results. For example, these transactions may entail numerous operational and financial risks, including:

- exposure to unknown liabilities;
- disruption of our business and diversion of our management s time and attention in order to develop acquired products, product candidates or technologies;

incurrence of substantial debt or dilutive issuances of equity securities to pay for acquisitions;

higher than expected acquisition and integration costs;

write-downs of assets or goodwill or impairment charges;

increased amortization expenses;

difficulty and cost in combining the operations and personnel of any acquired businesses with our operations and personnel;

impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership; and

inability to retain key employees of any acquired businesses.

Accordingly, although there can be no assurance that we will undertake or successfully complete any transactions of the nature described above, any transactions that we do complete could have a material adverse effect on our business, results of operations, financial condition and prospects.

If we are unable to achieve and maintain adequate levels of coverage and reimbursement for Sumavel DosePro, ZX002, if approved, or any of our other product candidates for which we may receive regulatory approval on reasonable pricing terms, their commercial success may be severely hindered.

Successful sales of our products depend on the availability of adequate coverage and reimbursement from third-party payors. Patients who are prescribed medicine for the treatment of their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their prescription drugs. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available. Assuming coverage is approved, the resulting reimbursement payment rates might not be adequate or may require co-payments that patients find unacceptably high. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products.

In addition, the market for our products will depend significantly on access to third-party payors drug formularies, or lists of medications for which third-party payors provide coverage and reimbursement. The industry competition to be included in such formularies often leads to downward pricing pressures on pharmaceutical companies. Also, third-party payors may refuse to include a particular branded drug in their formularies or otherwise restrict patient access to a branded drug when a less costly generic equivalent or other alternative is available.

Third-party payors, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In addition, in the United States, no uniform policy of coverage and reimbursement for drug products exists among third-party payors. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor.

Further, we believe that future coverage and reimbursement will likely be subject to increased restrictions both in the United States and in international markets. Third-party coverage and reimbursement for Sumavel DosePro or any of our other product candidates for which we may receive regulatory approval may not be available or adequate in either the United States or international markets, which could have a material adverse effect on our business, results of operations, financial condition and prospects.

We face potential product liability exposure, and if successful claims are brought against us, we may incur substantial liability if our insurance coverage for those claims is inadequate.

The commercial use of our product and clinical use of our product and product candidates expose us to the risk of product liability claims. This risk exists even if a product is approved for commercial sale by the FDA and manufactured in facilities licensed and regulated by the FDA, such as the case with Sumavel DosePro, or an applicable foreign regulatory authority. Our product and product candidates are designed to affect important bodily functions and processes. Any side effects, manufacturing defects, misuse or abuse associated with Sumavel DosePro or our product candidates could result in injury to a patient or even death. For example, because our DosePro technology is designed to be self-administered by patients, it is possible that a patient could fail to follow instructions and as a result apply a dose in a manner that results in injury. In addition, ZX002 is an opioid pain reliever that contains *hydrocodone*, which is a regulated controlled substance under the Controlled Substances Act of 1970, or CSA, and could result in harm to patients relating to its potential for abuse. In addition, a liability claim may be brought against us even if our product or product candidates merely appear to have caused an injury. Product liability claims may be brought against us by consumers, health care providers, pharmaceutical companies or others selling or otherwise coming into contact with our product candidates, among others. If we cannot successfully defend ourselves against product liability claims we will incur substantial liabilities. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- the inability to commercialize our product or product candidates;
- decreased demand for our product or product candidates;
- impairment of our business reputation;
- product recall or withdrawal from the market;
- withdrawal of clinical trial participants;
- costs of related litigation;
- distraction of management s attention from our primary business;
- substantial monetary awards to patients or other claimants; or
- loss of revenues.

We have obtained product liability insurance coverage for commercial product sales and clinical trials with a $5 million per occurrence and a $5 million annual aggregate coverage limit. Our insurance coverage may not be sufficient to cover all of our product liability related expenses or losses and may not cover us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain insurance coverage at a reasonable cost, in sufficient amounts or upon adequate terms to protect us against losses due to product liability. If we determine that it is prudent to increase our product liability coverage based on sales of Sumavel DosePro, approval of ZX002 or otherwise, we may be unable to obtain this increased product liability insurance on commercially reasonable terms or at all. Large judgments have been awarded in class action or individual lawsuits based on drugs that had unanticipated side effects, including side effects that are less severe than those of Sumavel DosePro and our product candidates. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could decrease our cash and have a material adverse affect our business, results of operations, financial condition and prospects.

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

Despite the implementation of security measures, our internal computer systems and those of our current and any future partners, contractors and consultants are vulnerable to damage from computer

viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any such material system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our commercialization activities, drug development programs and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on a large number of third parties to supply components for and manufacture our product and product candidates, warehouse and distribute Sumavel DosePro and conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our product and product candidates could be delayed.

We may be adversely affected by earthquakes or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Our corporate headquarters and other facilities are located in San Diego and the San Francisco Bay Area, which in the past have both experienced severe earthquakes. We do not carry earthquake insurance. As a result, earthquakes or other natural disasters could severely disrupt our operations, and have a material adverse effect on our business, results of operations, financial condition and prospects.

Our enterprise financial systems are located in our San Diego, California headquarters. Our manufacturing resource planning and enterprise quality systems are located in our Emeryville, California facility. If a disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters or our Emeryville facility, that damaged critical infrastructure, such as enterprise financial systems or manufacturing resource planning and enterprise quality systems, or that otherwise disrupted operations at either location, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place currently are limited and are unlikely to prove adequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans which, particularly when taken together with our lack of earthquake insurance, could have a material adverse effect on our business.

Our business involves the use of hazardous materials and we and our third-party manufacturers and suppliers must comply with environmental laws and regulations, which can be expensive and restrict how we do business.

Our research and development activities and our third-party manufacturers and suppliers activities involve the controlled storage, use and disposal of hazardous materials owned by us, including the components of our product and product candidates and other hazardous compounds. We and our manufacturers and suppliers are subject to laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. In some cases, these hazardous materials and various wastes resulting from their use are stored at our and our manufacturers facilities pending use and disposal. We cannot completely eliminate the risk of contamination, which could cause an interruption of our commercialization efforts, research and development efforts and business operations, injury to our employees and others, environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by our third-party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources. We do not currently carry biological or hazardous waste insurance coverage.

In connection with the reporting of our financial condition and results of operations, we are required to make estimates and judgments which involve uncertainties, and any significant differences between our estimates and actual results could have an adverse impact on our financial position, results of operations and cash flows.

Our discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States, or GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and related disclosure of contingent assets and liabilities. In particular, as part of our revenue recognition policy, our estimates of product returns, rebates and chargebacks require our most subjective and complex judgment due to the need to make estimates about matters that are inherently uncertain. Any significant differences between our actual results and our estimates and assumptions could negatively impact our financial position, results of operations and cash flows.

Changes in accounting standards and their interpretations could adversely affect our operating results.

GAAP are subject to interpretation by the Financial Accounting Standards Board, the American Institute of Certified Public Accountants, the Securities and Exchange Commission, or SEC, and various other bodies that promulgate and interpret appropriate accounting principles. These principles and related implementation guidelines and interpretations can be highly complex and involve subjective judgments. A change in these principles or interpretations could have a significant effect on our reported financial results, and could affect the reporting of transactions completed before the announcement of a change.

Fluctuations in the value of the Euro or U.K. pound sterling could negatively impact our results of operations and increase our costs.

Payments to our material suppliers and contract manufactures are denominated in the Euro and U.K. pounds sterling. Our reporting currency is the U.S. dollar and to date all of the revenues generated by sales of Sumavel DosePro have been in U.S. dollars. For the nine months ended September 30, 2010, $25.4 million (based on exchange rates as of September 30, 2010) of our materials, contract manufacturing costs and other manufacturing-related costs were denominated in foreign currencies. As a result, we are exposed to foreign exchange risk, and our results of operations may be negatively impacted by fluctuations in the exchange rate between the U.S. dollar and the Euro or U.K. pound sterling. A significant appreciation in the Euro or U.K. pound sterling relative to the U.S. dollar will result in higher expenses and cause increases in our net losses. Likewise, to the extent that we generate any revenues denominated in foreign currencies, or become required to make payments in other foreign currencies, fluctuations in the exchange rate between the U.S. dollar and those foreign currencies could also negatively impact our results of operations. We currently have not entered into any foreign currency hedging contracts to reduce the effect of changes in foreign currency exchange rates, and foreign currency hedging is inherently risky and may result in unanticipated losses.

Our operating results are partially dependent on freight costs and our costs may increase significantly if we are unable to ship and transport finished products efficiently and economically across long distances and international borders.

Our Sumavel DosePro product is manufactured in Europe and we transport significant volumes of that product across long distances and international borders. As a result, our operating results can be affected by changes in transportation costs. We generally ship our product by air freight, and freight rates can vary significantly due to a large number of factors beyond our control, including changes in fuel prices or general economic conditions. If demand for air freight should increase substantially, it could make it difficult for us to procure transportation space at prices we consider acceptable.

Because our products must cross international borders, we are subject to risk of delay due to customs inspection, if our documentation does not comply with customs rules and regulations or for similar reasons. In addition, any increases in customs duties or tariffs, as a result of changes to existing trade agreements between countries or otherwise, could increase our costs or the final cost of our products to our customers or increase our expenses. The laws governing customs and tariffs in many countries are complex, subject to many interpretations and often includes substantial penalties for noncompliance.

Risks Related to Our Financial Position and Capital Requirements

We have never generated net income or positive cash flow from operations and are dependent upon external sources of financing to fund our business and development.

We are at an early stage of commercialization, having launched our only approved product, Sumavel DosePro, in January 2010. Without a long history of sales, we may not accurately predict future sales, and we may never be able to significantly increase these sales, especially in light of our reliance on our partnership with Astellas to co-promote Sumavel DosePro. We have financed our operations almost exclusively through private placements of preferred stock and debt and have incurred losses and negative cash flow from operations in each year since our inception. Our net loss applicable to common stockholders was $46.0 million in 2007, $45.6 million in 2008, $45.9 million in 2009 and $71.4 million for the nine months ended September 30, 2010, and our cash used in operating activities was $26.8 million in 2007, $41.3 million in 2008, $32.4 million in 2009 and $58.5 million for the nine months ended September 30, 2010. As of September 30, 2010, we had an accumulated deficit of $196.0 million. These losses and negative cash flow from operations have had a material adverse effect on our stockholders equity and working capital. Further, despite the revenues from Sumavel DosePro, we expect our losses to continue for at least the next several years as a result of the cost of the sales and marketing expense associated with Sumavel DosePro and the increasing development expenses in connection with our ongoing Phase 3 clinical trials for ZX002. In addition, if we obtain regulatory approval for ZX002 or any of our other product candidates, we expect to incur significant sales, marketing and manufacturing expenses as well as continued development expenses. As a result, we are and will remain dependent upon external sources of financing to finance our business and the development and commercialization of our approved product and product candidates. We cannot assure you that debt or equity financing will be available to us in amounts, at times or on terms that will be acceptable to us, or at all. Any shortfall in our cash resources could require that we delay or abandon certain development and commercialization activities and could otherwise have a material adverse effect on our business, results of operations, financial condition and prospects.

Our independent registered public accounting firm has expressed substantial doubt as to our ability to continue as a going concern.

In its report accompanying our audited financial statements for the year ended December 31, 2009, our independent registered public accounting firm included an explanatory paragraph stating that our recurring losses from operations and lack of sufficient working capital raise substantial doubt as to our ability to continue as a going concern. A going concern opinion could impair our ability to finance our operations through the sale of debt or equity securities or commercial bank loans. Our ability to continue as a going concern will depend, in large part, on our ability to generate positive cash flow from operations and obtain additional financing, neither of which is certain. If we are unable to achieve these goals, our business would be jeopardized and we may not be able to continue operations and may have to liquidate our assets and may receive less than the value at which those assets are carried on our financial statements, and it is likely that investors will lose all or a part of their investment. In addition, our amended loan and security agreement with Oxford Finance Corporation and Silicon Valley Bank includes a covenant that the audit reports accompanying our annual financial statements for fiscal year 2010 and thereafter not include a going concern qualification and any breach of that covenant would permit the lenders to demand immediate repayment of all loans outstanding under the agreement and to seize and sell the collateral.

Our level of indebtedness could adversely affect our ability to raise additional capital to fund our operations, limit our ability to react to changes in the economy or our industry and prevent us from meeting our obligations.

As of September 30, 2010, the principal amount of our total indebtedness was approximately $43.7 million. We have and expect to continue to make borrowings under our $10.0 million revolving credit facility to fund working capital and other cash needs and we may incur substantial additional indebtedness in the future, both under our $10.0 million revolving credit facility and any other debt facilities we may enter into in the future. Our outstanding debt and related debt service obligations could have important adverse consequences to us, including:

- heightening our vulnerability to downturns in our business or our industry or the general economy and restricting us from making improvements or acquisitions, or exploring business opportunities;
- requiring a significant portion of our available cash to be dedicated to the payment of principal and interest on our indebtedness, therefore reducing our ability to use our available cash to fund our operations, capital expenditures and future business opportunities;
- limiting our ability to obtain additional financing for working capital, capital expenditures, debt service requirements, acquisitions and general corporate or other purposes;
- limiting our ability to adjust to changing market conditions and placing us at a competitive disadvantage compared to our competitors who have greater capital resources; and
- subjecting us to financial and other restrictive covenants in our debt instruments, the failure with which to comply could result in an event of default under the applicable debt instrument that allows the lender to demand immediate repayment of the related debt.

If our cash flows and capital resources are insufficient to fund our debt service obligations, we may be forced to reduce or delay product development, sales and marketing, capital and other expenditures, sell assets, seek additional capital or restructure or refinance our indebtedness. These alternative measures may not be successful and may not permit us to meet our scheduled debt service obligations. This risk is increased by the fact that borrowings under certain of our credit facilities bear interest at a variable rates, exposing us to the risk that the amount of cash required to pay interest will increase to the extent that market interest rates increase.

Our debt instruments contain a number of financial covenants and other provisions, including a requirement that we attain specified future levels of revenues, which, if violated, could result in the immediate acceleration of our outstanding indebtedness.

Our $35.0 million amended and restated loan and security agreement with Oxford Finance Corporation and Silicon Valley Bank includes covenants requiring, among other things, that (1) we achieve, as of the last day of each month measured on a trailing three-month basis, actual revenues of at least a specified percentage of our projected revenue as provided to Oxford Finance Corporation and Silicon Valley Bank in the event we fail to maintain a liquidity ratio (defined, in general, as the ratio of (a) cash and cash equivalents deposited with Silicon Valley Bank plus unused borrowing capacity under that agreement to (b) all debt, capital lease obligations and contingent obligations owed to the lenders) of 1.25 to 1.00, (2) we complete an equity or subordinated debt financing of at least $10.0 million prior to November 30, 2010 and (3) the audit report accompanying our year-end financial statements for fiscal year 2010 and thereafter not include a going concern qualification. As discussed above, the audit report accompanying our 2009 financial statements includes a going concern qualification and, as a result, our results of operations and financial condition will have to improve to a point where our auditors can deliver their audit report without this qualification in order to avoid a breach of this covenant. In addition, the amended and restated loan and security agreement prohibits the occurrence of a change in control (as defined in the agreement) of our company. The agreement provides that an event of default will occur if,

among other customary events of default, (1) there is a material adverse change in our business, operations or condition (financial or otherwise) or material impairment in the prospects of us repaying any portion of our obligations under the agreement, (2) there is a material impairment in the value of the collateral pledged to secure our obligations under the agreement, (3) we default in the payment of any amount payable under the agreement when due, or (4) we breach any covenant in the agreement (subject to a grace period in some cases). Our loan and security agreement with General Electric Capital Corporation, or GE Capital, does not have any financial covenants, but it provides that an event of default will occur if, among other things, we fail to pay amounts owing under the agreement when due or if a material adverse change in our business occurs. In both 2009 and 2010, we were required to obtain amendments or waivers under our credit facilities, and we may in the future need to obtain waivers or amendments under our credit facilities or other debt instruments, in order to avoid a breach or default, particularly if our business deteriorates or does not perform in accordance with our expectations.

Our $35.0 million amended and restated loan and security agreement with Oxford Finance Corporation and Silicon Valley Bank is secured by our personal property (including, among other things, accounts receivable, equipment, inventory, contract rights, rights to payment of money, license agreements, general intangibles and cash), but excluding, among other things, copyrights, patents, patent applications, trademarks, service marks, trade secret rights and equipment pledged to secure the GE Capital credit facility, and our loan and security agreement with GE Capital is secured by a pledge of specific equipment used to manufacture DosePro. Each agreement contains provisions which allow the lenders to demand immediate repayment of the debt and to seize and sell the collateral to pay that debt upon the occurrence of an event of default under the agreement. If we are unable to pay the indebtedness secured by collateral when due, whether at maturity or if declared due and payable by the lender following a default, the lender generally has the right to seize and sell the collateral securing that indebtedness.

There can be no assurance that we will not breach the covenants or other terms of, or that an event of default will not occur under, our credit facilities or any other debt instruments and, if a breach or event of default occurs, there can be no assurance that we will be able to obtain necessary waivers or amendments from the lenders or refinance the related indebtedness on terms we find acceptable, or at all. As a result, any failure to pay our debt service obligations when due, any breach or default of our covenants or other obligations under debt instruments, or any other event that allows any lender to demand immediate repayment of borrowings, could have a material adverse effect on our business, results of operations, financial condition and prospects.

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

Our operations have consumed substantial amounts of cash since inception. To date, our operations have been primarily financed through the proceeds from the issuance of our preferred stock and borrowings under our loan agreements with GE Capital and Oxford Finance Corporation, Silicon Valley Bank and CIT Corporation. We expect to continue to spend substantial amounts on commercialization activities for Sumavel DosePro, development activities for ZX002 and our other product candidates and, if ZX002 or our other product candidates are approved, the commercialization of those products, including significant amounts on conducting clinical trials, manufacturing, clinical supplies and expanding our product development and sales and marketing programs. Developing products for the pain-relief market, conducting clinical trials, establishing outsourced manufacturing relationships and successfully manufacturing and marketing Sumavel DosePro and any other approved drugs is expensive and we expect that our monthly cash used by operations will increase substantially for the next several years. We will likely need to raise additional capital to:

maintain and continue to increase our sales and marketing activities for Sumavel DosePro;

qualify secondary sources for the manufacturing of Sumavel DosePro;

fund our operations and continue to conduct clinical trials of ZX002 and any other product candidate to support potential regulatory approval of marketing applications; and

commercialize any of our product candidates or any products or product candidates that we may develop, in-license or otherwise acquire, if any of these product candidates receive regulatory approval.

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

the commercial success of Sumavel DosePro;

the timing of regulatory approval, if granted, of ZX002 or any other product candidates;

the rate of progress and cost of our clinical trials and other product development programs for ZX002 and our other product candidates and any other product candidates that we may develop, in-license or acquire;

the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights associated with Sumavel DosePro, ZX002 and any of our other product candidates;

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

the costs of maintaining and expanding our sales and marketing infrastructure or establishing distribution capabilities, should we elect to do so;

the effect of competing technological and market developments; and

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

Until we can generate a sufficient amount of product revenue and cash flow from operations and achieve profitability, we expect to finance future cash needs through public or private equity offerings, debt financings, receivables or royalty financings or corporate collaboration and licensing arrangements. If we raise additional funds by issuing equity securities, substantial dilution to existing stockholders would result. If we raise additional funds by incurring debt financing, the terms of the debt may involve significant cash payment obligations as well as covenants and specific financial ratios that may restrict our ability to operate our business. We cannot be certain that additional funding will be available on acceptable terms, or at all. If adequate funds are not available, we may be required to significantly delay, reduce the scope of or eliminate one or more of our development programs or our commercialization efforts. We also may be required to relinquish, license or otherwise dispose of rights to product candidates or products that we would otherwise seek to develop or commercialize ourselves on terms that are less favorable than might otherwise be available. Any of the foregoing could have a material adverse effect on our business, results of operations, financial condition and prospects.

Our results of operations and liquidity needs could be materially negatively affected by market fluctuations and economic downturn.

Our results of operations and liquidity could be materially negatively affected by economic conditions generally, both in the U.S. and elsewhere around the world. Domestic and international equity and debt markets have experienced and may continue to experience heightened volatility and turmoil based on domestic and international economic conditions and concerns. In the event these economic conditions and concerns continue or worsen and the markets continue to remain volatile, our results of operations and liquidity could be adversely affected by those

factors in many ways, including

making it more difficult for us to raise funds if necessary, and our stock price may decline. In addition, we maintain significant amounts of cash and cash equivalents at one or more financial institutions that are not federally insured. If economic instability continues, we cannot provide assurance that we will not experience losses on these investments.

Raising additional funds by issuing securities may cause dilution to existing stockholders and raising funds through lending and licensing arrangements may restrict our operations or require us to relinquish proprietary rights.

We may raise additional funds through public or private equity offerings, debt financings, receivables or royalty financings or corporate collaboration and licensing arrangements. To the extent that we raise additional capital by issuing equity securities or convertible debt, your ownership interest in us will be diluted. Debt financing typically contains covenants that restrict operating activities. Our loan and security agreement with Oxford Finance Corporation and Silicon Valley Bank is secured by our personal property, including, among other things, accounts receivable, equipment, inventory, contract rights, rights to payment of money, license agreements, general and tangibles and cash, but excluding, among other things, copyrights, patents, patent applications, trademarks, service markets, trade secret rights and equipment pledged to secure the GE Capital loan facility and our loan and security agreement with GE Capital is secured by a pledge of specific equipment used to manufacture DosePro. Each such agreement contains provisions which allow such lenders to accelerate the debt and seize and sell the collateral if, among other things, we fail to pay principal or interest when due or breach our obligations under the agreements or if a material adverse change in our business or any other event of default occurs. Any future debt financing we enter into may involve more onerous covenants that restrict our operations, may be secured by some or all of our assets and will likely allow the lenders to accelerate the debt and seize and sell any collateral following a default. Our obligations under these loan and security agreements or any future debt financing will need to be repaid, which creates additional financial risk for our company, particularly if our business or prevailing financial market conditions are not conducive to paying-off or refinancing our outstanding debt obligations.

If we raise additional funds through collaboration, licensing or other similar arrangements, it may be necessary to relinquish potentially valuable rights to our current product or product candidates or proprietary technologies, or grant licenses on terms that are not favorable to us. If adequate funds are not available, our ability to achieve profitability or to respond to competitive pressures would be significantly limited and we may be required to delay, significantly curtail or eliminate the commercialization and development of our product or product candidates.

Our ability to utilize our net operating loss and research and development income tax credit carryforwards may be limited.

Under Section 382 of the Internal Revenue Code of 1986, as amended, or the IRC, substantial changes in our ownership may limit the amount of net operating loss and research and development income tax credit carryforwards that could be utilized annually in the future to offset taxable income, if any. Specifically, this limitation may arise in the event of a cumulative change in ownership of our company of more than 50% within a three-year period. Any such annual limitation may significantly reduce the utilization of the net operating loss carryforwards before they expire. We performed a Section 382 and 383 analysis and determined that we had one ownership change, as defined by IRC Sections 382 and 383, which occurred in August 2006 upon the issuance of Series A-1 preferred shares. As a result of this ownership change, we reduced our net operating loss carryforwards by $1.9 million and research and development income tax credit by $8,000. The closing of this offering, together with private placements and other transactions that have occurred since our inception, may trigger an ownership change pursuant to Sections 382 and 383, which could further limit the amount of net operating loss carryforwards that could be utilized annually in the future to offset taxable income, if any. Any such limitation, whether as the result of prior private placements, sales of common stock by our existing stockholders or additional sales of common stock by us after this offering, could have an adverse effect on our results of operations.

Risks Related to Regulation of our Product and Product Candidates

Our currently marketed product, Sumavel DosePro, is and any of our other product candidates that receive regulatory approval will be subject to ongoing and continued regulatory review, which may result in significant expense and limit our ability to commercialize such products.

Even after we achieve U.S. regulatory approval for a product, the FDA may still impose significant restrictions on the approved indicated uses for which the product may be marketed or on the conditions of approval. For example, a product s approval may contain requirements for potentially costly post-approval studies and surveillance, including Phase 4 clinical trials, to monitor the safety and efficacy of the product. We will also be subject to ongoing FDA obligations and continued regulatory review with respect to the manufacturing, processing, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs and with GCPs and good laboratory practices, which are regulations and guidelines enforced by the FDA for all of our products in clinical and pre-clinical development, and for any clinical trials that we conduct post-approval. To the extent that a product is approved for sale in other countries, we may be subject to similar restrictions and requirements imposed by laws and government regulators in those countries.

In the case of ZX002 and any other product candidates or products containing controlled substances, we and our contract manufacturers will also be subject to ongoing DEA regulatory obligations, including, among other things, annual registration renewal, security, recordkeeping, theft and loss reporting, periodic inspection and annual quota allotments for the raw material for commercial production of our products. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP regulations, QSR requirements for medical device components or similar requirements, if applicable. If we or a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where, or processes by which, the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturer or us, including requiring product recall, notice to physicians, withdrawal of the product from the market or suspension of manufacturing. In that regard, because all of our contract manufacturers for Sumavel DosePro are located outside the United States, they may be subject to foreign laws and regulations governing the manufacture of drugs and devices, and any failure by them to comply with those laws and regulations may delay or interrupt supplies of our product.

If we, our product or product candidates or the manufacturing facilities for our product or product candidates fail to comply with applicable regulatory requirements, a regulatory agency may:

- impose restrictions on the marketing or manufacturing of the product, suspend or withdraw product approvals or revoke necessary licenses;
- issue warning letters, show cause notices or untitled letters describing alleged violations, which may be publicly available;
- commence criminal investigations and prosecutions;
- impose injunctions, suspensions or revocations of necessary approvals or other licenses;
- impose fines or other civil or criminal penalties;
- suspend any ongoing clinical trials;
- deny or reduce quota allotments for the raw material for commercial production of our controlled substance products;
- delay or refuse to approve pending applications or supplements to approved applications filed by us;

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refuse to permit drugs or precursor chemicals to be imported or exported to or from the United States;

suspend or impose restrictions on operations, including costly new manufacturing requirements; or

seize or detain products or require us to initiate a product recall.

In addition, our product labeling, advertising and promotion are subject to regulatory requirements and continuing regulatory review. The FDA strictly regulates the promotional claims that may be made about prescription drug products. In particular, a drug may not be promoted for uses that are not approved by the FDA as reflected in the product s approved labeling, although the FDA does not regulate the prescribing practices of physicians. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability, including substantial monetary penalties and criminal prosecution.

The FDA s regulations, policies or guidance may change and new or additional statutes or government regulations may be enacted that could prevent or delay regulatory approval of our product candidates or further restrict or regulate post-approval activities. We cannot predict the likelihood, nature or extent of adverse government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are not able to achieve and maintain regulatory compliance, we may not be permitted to market our drugs, which would adversely affect our ability to generate revenue and achieve or maintain profitability.

Sumavel DosePro, ZX002 and our other product candidates may cause undesirable side effects or have other unexpected properties that could result in post-approval regulatory action.

If we or others identify undesirable side effects, or other previously unknown problems, caused by our products, other products or our product candidates with the same or related active ingredients, after obtaining U.S. regulatory approval, a number of potentially significant negative consequences could result, including:

regulatory authorities may withdraw their approval of the product;

regulatory authorities may require us to recall product;

regulatory authorities may require the addition of warnings in the product label or narrowing of the indication in the product label;

we may be required to create a Medication Guide outlining the risks of such side effects for distribution to patients;

we may be required to change the way the product is administered or modify the product in some other way;

the FDA may require us to conduct additional clinical trials or costly post-marketing testing and surveillance to monitor the safety or efficacy of the product;

we could be sued and held liable for harm caused to patients; and

our reputation may suffer.

The most common treatment-emergent adverse reactions (reported by at least 5% of patients) for *sumatriptan* injection as described in the Sumavel DosePro Prescribing Information summarizing two large placebo-controlled clinical trials were injection site reaction (59%), atypical sensations (42%), dizziness (12%), flushing (7%), chest discomfort (5%), weakness (5%), and neck pain/stiffness (5%).

While the adverse reaction profile for ZX002 has not yet been fully characterized in Phase 3 clinical trials, in two completed Phase 2 studies of ZX002 patients experienced mild to moderate adverse

events, such as nausea, vomiting, headache, dizziness, sweating, constipation and drowsiness, which are similar to the reported effects of opioids currently prescribed for chronic pain.

Any of the above events resulting from undesirable side effects or other previously unknown problems could prevent us from achieving or maintaining market acceptance of the affected product and could substantially increase the costs of commercializing our product candidates.

Our development and commercialization strategy for ZX002 depends upon the FDA s prior findings of safety and effectiveness of ZX002 based on data not developed by us, but which the FDA may rely upon in reviewing our NDA.

The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Amendments, added Section 505(b)(2) to the FFDCA. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. Under this statutory provision, the FDA may rely, for purposes of approving an NDA, on findings of safety and effectiveness based on data not developed by the filer of the NDA. Similar to Sumavel DosePro, we intend to submit the NDA for ZX002 under Section 505(b)(2), and as such the NDA will rely, in part, on the FDA s previous findings of safety and effectiveness for *hydrocodone*. Even though we may be able to take advantage of Section 505(b)(2) to support potential U.S. approval for ZX002, the FDA may require us, and did require us with respect to Sumavel DosePro, to perform additional studies or measurements to support approval. In addition, the FDA s interpretation and use of Section 505(b)(2) has been controversial and has previously been challenged in court, but without a definitive ruling on the propriety of the FDA s approach. Future challenges, including a direct challenge to the approval of our products, may be possible and, if successful, could limit or eliminate our ability to rely on the Section 505(b)(2) pathway for the approval of our products. Such a result could require us to conduct additional testing and costly clinical trials, which could substantially delay or prevent the approval and launch of our products.

ZX002 will be subject to DEA regulations and, failure to comply with these regulations, or the cost of compliance with these regulations, may adversely affect our business.

ZX002 contains *hydrocodone*, a regulated controlled substance under the CSA, which establishes, among other things, certain registration, production quotas, security, recordkeeping, reporting, import, export and other requirements administered by the DEA. The DEA regulates controlled substances as Schedule I, II, III, IV or V substances. Schedule I substances by definition have no established medicinal use and may not be marketed or sold in the United States. A pharmaceutical product may be listed as Schedule II, III, IV or V, with Schedule II substances considered to present the highest risk of abuse and Schedule V substances the lowest relative risk of abuse among such substances. ZX002, because it is a single-entity *hydrocodone* product, is expected to be regulated by the DEA as a Schedule II controlled substance under the CSA. All Schedule II substance prescriptions, such as prescriptions for ZX002, must be in writing and signed by a physician, physically presented to a pharmacist and may not be refilled without a new prescription.

The manufacture, shipment, storage, sale and use, among other things, of controlled substances that are pharmaceutical products are subject to a high degree of regulation, including security, record-keeping and reporting obligations enforced by the DEA. Our failure to comply with these requirements could result in the loss of our DEA registration, significant restrictions on ZX002, civil penalties or criminal prosecution.

The DEA, and some states, also conduct periodic inspections of registered establishments that handle controlled substances. Facilities that conduct research, manufacture, store, distribute, import or export controlled substances must be registered to perform these activities and have the security, control and inventory mechanisms required by the DEA to prevent drug loss and diversion. Failure to

maintain compliance, particularly non-compliance resulting in loss or diversion, can result in regulatory action that could have a material adverse effect on our business, results of operations, financial condition and prospects. The DEA may seek civil penalties, refuse to renew necessary registrations, or initiate proceedings to revoke those registrations. In certain circumstances, violations could lead to criminal proceedings.

Individual states also have controlled substances laws. Though state controlled substances laws often mirror federal law, because the states are separate jurisdictions, they may separately schedule drugs, as well. While some states automatically schedule a drug when the DEA does so, in other states there has to be rulemaking or a legislative action. State scheduling may delay commercial sale of any controlled substance drug product for which we obtain federal regulatory approval and adverse scheduling could have a material adverse effect on the commercial attractiveness of such product. We or our partners must also obtain separate state registrations in order to be able to obtain, handle, and distribute controlled substances for clinical trials or commercial sale, and failure to meet applicable regulatory requirements could lead to enforcement and sanctions from the states in addition to those from the DEA or otherwise arising under federal law.

The FDA, in consultation with the DEA, will require us to develop a comprehensive risk management program to reduce the inappropriate use of our product candidate, including restrictions on the manner in which it is marketed and sold, so as to reduce the risk of improper patient selection and diversion or abuse of the product. Developing such a program in consultation with the FDA may be a time-consuming process and could delay approval of our product candidate. Such a program or delays of any approval from the FDA could limit market acceptance of the product.

Under the terms of our license agreement with Elan, Elan has the exclusive right to manufacture and supply both clinical and commercial supplies of ZX002. While Elan is required to comply with applicable laws and regulations regarding controlled substances, we do not have any direct control over Elan s compliance in these regards, and any failure by Elan to comply with those laws and regulations could result in a reduction or cessation of production of ZX002.

Annual DEA quotas on the amount of hydrocodone allowed to be produced in the United States and our specific allocation of hydrocodone by the DEA could significantly limit the clinical development of ZX002 as well as the production or sale of ZX002 even if we obtain FDA approval.

The DEA limits the availability and production of all Schedule II substances through a quota system which includes a national aggregate quota and individual quotas. Because *hydrocodone* is subject to the DEA s production and procurement quota scheme, the DEA establishes annually an aggregate quota for how much *hydrocodone* may be produced in total in the United States based on the DEA s estimate of the quantity needed to meet legitimate scientific and medicinal needs. This limited aggregate amount of *hydrocodone* that the DEA allows to be produced in the United States each year is allocated among individual companies, who must submit applications annually to the DEA for individual production and procurement quotas. The DEA requires substantial evidence and documentation of expected legitimate medical and scientific needs before assigning quotas to manufacturers. The DEA may adjust aggregate production quotas and individual production and procurement quotas from time to time during the year, although the DEA has substantial discretion in whether or not to make such adjustments. Elan, which has licensed us the right to sell ZX002 in the United States, if approved, was allocated a sufficient quantity of *hydrocodone* to meet our planned clinical and pre-clinical needs during 2010. However, in future years, we may need greater amounts of *hydrocodone* to sustain and complete our Phase 3 development program for ZX002 which we commenced in March 2010, and we will need significantly greater amounts of *hydrocodone* to implement our commercialization plans if the FDA approves ZX002.

Moreover, we do not know what amounts of *hydrocodone* other companies developing product candidates containing *hydrocodone* may request for future years. The DEA, in assessing factors such as medical need, abuse and diversion potential and other policy considerations, may choose to set the

aggregate *hydrocodone* quota lower than the total amount requested by the companies. Elan is permitted to petition the DEA to increase the annual aggregate quota after it is initially established, but there is no guarantee that the DEA would act favorably upon such a petition. Our procurement quota of *hydrocodone* may not be sufficient to meet our future clinical development needs or commercial demand if we receive regulatory approval for ZX002. Any delay or refusal by the DEA in establishing the procurement quota or a reduction in our quota for *hydrocodone* or a failure to increase it over time as we anticipate could delay or stop the clinical development of ZX002 or if approved, the product launch or commercial sale of ZX002 or cause us to fail to achieve our expected operating results, which could have a material adverse effect on our business, results of operations, financial condition and prospects.

We will need to obtain FDA approval of our proposed product trade names and any failure or delay associated with such approval may adversely impact our business.

Any trade name we intend to use for our products will require approval from the FDA regardless of whether we have secured a formal trademark registration from the U.S. Patent and Trademark Office, or PTO. The FDA typically conducts a rigorous review of proposed trade names, including an evaluation of potential for confusion with other trade names. The FDA may also object to a trade name if it believes the name inappropriately implies medical claims. If the FDA objects to our proposed trade names, we may be required to adopt an alternative name for our product candidate. If we adopt an alternative name, we would lose the benefit of our existing trademark applications and may be required to expend significant additional resources in an effort to identify a suitable trade name that would qualify under applicable trademark laws, and not infringe the existing rights of third parties and be acceptable to the FDA. We may be unable to build a successful brand identity for a new trademark in a timely manner or at all, which would limit our ability to generate revenues from our products.

Even though Sumavel DosePro has received regulatory approval in the United States, we, Desitin, or any other potential partners may never receive approval or commercialize our products outside of the United States.

We have established an exclusive commercial partnership for Sumavel DosePro with Desitin in the European Union and three other countries in order to seek to accelerate the development and regulatory approvals in those territories. We may also seek to establish commercial partnerships for Sumavel DosePro in other foreign countries. In order to market Sumavel DosePro or any other products outside of the United States, we, Desitin, or any potential partner must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy and governing, among other things, clinical trials and commercial sales, pricing and distribution of our products. The time required to obtain approval in other countries might differ from and be longer than that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks detailed in these Risk Factors and elsewhere in this prospectus regarding FDA approval in the United States, as well as other risks. For example, legislation analogous to Section 505(b)(2) of the FFDCA in the United States does not exist in other countries. In territories where data is not freely available, we or our partners may not have the ability to commercialize our products without negotiating rights from third parties to refer to their clinical data in our regulatory applications, which could require the expenditure of significant additional funds. We, Desitin, or any potential partner may be unable to obtain rights to the necessary clinical data and may be required to develop our own proprietary safety effectiveness dossiers. Desitin submitted a Marketing Authorization Application for Sumavel DosePro to the Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM)) in Germany, the reference member state, through the Decentralized Procedure in October 2009, following completion of a European pivotal bioequivalence trial comparing needle-free Sumavel DosePro to a traditional needle-based autoinjector, Imigran-Inject, the European brand of Imitrex STATdose. However, regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others.

Failure to obtain regulatory approval in other countries or any delay or setback in obtaining such approval could have the same adverse effects detailed in these Risk Factors and elsewhere in this prospectus regarding FDA approval in the United States. As described above, such effects include the risks that our product candidates may not be approved at all or for all requested indications, which could limit the uses of our product candidates and have an adverse effect on their commercial potential or require costly, post-marketing studies. In addition, we, Desitin, or any potential partner may be subject to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution if we fail to comply with applicable foreign regulatory requirements.

Health care reform measures and changes in policies, funding, staffing and leadership at the FDA and other agencies could hinder or prevent the commercial success of Sumavel DosePro and any of our product candidates that may be approved by the FDA.

In the United States, there have been a number of legislative and regulatory changes to the healthcare system in ways that could affect our future results of operations and the future results of operations of our potential customers. For example, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 established a new Part D prescription drug benefit, which became effective January 1, 2006. Under the prescription drug benefit, Medicare beneficiaries can obtain prescription drug coverage from private sector plans that are permitted to limit the number of prescription drugs that are covered in each therapeutic category and class on their formularies. If Sumavel DosePro or any of our product candidates that are approved by the FDA are not widely included on the formularies of these plans, our ability to market our products to the Medicare population could suffer.

Furthermore, there have been and continue to be a number of initiatives at the federal and state levels that seek to reduce healthcare costs. Most recently, in March 2010, President Obama signed into law the Patient Protection and Affordable Health Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively the PPACA, which includes measures to significantly change the way health care is financed by both governmental and private insurers. Among the provisions of the PPACA of greatest importance to the pharmaceutical industry are the following:

- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs, beginning in 2011;

- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program, retroactive to January 1, 2010, to 23% and 13% of the average manufacturer price for most branded and generic drugs, respectively;

- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% 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, beginning in 2011;

- extension of manufacturers Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations, effective March 23, 2010;

- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals beginning in April 2010 and by adding new mandatory eligibility categories for certain individuals with income at or below 133% of the Federal Poverty Level beginning in 2014, thereby potentially increasing both the volume of sales and manufacturers Medicaid rebate liability;

- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program, effective in January 2010;

- new requirements to report certain financial arrangements with physicians and others, including reporting any transfer of value made or distributed to prescribers and other healthcare

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providers and reporting any investment interests held by physicians and their immediate family members during each calendar year beginning in 2012, with reporting starting in 2013;

a new requirement to annually report drug samples that manufacturers and distributors provide to physicians, effective April 1, 2012;

a licensure framework for follow-on biologic products;

a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;

creation of the Independent Payment Advisory Board which, beginning in 2014, will have authority to recommend certain changes to the Medicare program that could result in reduced payments for prescription drugs and those recommendations could have the effect of law even if Congress does not act on the recommendations; and

establishment of a Center for Medicare Innovation at the Centers for Medicare & Medicaid Services to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending beginning by January 1, 2011.

Many of the details regarding the implementation of the PPACA are yet to be determined, and at this time, it remains unclear the full effect that the PPACA would have on our business.

Additionally, individual states have become increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, and marketing cost disclosure and transparency measures, and designed to encourage importation from other countries and bulk purchasing. Legally-mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, results of operations, financial condition and prospects.

In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This can reduce demand for our products or put pressure on our product pricing, which could negatively affect our business, results of operations, financial condition and prospects.

In certain foreign markets, the pricing of prescription drugs is subject to government control and reimbursement and may, in some cases, be unavailable. In the United States, the commercial success of Sumavel DosePro and our product candidates, if and when commercialized, will depend, in part, upon the availability of coverage and reimbursement from third-party payors at the federal, state and private levels. Third-party payors include governmental programs such as Medicare or Medicaid, private insurance plans and managed care plans. These third-party payors may deny coverage or reimbursement for a product or therapy in whole or in part if they determine that the product or therapy was not medically appropriate or necessary. Also, third-party payors have attempted to control costs by limiting coverage through the use of formularies and other cost-containment mechanisms and the amount of reimbursement for particular procedures or drug treatments.

Additionally, given recent federal and state government initiatives directed at lowering the total cost of healthcare, Congress and state legislatures will likely continue to focus on healthcare reform, the cost of prescription drugs and the reform of the Medicare and Medicaid programs. While we cannot predict the full outcome of any such legislation, it may result in decreased reimbursement for prescription drugs, which may further exacerbate industry-wide pressure to reduce prescription drug prices. This could harm our ability to market our products and generate revenues. In addition, legislation has been introduced in Congress that, if enacted, would permit more widespread importation or re-importation of pharmaceutical products from foreign countries into the United States, including from countries where the products are sold at lower prices than in the United States. Such legislation, or similar regulatory changes, could lead to a decision to decrease our prices to better

compete, which, in turn, could adversely affect our business, results of operations, financial condition and prospects. Alternatively, in response to legislation such as this, we might elect not to seek approval for or market our products in foreign jurisdictions in order to minimize the risk of re-importation, which could also reduce the revenue we generate from our product sales. It is also possible that other legislative proposals having similar effects will be adopted.

Furthermore, regulatory authorities assessment of the data and results required to demonstrate safety and efficacy can change over time and can be affected by many factors, such as the emergence of new information, including on other products, changing policies and agency funding, staffing and leadership. We cannot be sure whether future changes to the regulatory environment will be favorable or unfavorable to our business prospects. For example, average review times at the FDA for marketing approval applications have fluctuated over the last ten years, and we cannot predict the review time for any of our submissions with any regulatory authorities. In addition, review times can be affected by a variety of factors, including budget and funding levels and statutory, regulatory and policy changes.

We may incur liability if our continuing medical or health education programs and/or product promotions are determined, or are perceived, to be inconsistent with regulatory guidelines.

The FDA provides guidelines with respect to appropriate promotion and continuing medical and health education activities. Although we endeavor to follow these guidelines, the FDA or the Office of the Inspector General: U.S. Department of Health and Human Services 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 and our reputation could be damaged.

If we fail to comply with federal and state healthcare laws, including fraud and abuse and health information privacy and security laws, we could face substantial penalties and our business, results of operations, financial condition and prospects could be adversely affected.

As a pharmaceutical company, even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients rights are and will be applicable to our business. We could be subject to healthcare fraud and abuse and patient privacy regulation 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 Anti-Kickback Law, which constrains our marketing practices, educational programs, pricing policies, and relationships with healthcare providers or other entities, by prohibiting, among other things, soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;

- federal civil and criminal false claims laws and civil monetary penalty 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 payors that are false or fraudulent, and which may apply to entities like us which provide coding and billing advice to customers;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, and its implementing regulations, and the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, which prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters and which also imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information;

- federal physician self-referral laws, such as the Stark law, which prohibit a physician from making a referral to a provider of certain health services with which the physician or the

physician s family member has a financial interest, and prohibit submission of a claim for reimbursement pursuant to a prohibited referral; and

state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available under the U.S. federal Anti-Kickback Statute, it is possible that some of our business activities could be subject to challenge under one or more of such laws. To the extent that any product we make is sold in a foreign country, we may be subject to similar foreign laws and regulations. If we or our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from participation in U.S. federal or state health care programs, and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could materially adversely affect our ability to operate our business and our financial results. Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. 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. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security and fraud laws may prove costly.

Import/export regulations and tariffs may change and increase our costs.

We are subject to risks associated with the regulations relating to the import and export of products and materials. We cannot predict whether the import and/or export of our products will be adversely affected by changes in, or enactment of, new quotas, duties, taxes or other charges or restrictions imposed by India (where our supplier of the *sumatriptan* used in Sumavel DosePro is located), the United Kingdom (where the assembly of Sumavel DosePro takes place) or any other country in the future. Any of these factors could adversely affect our business, results of operations, financial condition and prospects.

Risks Related to Intellectual Property

Our success depends in part on our ability to protect our intellectual property. It is difficult and costly to protect our proprietary rights and technology, and we may not be able to ensure their protection.

Our commercial success will depend in large part on obtaining and maintaining patent, trademark and trade secret protection of our product, Sumavel DosePro, and our product candidate, ZX002, their respective components, formulations, methods used to manufacture them and methods of treatment, as well as successfully defending these patents against third-party challenges. Our ability to stop third parties from making, using, selling, offering to sell or importing Sumavel DosePro or our product candidates is dependent upon the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities.

We in-license certain intellectual property for ZX002 from Elan, and we rely on Elan to file and prosecute patent applications and maintain patents and otherwise protect the licensed intellectual property. We have not had and do not have primary control over these activities or any other intellectual property that may be related to our in-licensed intellectual property. We cannot be certain that such activities by Elan have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights. Elan has

retained the first right, but not the obligation, to initiate an infringement proceeding against a third-party infringer of the intellectual property rights that Elan has licensed to us, and enforcement of our licensed patents or defense of any claims asserting the invalidity or unenforceability of these patents would also be subject to the control or cooperation of Elan. We are not entitled to control the manner in which Elan may defend the intellectual property that is licensed to us and it is possible that their defense activities may be less vigorous than had we conducted the defense ourselves.

Most of our patents related to DosePro were acquired from Aradigm, who acquired those patents from a predecessor owner. Our patents related to ZX002 are licensed from Elan. Thus, most of our patents, as well as many of our pending patent applications, were not written by us or our attorneys, and we did not have control over the drafting and prosecution of these patents. Further, the former patent owners and our licensor might not have given the same attention to the drafting and prosecution of these patents and applications as we would have if we had been the owners of the patents and applications and had control over the drafting and prosecution. In addition, the former patent owners and Elan may not have been completely familiar with U.S. patent law, possibly resulting in inadequate disclosure and/or claims. This could possibly result in findings of invalidity or unenforceability of the patents we own and in-license, patents issuing with reduced claim scope, or in pending applications not issuing as patents.

In addition, as part of the agreement where we acquired patents related to DosePro from Aradigm, Aradigm retained, and we granted to Aradigm, a non-exclusive, worldwide, royalty free license to the acquired patents solely for purposes of the delivery of one or more aerosolized APIs directly into the bronchia or lungs. The agreement with Aradigm also includes a covenant not to compete with us regarding technologies or products for the delivery of one or more APIs via needle free injection. That covenant expired on August 26, 2010, giving Aradigm or its licensees the right to develop and sell other needle-free injection technologies and products.

The patent positions of pharmaceutical, biopharmaceutical and medical device companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in patents in these fields has emerged to date in the United States. There have been recent changes regarding how patent laws are interpreted, and both the PTO and Congress have recently proposed radical changes to the patent system. We cannot accurately predict future changes in the interpretation of patent laws or changes to patent laws which might be enacted into law. Those changes may materially affect our patents, our ability to obtain patents and/or the patents and applications of our collaborators and licensors. The patent situation in these fields outside the United States is even more uncertain. Changes in either the patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in the patents we own or to which we have a license or third-party patents.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- others may be able to make or use compounds that are similar to the pharmaceutical compounds used in Sumavel DosePro and our product candidates but that are not covered by the claims of our patents;

- the APIs in Sumavel DosePro and our current product candidates are, or will soon become, commercially available in generic drug products, and no patent protection will be available without regard to formulation or method of use;

- we or our licensor, as the case may be, may not be able to detect infringement against our in-licensed patents, which may be especially difficult for manufacturing processes or formulation patents;

we or our licensor, as the case may be, might not have been the first to make the inventions covered by our owned or in-licensed issued patents or pending patent applications;

we or our licensor, as the case may be, might not have been the first to file patent applications for these inventions;

others may independently develop similar or alternative technologies or duplicate any of our technologies;

it is possible that our pending patent applications will not result in issued patents;

it is possible that there are dominating patents to Sumavel DosePro or our product candidates of which we are not aware;

it is possible that there are prior public disclosures that could invalidate our inventions, or our licensor s as the case may be, or parts of our inventions of which we or they are not aware;

it is possible that others may circumvent our owned or in-licensed patents;

it is possible that there are unpublished applications or patent applications maintained in secrecy that may later issue with claims covering our products or technology similar to ours;

the laws of foreign countries may not protect our or our licensor s, as the case may be, proprietary rights to the same extent as the laws of the Untied States;

the claims of our owned or in-licensed issued patents or patent applications when issued may not cover our device or product candidates;

our owned or in-licensed issued patents may not provide us with any competitive advantages, or may be narrowed in scope, be held invalid or unenforceable as a result of legal challenges by third parties;

we may not develop additional proprietary technologies for which we can obtain patent protection; or

the patents of others may have an adverse effect on our business.

We also may rely on trade secrets to protect our technology, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect, and we have limited control over the protection of trade secrets used by our licensors, collaborators and suppliers. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, outside scientific collaborators and other advisors may unintentionally or willfully disclose our information to competitors. Enforcing a claim that a third party illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how. If our confidential or proprietary information is divulged to or acquired by third parties, including our competitors, our competitive position in the marketplace will be harmed and our ability to successfully penetrate our target markets could be severely compromised.

If any of our owned or in-licensed patents are found to be invalid or unenforceable, or if we are otherwise unable to adequately protect our rights, it could have a material adverse impact on our business and our ability to commercialize or license our technology and products. Likewise, our patents covering certain technology used in our DosePro device are expected to expire on various dates from 2014 through 2023 and the patents licensed to us by Elan are expected to expire in 2019. Three of our patents, U.S. Patent Nos. 5,891,086, 5,957,886 and 6,135,979, are expected to expire in 2014, 2016 and 2017, respectively. U.S. Patent No. 5,891,086 covers a particular actuator mechanism forming a part of the needleless injector device; U.S. Patent No. 5,597,886 claims a needleless injector system using a viscous damping medium; and U.S. Patent No. 6,137,979 covers the needleless injector with particular

safety mechanisms. Upon the expiration of these patents, we will lose the right to exclude others from practicing these inventions. Additionally, since these three patents are the only patents currently listed in the FDA Orange Book for Sumavel DosePro, their expiration will mean that we lose certain advantages that come with Orange Book listing of patents. The expiration of these patents could also have a similar material adverse effect on our business, results of operations, financial condition and prospects. Moreover, if Elan decides not to commence or continue any action relating to the defense of the patents they have licensed to us, they are required to notify us and we have the right to initiate proceedings after receiving their notice. Such proceedings will require the assistance of Elan, and we have limited control over the amount or timing of resources Elan devotes on our behalf or the priority they place on enforcing these patent rights.

If we fail to comply with our obligations in our intellectual property licenses with third parties, we could lose license rights that are important to our business.

We are a party to a license agreement with Elan, pursuant to which we license key intellectual property for ZX002. This existing license imposes various diligence, milestone payment, royalty, insurance and other obligations on us. If we fail to comply with these obligations, Elan may have the right to terminate the license, in which event we would not be able to develop or market ZX002. If we lose such license rights, our business, results of operations, financial condition and prospects may be materially adversely affected. We may enter into additional licenses in the future and if we fail to comply with obligations under those agreements, we could suffer similar consequences.

We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights, and we may be unable to protect our rights to our products and technology.

If we or our collaborators or licensors choose to go to court to stop a third party from using the inventions claimed in our owned or in-licensed patents, that third party may ask the court to rule that the patents are invalid and/or should not be enforced against that third party. These lawsuits are expensive and would consume time and other resources even if we or they, as the case may be, were successful in stopping the infringement of these patents. In addition, there is a risk that the court will decide that these patents are not valid and that we or they, as the case may be, do not have the right to stop others from using the inventions.

There is also the risk that, even if the validity of these patents is upheld, the court will refuse to stop the third party on the ground that such third-party s activities do not infringe our owned or in-licensed patents. In addition, the U.S. Supreme Court has recently changed some tests regarding granting patents and assessing the validity of patents. As a consequence, issued patents may be found to contain invalid claims according to the newly revised standards. Some of our own or in-licensed patents may be subject to challenge and subsequent invalidation or significant narrowing of claim scope in a reexamination proceeding before the PTO, or during litigation, under the revised criteria which make it more difficult to obtain patents.

We may also not be able to detect infringement of our own or in-licensed patents, which may be especially difficult for methods of manufacturing or formulation products. While we intend to take actions reasonably necessary to enforce our patent rights, we depend, in part, on our licensors and collaborators to protect a substantial portion of our proprietary rights. For example, Elan, our licensor, is primarily responsible for the enforcement of the intellectual property rights related to ZX002. Under the agreement, Elan has the first right, but not the obligation, to initiate an infringement proceeding against a third-party infringer. If Elan decides not to commence or continue any action, they are required to notify us and grant us step in rights to enforce the in-licensed intellectual property. Such enforcement will require the cooperation of Elan, and we will be responsible for Elan s reasonable expenses and attorney s fees incurred as a result of that cooperation. We have limited control over the amount or timing of resources Elan devotes on our behalf or the priority they place on enforcing these patent rights to our advantage.

If we are sued for infringing intellectual property rights of third parties, it will be costly and time consuming, and an unfavorable outcome in that litigation would have a material adverse effect on our business.

Our commercial success depends upon our ability and the ability of our collaborators to develop, manufacture, market and sell our device and product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields relating to Sumavel DosePro and our product candidates. As the medical device, biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that others may assert our product or product candidates infringe the patent rights of others. Moreover, it is not always clear to industry participants, including us, which patents cover various types of medical devices, drugs, products or their methods of use. Thus, because of the large number of patents issued and patent applications filed in our fields, there may be a risk that third parties may allege they have patent rights encompassing our product, product candidates, technology or methods.

In addition, there may be issued patents of third parties of which we are currently unaware, that are infringed or are alleged to be infringed by our product, product candidates or proprietary technologies. Because some patent applications in the United States may be maintained in secrecy until the patents are issued, because patent applications in the United States and many foreign jurisdictions are typically not published until eighteen months after filing, and because publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our owned and in-licensed issued patents or our pending applications, or that we or, if applicable, a licensor were the first to invent the technology. Our competitors may have filed, and may in the future file, patent applications covering our products or technology similar to ours. Any such patent application may have priority over our owned and in-licensed patent applications or patents, which could further require us to obtain rights to issued patents covering such technologies. If another party has filed a U.S. patent application on inventions similar to those owned or in-licensed to us, we or, in the case of in-licensed technology, the licensor may have to participate in an interference proceeding declared by the PTO to determine priority of invention in the United States. If another party has reason to assert a substantial new question of patentability against any of our claims in our owned and in-licensed U.S. patents, the third party can request that the PTO reexamine the patent claims, which may result in a loss of scope of some claims or a loss of the entire patent. In addition to potential infringement claims, interference and reexamination proceedings, we may become a party to patent opposition proceedings in the European Patent Office where either our patents are challenged, or we are challenging the patents of others. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful if the other party had independently arrived at the same or similar invention prior to our own or, if applicable, our licensor s invention, resulting in a loss of our U.S. patent position with respect to such inventions.

We may be exposed to, or threatened with, future litigation by third parties having patent or other intellectual property rights alleging that our device and/or product candidates and/or proprietary technologies infringe their intellectual property rights. These lawsuits are costly and could adversely affect our results of operations and divert the attention of managerial and technical personnel. There is a risk that a court would decide that we or our commercialization partners are infringing the third party s patents and would order us or our partners to stop the activities covered by the patents. In addition, there is a risk that a court will order us or our partners to pay the other party damages for having violated the other party s patents.

If a third-party s patents was found to cover our device and/or product candidates, proprietary technologies or their uses, we or our collaborators could be enjoined by a court and required to pay damages and could be unable to commercialize Sumavel DosePro or our product candidates or use our proprietary technologies unless we or they obtained a license to the patent. A license may not be available to us or our collaborators on acceptable terms, if at all. In addition, during litigation, the patent

holder could obtain a preliminary injunction or other equitable relief which could prohibit us from making, using or selling our products, technologies or methods pending a trial on the merits, which could be years away.

There is a substantial amount of litigation involving patent and other intellectual property rights in the device, biotechnology and pharmaceutical industries generally. If a third party claims that we or our collaborators infringe its intellectual property rights, we may face a number of issues, including, but not limited to:

- infringement and other intellectual property claims which, regardless of merit, may be expensive and time-consuming to litigate and may divert our management s attention from our core business;
- substantial damages for infringement, which we may have to pay if a court decides that the product at issue infringes on or violates the third party s rights, and if the court finds that the infringement was willful, we could be ordered to pay treble damages and the patent owner s attorneys fees;
- a court prohibiting us from selling or licensing the product unless the third party licenses its product rights to us, which it is not required to do;
- if a license is available from a third party, we may have to pay substantial royalties, upfront fees and/or grant cross-licenses to intellectual property rights for our products; and
- redesigning our products or processes so they do not infringe, which may not be possible or may require substantial monetary expenditures and time.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations or otherwise have a material adverse effect on our business, results of operations, financial condition and prospects.

Although we own worldwide rights to Sumavel DosePro, we do not have patent protection for the product in a significant number of countries, and we will be unable to prevent infringement in those countries.

Our patent portfolio related to DosePro includes patents in the United States, Canada, Germany, Spain, France, the United Kingdom, Italy, and Japan. The covered technology and the scope of coverage varies from country to country. For those countries where we do not have granted patents, we have no ability to prevent the unauthorized use of our intellectual property, and third parties in those countries may be able to make, use, or sell products identical to, or substantially similar to DosePro.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees on our owned and in-licensed patents are due to be paid to the PTO in several stages over the lifetime of the patents. Future maintenance fees will also need to be paid on other patents which may be issued to us. We have systems in place to remind us to pay these fees, and we employ outside firms to remind us or our in-licensor to pay annuity fees due to foreign patent agencies on our pending foreign patent applications. The PTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are

situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to enter the market and this circumstance would have a material adverse effect on our business.

For the patents and patent applications related to ZX002, Elan is obligated to maintain our in-licensed patents in the United States under our license agreement. Should Elan fail to pursue maintenance of our licensed patents and patent applications, Elan is obligated to notify us and, at that time, we will be granted an opportunity to maintain the prosecution and avoid withdrawal, cancellation, expiration or abandonment of the licensed U.S. patents and applications.

We also may rely on trade secrets and confidentiality agreements to protect our technology and know-how, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect, and we have limited control over the protection of trade secrets used by our licensors, collaborators and suppliers. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, outside scientific collaborators and other advisors may unintentionally or willfully disclose our information to competitors. Enforcing a claim that a third party illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how. If our confidential or proprietary information is divulged to or acquired by third parties, including our competitors, our competitive position in the marketplace will be harmed and our ability to successfully generate revenues from Sumavel DosePro and, if approved by the FDA or other regulatory authorities, our product candidates could be adversely affected.

We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

As is common in the device, biotechnology and pharmaceutical industries, we employ individuals who were previously employed at other device, biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management, which would adversely affect our financial condition.

Risks Relating to this Offering and an Investment in Our Stock

We expect that the price of our common stock will fluctuate substantially.

The initial public offering price for the shares of our common stock sold in this offering has been determined by negotiation between the representatives of the underwriters and us. This price may not reflect the market price of our common stock following this offering. The price of our common stock may decline, perhaps substantially. In addition, following this offering the market price of our common stock is likely to be highly volatile and may fluctuate substantially due to many factors, including those described elsewhere in this Risk Factors section in this prospectus and the following:

- announcements concerning our and Astellas commercial progress in promoting and selling Sumavel DosePro, including sales and revenue trends;
- the development status of ZX002 or any of our other product candidates, including the results from our clinical trials;
- FDA or international regulatory actions, including whether and when we receive regulatory approval, for any of our product candidates;

other regulatory developments, including the FDA s potential grant of regulatory exclusivity to a competitor who receives FDA approval before us for an extended-release *hydrocodone* product, which could significantly delay our ability to receive approval for ZX002;

announcements of the introduction of new products by us or our competitors;

announcements concerning product development results or intellectual property rights of others;

announcements relating to litigation, intellectual property or our business, and the public s response to press releases or other public announcements by us or third parties;

variations in the level of expenses related to ZX002 or any of our other product candidates or clinical development programs, including relating to the timing of invoices from, and other billing practices of, our CROs and clinical trial sites;

market conditions or trends in the pharmaceutical sector or the economy as a whole;

changes in operating performance and stock market valuations of other pharmaceutical companies and price and volume fluctuations in the overall stock market;

litigation or public concern about the safety of Sumavel DosePro or our product candidates;

actual and anticipated fluctuations in our quarterly operating results;

the financial projections we may provide to the public, any changes in these projections or our failure to meet these projections;

deviations from securities analysts estimates or the impact of other analyst comments;

ratings downgrades by any securities analysts who follow our common stock;

additions or departures of key personnel;

third-party payor coverage and reimbursement policies;

developments concerning current or future strategic collaborations, and the timing of payments we may make or receive under these arrangements;

developments affecting our contract manufacturers, component fabricators and service providers;

the development and sustainability of an active trading market for our common stock;

future sales of our common stock by our officers, directors and significant stockholders;

other events or factors, including those resulting from war, incidents of terrorism, natural disasters or responses to these events;

changes in accounting principles; and

discussion of us or our stock price by the financial and scientific press and in online investor communities.

In addition, the stock markets, and in particular the Nasdaq Global Market, have experienced extreme price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many pharmaceutical companies. Stock prices of many pharmaceutical companies have fluctuated in a manner unrelated or disproportionate to the operating performance of those companies. The realization of any of the above risks or any of a broad range of other risks, including those or any of a broad range of other risks, including those described in these Risk Factors, could have a dramatic and material adverse impact on the market price of our common stock.

There may not be a viable public market for our common stock.

Prior to this offering, there has been no public market for our common stock, and there can be no assurance that a regular trading market will develop and continue after this offering or that the market price of our common stock will not decline, perhaps substantially, below the initial public offering price. The initial public offering price has been determined through negotiations between us and the representatives of the underwriters and may not be indicative of the market price of our common stock following this offering. Among the factors considered in such negotiations were prevailing market conditions; our results of operations and financial condition; financial and operating information and market valuations with respect to other companies that we and the representatives of the underwriters believe to be comparable or similar to us; the present state of our development; and our future prospects. See Underwriting for additional information. If you purchase shares of our common stock, you may not be able to resell those shares at or above the initial public offering price. We cannot predict the extent to which investor interest in our company will lead to the development of an active trading market on the Nasdaq Global Market or otherwise or how liquid that market might become. An active public market for our common stock may not develop or be sustained after the offering. If an active public market does not develop or is not sustained, it may be difficult for you to sell your shares of common stock at a price that is attractive to you, or at all. Further, an inactive market may also impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic partnerships or acquire companies or products, product candidates or technologies by using our shares of common stock as consideration.

If you purchase shares of our common stock sold in this offering, you will experience immediate and substantial dilution in the net tangible book value of your shares.

The initial public offering price of our common stock in this offering is considerably more than the net tangible book value (deficit) per share of our outstanding common stock. Investors purchasing shares of common stock in this offering will pay a price that substantially exceeds the value of our tangible assets after subtracting liabilities. As a result, these investors will:

- incur immediate dilution of $2.62 per share, based on the initial public offering price of $4.00 per share; and
- contribute 25.3% of the total amount invested to date to fund our company based on the initial offering price to the public of $4.00 per share, and will own approximately 41.7% of the shares of common stock outstanding after the offering.

For additional information on how the foregoing amounts were calculated, see Dilution. To the extent outstanding stock options or warrants are exercised, there will be further dilution to new investors.

Because we may need to raise additional capital to fund our commercialization efforts and clinical development programs, among other things, we may in the future sell substantial amounts of common stock or securities convertible into or exchangeable for common stock. These future issuances of common stock or common stock-related securities, together with the exercise of outstanding options and warrants and any additional shares issued in connection with acquisitions, if any, may result in further dilution to investors. See the Dilution section in this prospectus.

We may invest or spend the proceeds of this offering in ways with which you may not agree or in ways which may not yield a significant return.

Our management will have considerable discretion in the application of the net proceeds of this offering, and you will not have the opportunity, as part of your investment decision, to assess whether the proceeds are being used appropriately. The net proceeds may be used for purposes that do not increase our operating results or market value. Until the net proceeds are used, they may be placed in

investments that do not produce significant income or that may lose value. The failure of our management to apply these funds effectively could result in unfavorable returns and uncertainty about our prospects, each of which could cause the price of our common stock to decline.

Our quarterly operating results may fluctuate significantly.

Our quarterly operating results are difficult to predict and may fluctuate significantly from period to period, particularly because the commercial success of, and demand for, Sumavel DosePro, as well as the success and costs of our ZX002 and other product candidate development programs are uncertain and therefore our future prospects are uncertain. Our net loss and other operating results will be affected by numerous factors, including:

- fluctuations in the quarterly revenues of Sumavel DosePro, including based on our distributors inventory management practices and buying patterns and the performance by Astellas;
- the level of underlying demand for Sumavel DosePro or any of our other product candidates that may receive regulatory approval;
- variations in the level of development expenses related to ZX002 or other development programs;
- results of clinical trials for ZX002;
- any intellectual property infringement lawsuit in which we may become involved;
- regulatory developments and legislative changes, including healthcare reform, affecting our product and product candidates or those of our competitors; and
- our execution of any collaborative, licensing or similar arrangements, and the timing of payments we may make or receive under these arrangements.

If our quarterly operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly fluctuations in our operating results may, in turn, cause the price of our stock to fluctuate substantially.

We may become involved in securities class action litigation that could divert management s attention and adversely affect our business and could subject us to significant liabilities.

The stock markets have from time to time experienced significant price and volume fluctuations that have affected the market prices for the common stock of pharmaceutical companies. These broad market fluctuations as well a broad range of other factors, including the realization of any of the risks described in these Risk Factors, may cause the market price of our common stock to decline. In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and pharmaceutical companies generally experience significant stock price volatility. We may become involved in this type of litigation in the future. Litigation often is expensive and diverts management s attention and resources, which could adversely affect our business. Any adverse determination in any such litigation or any amounts paid to settle any such actual or threatened litigation could require that we make significant payments.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. We do not currently have and may never obtain research coverage by securities and industry analysts. If no securities or industry analysts commence coverage of our company, the trading price for our stock would be negatively impacted. If we obtain securities or industry analyst coverage and if one or more of the analysts who covers us

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downgrades our stock, publishes inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, demand for our stock could decrease, which could cause our stock price and trading volume to decline.

Our executive officers, directors and their affiliates will exercise significant control over stockholder voting matters in a manner that may not be in the best interests of all of our stockholders.

Immediately following this offering, our executive officers, directors and their affiliates will together control approximately 69.2% of our outstanding common stock, assuming no exercise of the underwriters over-allotment option shares and no exercise of outstanding options or warrants. Five of our non-employee directors are, or are representatives designated by, significant stockholders and two of our directors are executive officers. As a result, these stockholders will collectively be able to significantly influence and may be able to control all matters requiring approval of our stockholders, including the election of directors and approval of significant corporate transactions such as mergers, consolidations or the sale of all or substantially all of our assets. The concentration of ownership may delay, prevent or deter a change in control of our company even when such a change may be in the best interests of some stockholders, impede a merger, consolidation, takeover or other business combination involving us, or could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of our company or our assets and might adversely affect the prevailing market price of our common stock.

In addition, sales of shares beneficially owned by executive officers and directors and their affiliates could be viewed negatively by third parties and have a negative impact on our stock price. Moreover, we cannot assure you as to how these shares will may be distributed and subsequently voted.

Future sales of our common stock or securities convertible or exchangeable for our common stock may depress our stock price.

If our existing stockholders or holders of our currently outstanding convertible notes, options or warrants sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after the lock-up and other legal restrictions on resale discussed in this prospectus lapse, the trading price of our common stock could decline. The perception in the market that these sales may occur could also cause the trading price of our common stock to decline. Based on shares of common stock outstanding as of September 30, 2010, upon completion of this offering we will have outstanding a total of 33,563,802 shares of common stock, assuming no exercise of the underwriters over-allotment option and (based on the assumptions set forth under Prospectus Summary The Offering) the conversion of our outstanding convertible preferred stock and 2010 Notes in connection with the closing of this offering. Of these shares, only the shares of common stock sold by us in this offering, plus any shares sold upon exercise of the underwriters overallotment option will be freely tradable, without restriction, in the public market immediately following this offering. Our underwriters may, however, in their sole discretion, permit our officers, directors and other stockholders and the holders of our outstanding options and warrants who are subject to these lock-up agreements to sell shares prior to the expiration of the lock-up agreements.

We expect that the lock-up agreements pertaining to this offering will expire 180 days from the date of this prospectus (subject to extension upon the occurrence of specified events). After the lock-up agreements expire, up to an additional 26,702,697 shares of common stock, and up to approximately 256,816 shares of common stock issuable upon exercise of our outstanding warrants, will be eligible for sale in the public market, subject to volume limitations under Rule 144 under the Securities Act of 1933, as amended, or the Securities Act, with respect to shares held by directors, executive officers and other affiliates. In addition, shares of common stock that are either subject to outstanding options or reserved for future issuance under our employee benefit plans will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, the lock-up agreements and Rule

144 and Rule 701 under the Securities Act and, in any event, we plan to file a registration statement permitting shares of common stock issued on exercise of options to be freely sold in the public market. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

Certain holders of shares of our common stock, warrants to purchase our capital stock and the shares of common stock issuable upon exercise of those warrants are entitled to rights with respect to the registration of their shares under the Securities Act, subject to the 180-day lock-up agreements described above. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares purchased by affiliates. In addition, after the lock-up agreements described above expire, our directors may and we expect that our executive officers will establish programmed selling plans under Rule 10b5-1 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, for the purpose of effecting sales of our common stock. Any sales of securities by these stockholders, or the perception that those sales may occur, including the entry into such programmed selling plans, could have a material adverse effect on the trading price of our common stock.

Anti-takeover provisions under our charter documents and Delaware law could delay or prevent a change of control which could limit the market price of our common stock and may prevent or frustrate attempts by our stockholders to replace or remove our current management.

Our amended and restated certificate of incorporation and amended and restated bylaws, which are to become effective at or prior to the closing of this offering, contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions include:

- a board of directors divided into three classes serving staggered three-year terms, such that not all members of the board will be elected at one time;
- a prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at a meeting of our stockholders;
- a requirement that special meetings of stockholders be called only by the chairman of the board of directors, the chief executive officer, the president or by a majority of the total number of authorized directors;
- advance notice requirements for stockholder proposals and nominations for election to our board of directors;
- a requirement that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than $66^2/_3\%$ of all outstanding shares of our voting stock then entitled to vote in the election of directors;
- a requirement of approval of not less than $66^2/_3\%$ of all outstanding shares of our voting stock to amend any bylaws by stockholder action or to amend specific provisions of our certificate of incorporation; and
- the authority of the board of directors to issue preferred stock on terms determined by the board of directors without stockholder approval and which preferred stock may include rights superior to the rights of the holders of common stock.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporate Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These anti-takeover provisions and other provisions in our amended and restated certificate of incorporation and amended and restated bylaws could make it more difficult for stockholders or potential acquirors to obtain control of

our board of directors or initiate actions that are opposed by the then-current board of directors and could also delay or impede a merger, tender offer or proxy contest involving our company. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors of your choosing or cause us to take other corporate actions you desire. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

We have never paid dividends on our capital stock, and we do not anticipate paying any cash dividends in the foreseeable future.

The continued operation and expansion of our business will require substantial funding. Investors seeking cash dividends in the foreseeable future should not purchase our common stock. We have paid no cash dividends on any of our classes of capital stock to date and we currently intend to retain our available cash to fund the development and growth of our business. Any determination to pay dividends in the future will be at the discretion of our board of directors and will depend upon results of operations, financial condition, contractual restrictions, restrictions imposed by applicable law and other factors our board of directors deems relevant. In addition, our ability to pay cash dividends is currently prohibited by the terms of our loan and security agreements. We do not anticipate paying any cash dividends on our common stock in the foreseeable future. Accordingly, if you purchase shares in this offering, realization of a gain on your investment will depend on the appreciation of the price of our common stock, which may never occur.

We will incur significant increased costs as a result of operating as a public company, and our management will be required to devote substantial time to meet compliance obligations.

As a public company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. We will be subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, as well as rules subsequently implemented by the SEC and the Nasdaq Stock Market, or Nasdaq, that impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. The Exchange Act will require, among other things, that we file annual, quarterly and current reports with respect to our business and financial condition. In addition, on July 21, 2010, the Dodd-Frank Wall Street Reform and Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation-related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas such as say on pay and proxy access. The requirements of these rules and regulations will increase our legal and financial compliance costs, make some activities more difficult, time-consuming or costly and may also place undue strain on our personnel, systems and resources. Our management and other personnel will need to devote a substantial amount of time to these new compliance initiatives. In addition, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified people to serve on our board of directors, our board committees or as executive officers.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. Ensuring that we have adequate internal financial and accounting controls and procedures in place is a costly and time-consuming effort that needs to be re-evaluated frequently. In particular, commencing in fiscal 2011, we must perform system and process evaluation and testing of our internal controls over financial reporting to allow management and our independent registered public accounting firm to report on the effectiveness of our internal controls over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act, or Section 404. Although we may qualify for an exemption from the requirements of Section 404 as a result of provisions in the Dodd-Frank Act, we currently do not intend to take advantage of the exception even if it is

available to us. Our testing, or the subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. We expect to incur significant expense and devote substantial management effort toward ensuring compliance with Section 404. We currently do not have an internal audit function, and we may need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge. Implementing any appropriate changes to our internal controls may require specific compliance training for our directors, officers and employees, entail substantial costs to modify our existing accounting systems, and take a significant period of time to complete. Such changes may not, however, be effective in maintaining the adequacy of our internal controls, and any failure to maintain that adequacy, or consequent inability to produce accurate financial statements or other reports on a timely basis, could increase our operating costs and could materially impair our ability to operate our business. Moreover, effective internal controls are necessary for us to produce reliable financial reports and are important to help prevent fraud. If we are not able to comply with the requirements of Section 404 in a timely manner, or if we or our independent registered public accounting firm identifies deficiencies in our internal controls that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities, which would entail expenditure of additional financial and management resources.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS AND MARKET DATA

This prospectus contains forward-looking statements that involve substantial risks and uncertainties, including statements regarding the future sales potential for Sumavel DosePro, the progress and timing of clinical trials, the safety and efficacy of our product candidates, the goals of our development activities, estimates of the potential markets for our product candidates, estimates of the capacity of manufacturing and other facilities to support our products, projected cash needs and our expected future revenues, operations and expenditures. The forward-looking statements are contained principally in the sections entitled Prospectus Summary, Risk Factors, Management s Discussion and Analysis of Financial Condition and Results of Operations and Business. In some cases, you can identify forward-looking statements by the following words: may, will, could, would, should, expect, intend, plan, anticipate, believe, estimate, predict, project, potentia negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. These statements relate to future events or our future financial performance or condition and involve known and unknown risks, uncertainties and other factors that could cause our actual results, levels of activity, performance or achievement to differ materially from those expressed or implied by these forward-looking statements. These risk and uncertainties, include, among others discussed in the Risk Factors section of this prospectus:

our dependence on the commercial success of Sumavel DosePro, including our ability to maintain and increase market demand for, and sales of, Sumavel DosePro;

our short operating history, our early stage of commercialization, our lack of significant revenue, our history of significant net losses and negative cash flow from operations and our ability to obtain additional funding to continue to operate our business, which funding may not be available on commercially reasonable terms, or at all;

our ability to successfully execute our sales and marketing strategy for the commercialization of Sumavel DosePro and our dependence on our collaboration with Astellas Pharma US, Inc. to promote Sumavel DosePro primarily to primary care physicians, OB/GYNs, emergency medicine physicians, and urologists;

the rate and degree of market acceptance of Sumavel DosePro;

our recurring losses from operations, which raise substantial doubt about our ability to continue as a going concern;

our reliance on a limited number of wholesale pharmaceutical distributors, of which the largest three collectively accounted for 95.6% of our total gross sales of Sumavel DosePro for the nine months ended September 30, 2010;

our ability to successfully complete Phase 3 clinical development of ZX002 or any of our other product candidates on expected timetables, or at all, which includes enrolling sufficient patients in our clinical trials and demonstrating the safety and efficacy of these product candidates in such trials;

the risk that one of our competitors will receive FDA approval for an extended-release *hydrocodone* product for the same condition of use as ZX002 before we receive FDA approval for ZX002, which could significantly delay our ability to commercialize ZX002;

the content and timing of submissions to, and decisions made by, the FDA and other regulatory agencies, including foreign regulatory agencies, and demonstrating the safety and efficacy of ZX002 or any other product candidates to the satisfaction of the FDA and such other agencies;

our ability to maintain regulatory approval for Sumavel DosePro;

the scope and validity of patent protection for Sumavel DosePro, ZX002 and our other product candidates and our ability to commercialize Sumavel DosePro, ZX002 and our other product candidates without infringing the patent rights of others;

adverse side effects or inadequate therapeutic efficacy of Sumavel DosePro that could result in product recalls, market withdrawals or product liability claims;

the intense competition in the pharmaceutical industry and the ability of our competitors, many of whom have greater resources than we do, to offer different or better therapeutic alternatives than our products;

our ability to obtain and maintain adequate levels of coverage and reimbursement for Sumavel DosePro or any of our other product candidates that may be approved for sale from the government or other third-party payors, and the extent of such coverage and reimbursement, and the willingness of third-party payors to pay for our products versus less expensive therapies;

our reliance on third-party single source manufacturers and suppliers for the manufacture and supply of our product and product candidates;

our ability to grow our business by identifying and acquiring or in-licensing new product candidates or approved products, increasing the size of our organization and attracting and retaining key personnel;

our compliance with our agreements with Astellas, Elan and Desitin and the right of the other parties to terminate those agreements under specified circumstances or, in some cases, at will; and

the impact of healthcare reform legislation.

You should read this prospectus and the documents that we reference in this prospectus and have filed as exhibits to the registration statement, of which this prospectus is a part, completely and with the understanding that our actual results may differ materially from what we expect and from those expressed or implied by our forward-looking statements. In light of the significant uncertainties in our forward-looking statements, you should not place undue reliance on or regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified timeframe, or at all. These forward-looking statements represent our estimates and assumptions only as of the date of this prospectus regardless of the time of delivery of this prospectus or any sale of our common stock and, except as required by law, we undertake no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise after the date of this prospectus. The forward-looking statements contained in this prospectus are excluded from the safe harbor protection provided by the Private Securities Litigation Reform Act of 1995 and Section 27A of the Securities Act of 1933, as amended.

This prospectus also contains estimates, projections and other information concerning our industry, our business, and the markets for Sumavel DosePro, ZX002 and other drugs, including data regarding the estimated size of those markets, their projected growth rates, the incidence of certain medical conditions, statements that certain drugs, classes of drugs or dosages are the most widely prescribed in the United States or other markets, the perceptions and preferences of patients and physicians regarding certain therapies and other prescription, prescriber and patient data, as well as data regarding market research, estimates and forecasts prepared by our management. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information. Unless otherwise expressly stated, we obtained this industry, business, market and other data from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources. In particular, unless otherwise specified, all prescription, prescriber and patient data in this prospectus is from Wolters Kluwer Pharma Solutions, Source® Pharmaceutical Audit Suite (PHAST) Institution/Retail, Source® PHAST Retail, Source® Prescriber, Source® LaunchTrac, Source® Dynamic Claims or Source® Lx PTA. In some cases, we do not expressly refer to the sources from which this data is derived. In that regard, when we refer to one or more sources of this type of data in any paragraph, you should assume that other data of this type appearing in the same paragraph is derived from the same sources, unless otherwise expressly stated or the context otherwise requires.

USE OF PROCEEDS

We estimate that we will receive net proceeds of approximately $50.7 million (or approximately $58.5 million if the underwriters over-allotment option is exercised in full) from the sale of the shares of common stock offered by us in this offering, based on the initial public offering price of $4.00 per share and after deducting the underwriting discounts and commissions and estimated offering costs payable by us and assuming that certain of our current stockholders purchase all of the 7,138,895 shares of common stock that they have indicated an interest in purchasing as described elsewhere in this prospectus.

The principal purposes of this offering are to obtain additional capital to support our operations, to create a public market for our common stock and to facilitate our future access to the public equity markets. We intend to use approximately $35.0 million of the net proceeds from this offering to fund Phase 3 clinical trials and related development activities for ZX002 and approximately $15.7 million to fund the ongoing commercialization of Sumavel DosePro and for working capital and other general corporate purposes. Although it is difficult to predict future liquidity requirements, we believe that the net proceeds from this offering, together with our existing cash and cash equivalents, future product revenues and borrowings available under our $10.0 million revolving credit facility will be sufficient to fund our operations for at least the next 12 months. In particular, we believe the portion of the net proceeds from this offering intended to fund Phase 3 clinical trials and related development activities for ZX002, together with our existing cash and cash equivalents, future product revenues and borrowings available under our $10.0 million revolving credit facility, will enable us to complete the development of ZX002 through our planned submission of an NDA with the FDA, although we cannot assure you that this will occur. We may also use a portion of the net proceeds to in-license, acquire or invest in complementary businesses or products; however, we have no current commitments or obligations to do so.

The amounts and timing of our actual expenditures will depend on numerous factors, including the commercial success of Sumavel DosePro and the progress of our clinical trials and other development and commercialization efforts, as well as the amount of cash used in our operations. We therefore cannot estimate the amount of net proceeds to be used for the purposes described above. We may find it necessary or advisable to use the net proceeds for other purposes, and we will have broad discretion in the application of the net proceeds. Pending the uses described above, we plan to invest the net proceeds from this offering in short- and intermediate-term, interest-bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the U.S. government.

DIVIDEND POLICY

We have never declared or paid any cash dividends on our capital stock and do not anticipate paying any cash dividends in the foreseeable future. We expect to retain available cash to finance ongoing operations and the potential growth of our business. Any future determination to pay dividends on our common stock will be at the discretion of our board of directors and will depend upon, among other factors, our results of operations, financial condition, capital requirements, contractual restrictions, business prospects and other factors our board of directors may deem relevant. In addition, unless waived, the terms of our amended and restated loan and security agreement with Oxford Finance Corporation and Silicon Valley Bank prohibit us from paying dividends on our common stock.

CAPITALIZATION

The following table sets forth our cash and cash equivalents and capitalization as of September 30, 2010:

on an actual basis; and

on a pro forma as adjusted basis to give effect to the following transactions as if they had occurred as of September 30, 2010:

(1) the sale of 14,000,000 shares of common stock in this offering and our receipt of the estimated net proceeds therefrom, based on the initial public offering price of $4.00 per share and after deducting the underwriting discounts and commissions and estimated offering costs payable by us and assuming that certain of our current stockholders purchase all of the 7,138,895 shares that they have indicated an interest in purchasing as described elsewhere in this prospectus;

(2) the conversion of all outstanding shares of our convertible preferred stock into an aggregate of 14,239,797 shares of our common stock upon the completion of this offering and the resultant reclassification of our convertible preferred stock warrant liability to stockholders equity (deficit) in connection with such conversion;

(3) the termination of outstanding warrants exercisable for an aggregate of 1,290,887 shares of our common stock, or the Series B Warrants, without having been exercised (the Series B Warrants will terminate automatically upon completion of this offering and we have assumed that these warrants will terminate without having been exercised because the exercise price exceeds the initial public offering price of our common stock in this offering);

(4) the issuance of 3,873,756 shares of our common stock upon completion of this offering as a result of the automatic conversion of $15.0 million in aggregate principal amount of convertible promissory notes issued in July 2010, or the 2010 Notes (including accrued interest thereon), based on the initial public offering price of $4.00 per share and assuming the conversion occurs on November 29, 2010 (the expected closing date of this offering);

(5) the conversion of our remaining warrants to purchase convertible preferred stock, which warrants are expected to remain outstanding upon the completion of this offering, into warrants to purchase our common stock; and

(6) the filing of our amended and restated certificate of incorporation upon completion of this offering.

You should read this table together with Management s Discussion and Analysis of Financial Condition and Results of Operations and our financial statements and the related notes appearing elsewhere in this prospectus.

	As of September 30, 2010	
	Actual	Pro Forma As Adjusted
	(In thousands, except per share amounts)	
Cash and cash equivalents	$ 11,673	$ 62,403
Long-term debt, less current portion	22,390	22,390
Convertible preferred stock warrant liability	20,301	
Series A and B convertible preferred stock, $0.001 par value; actual 172,750 shares authorized, 142,398 shares issued and outstanding; pro forma as adjusted no shares authorized, issued or outstanding	149,312	
Stockholders equity (deficit)		
Preferred stock, $0.001 par value; actual no shares authorized, issued or outstanding; pro forma as adjusted 10,000 shares authorized, no shares issued or outstanding		
Common stock, $0.001 par value; actual 205,000 shares authorized, 1,450 shares issued and outstanding; pro forma as adjusted 100,000 shares authorized, 33,564 shares issued and outstanding	1	34
Additional paid-in capital	12,186	242,180
Accumulated deficit	(195,967)	(195,967)
Total stockholders equity (deficit)	(183,780)	46,247
Total capitalization	$ 8,223	$ 68,637

The number of pro forma as adjusted shares of common stock shown in the prior table excludes:

256,816 shares of common stock issuable upon the exercise of warrants outstanding as of September 30, 2010, at a weighted average exercise price of $10.92 per share, which warrants are expected to remain outstanding upon completion of this offering;

1,482,780 shares of common stock issuable upon the exercise of options outstanding as of September 30, 2010, at a weighted average exercise price of $3.36 per share;

2,000,000 additional shares of common stock reserved for future issuance under our 2010 Equity Incentive Award Plan, or the 2010 Plan, which will become effective immediately prior to the completion of this offering, plus 233,689 shares of common stock reserved for future grant or issuance under our 2006 Equity Incentive Plan, or the 2006 Plan, as of September 30, 2010, which shares will be added to the shares to be reserved under our 2010 Plan upon the effectiveness of the 2010 Plan, plus any annual increases in the number of shares of common stock reserved for future issuance under the 2010 Plan pursuant to an evergreen provision and any other shares that may become issuable under the 2010 Plan pursuant to its terms, as more fully described in Compensation Discussion and Analysis Employee Equity Incentive Plans 2010 Equity Incentive Award Plan; and

500,000 shares of common stock reserved for issuance under our 2010 Employee Stock Purchase Plan, or the Purchase Plan, which will become effective following the completion of this offering, plus any annual increases in the number of shares of common stock reserved for issuance under the Purchase Plan pursuant to an evergreen provision, as more fully described in Compensation Discussion and Analysis Employee Equity Incentive Plans 2010 Employee Stock Purchase Plan.

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DILUTION

If you invest in our common stock in this offering, your interest will be diluted to the extent of the difference between the initial public offering price per share of our common stock and the pro forma as adjusted net tangible book value per share of our common stock upon the completion of this offering.

As of September 30, 2010, our historical net tangible book value (deficit) of our common stock was approximately $(183.8) million, or approximately $(126.72) per share, based on 1,450,249 shares of our common stock outstanding at September 30, 2010. Our historical net tangible book value (deficit) per share represents the amount of our total tangible assets reduced by the amount of our total liabilities and convertible preferred stock, divided by the total number of shares of our common stock outstanding as of September 30, 2010.

On a pro forma basis as of September 30, 2010, after giving effect to (1) the conversion of all outstanding shares of our convertible preferred stock into an aggregate of 14,239,797 shares of our common stock upon the completion of this offering and the resultant reclassification of our convertible preferred stock warrant liability to stockholders equity (deficit) in connection with such conversion; (2) the termination of outstanding warrants exercisable for an aggregate of 1,290,887 shares of our common stock, which we expect will terminate upon completion of this offering without having been exercised because the exercise price exceeds the initial public offering price of our common stock in this offering; (3) the issuance of 3,873,756 shares of our common stock upon completion of this offering as a result of the automatic conversion of $15.0 million in aggregate principal amount of convertible promissory notes issued in July 2010, or the 2010 Notes (including accrued interest thereon), based on the initial public offering price of $4.00 per share and assuming the conversion occurs on November 29, 2010 (the expected closing date of this offering); and (4) the conversion of our remaining outstanding warrants to purchase convertible preferred stock, which warrants are expected to remain outstanding upon the completion of this offering, into warrants to purchase our common stock, the pro forma net tangible book value (deficit) of our common stock would have been approximately $(4.4) million, or approximately $(0.22) per share of our pro forma outstanding common stock.

Investors participating in this offering will incur immediate, substantial dilution. After giving effect to (1) the sale of 14,000,000 shares of common stock in this offering at the initial public offering price of $4.00 per share and after deducting the underwriting discounts and commissions and estimated offering costs payable by us and assuming that certain of our current stockholders purchase all of the 7,138,895 shares of common stock that they have indicated an interest in purchasing as described elsewhere in this prospectus, and (2) the pro forma transactions and other adjustments described in the preceding paragraph, our pro forma as adjusted net tangible book value of our common stock as of September 30, 2010 would have been approximately $46.2 million, or approximately $1.38 per share of our pro forma as adjusted outstanding common stock. This represents an immediate increase in pro forma as adjusted net tangible book value of $1.60 per share to our existing stockholders and an immediate dilution in the pro forma as adjusted net tangible book value of $2.62 per share to investors participating in this offering. The following table illustrates this per share dilution:

Initial public offering price per share		$ 4.00
Historical net tangible book value (deficit) per share as of September 30, 2010	$ (126.72)	
Pro forma increase in net tangible book value (deficit) per share attributable to pro forma transactions described in the preceding paragraph	126.50	
Pro forma net tangible book value (deficit) per share before this offering	(0.22)	
Increase in pro forma net tangible book value per share attributable to investors participating in this offering	1.60	
Pro forma as adjusted net tangible book value (deficit) per share after this offering		$ 1.38
Pro forma as adjusted dilution per share to investors in this offering		$ 2.62

If the underwriters fully exercise their option to purchase 2,100,000 additional shares of common stock in the offering, our pro forma as adjusted net tangible book value per share after this offering would be $1.52 per share, the increase in our pro forma as adjusted net tangible book value per share attributable to investors participating in this offering would be $1.74 per share and the pro forma as adjusted dilution per share to new investors in this offering would be $2.48 per share.

The following table summarizes, on the pro forma as adjusted basis described above, as of September 30, 2010, the differences between the number of shares of common stock purchased from us, the total effective cash consideration paid to us and the average price per share paid to us by our existing stockholders and by investors participating in this offering based on the initial public offering price of $4.00 per share before deducting underwriting discounts and commissions and estimated offering costs payable by us, as if those transactions had occurred as of September 30, 2010:

	Shares Purchased		Total Consideration		Average Price Per Share
	Number	Percent	Amount	Percent	
Existing stockholders before this offering	19,563,802	58.3%	$ 165,492,852	74.7%	$ 8.46
Investors participating in this offering	14,000,000	41.7	56,000,000	25.3	4.00
Total	33,563,802	100.0%	$ 221,492,852	100.0%	

If the underwriters fully exercise their option to purchase 2,100,000 additional shares of common stock in this offering, our existing stockholders would own 54.9% and our new investors would own 45.1% of the total number of shares of our common stock outstanding upon completion of this offering.

The number of shares of common stock shown in the table is based on:

- 15,690,046 shares of common stock outstanding as of September 30, 2010, after giving effect to the conversion of all outstanding shares of our convertible preferred stock into 14,239,797 shares of common stock upon completion of this offering; and
- the issuance of 3,873,756 shares of our common stock upon completion of this offering as a result of the automatic conversion of the $15.0 million in aggregate principal amount of the 2010 Notes (including accrued interest thereon), based on the initial public offering price of $4.00 per share and assuming the conversion occurs on November 29, 2010 (the expected closing date of this offering).

For purposes of all of the data in this section, the number of shares of common stock to be outstanding after this offering excludes:

- 256,816 shares of common stock issuable upon the exercise of warrants outstanding as of September 30, 2010, at a weighted average exercise price of $10.92 per share, which warrants are expected to remain outstanding upon completion of this offering;
- 1,482,780 shares of common stock issuable upon the exercise of options outstanding as of September 30, 2010, at a weighted average exercise price of $3.36 per share;
- 2,000,000 additional shares of common stock reserved for future issuance under our 2010 Equity Incentive Award Plan, or the 2010 Plan, which will become effective immediately prior to the completion of this offering, plus 233,689 shares of common stock reserved for future grant or issuance under our 2006 Equity Incentive Plan, or the 2006 Plan, as of September 30, 2010, which shares will be added to the shares to be reserved under our 2010 Plan upon the effectiveness of the 2010 Plan, plus any annual increases in the number of shares of common stock reserved for future issuance under the 2010 Plan pursuant to an evergreen provision and any other shares that may become issuable under the 2010 Plan pursuant to its terms, as more fully described in Compensation Discussion and Analysis Employee Equity Incentive Plans 2010 Equity Incentive Award Plan; and
- 500,000 shares of common stock reserved for issuance under our 2010 Employee Stock Purchase Plan, or the Purchase Plan, which will become effective following the completion of this offering, plus any annual increases in the number of shares of common stock reserved for issuance under the Purchase Plan pursuant to an evergreen provision, as more fully described in Compensation Discussion and Analysis Employee Equity Incentive Plans 2010 Employee Stock Purchase Plan.

To the extent that outstanding options or warrants that are expected to remain outstanding upon the completion of this offering are exercised, you will experience further dilution. If all in-the-money outstanding options and warrants were exercised, our pro forma as adjusted net tangible book value (deficit) as of September 30, 2010 (calculated on the basis of the assumptions set forth above) would have been approximately $48.3 million, or approximately $1.41 per share, causing immediate pro forma as adjusted dilution of $2.59 per share to investors participating in this offering.

In addition, we may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that we raise additional capital by issuing equity securities or convertible debt, your ownership will be further diluted.

SELECTED FINANCIAL DATA

The following table summarizes certain of our selected financial data. The selected financial data for the years ended December 31, 2007, 2008 and 2009 and the period from inception (August 25, 2006) through December 31, 2006 have been derived from our audited financial statements, of which the 2007, 2008 and 2009 financial statements are included elsewhere in this prospectus. The selected financial data for the nine months ended September 30, 2009 and 2010 and the balance sheet data as of September 30, 2010 have been derived from our unaudited interim financial statements which are included elsewhere in this prospectus. The unaudited interim financial statements have been prepared on the same basis as the audited financial statements and reflect all adjustments, consisting primarily of normal recurring adjustments, that, in the opinion of our management, are necessary to fairly present our financial position as of September 30, 2010 and results of operations for the nine months ended September 30, 2009 and 2010. Our historical results and financial condition are not necessarily indicative of the results or financial condition that may be expected in the future. The selected financial data set forth below should be read together with our financial statements and related notes and Management s Discussion and Analysis of Financial Condition and Results of Operations included elsewhere in this prospectus.

	Inception (August 25, 2006) through December 31, 2006	Year Ended December 31,			Nine Months Ended September 30,	
		2007	2008	2009	2009	2010
	(In Thousands, Except Per Share Amounts)					
Statement of Operations Data						
Revenue:						
Net product revenue	$	$	$	$	$	$ 11,828
Contract revenue						2,810
Total revenue						14,638
Operating expenses:						
Cost of sales						9,403
Royalty expense						598
Research and development	4,902	24,329	33,910	21,438	22,305	19,394
Selling, general and administrative	1,474	4,725	11,820	14,102	8,027	36,792
Total operating expenses	6,376	29,054	45,730	35,540	30,332	66,187
Loss from operations	(6,376)	(29,054)	(45,730)	(35,540)	(30,332)	(51,549)
Other income (expense):						
Interest income	395	927	696	10	7	4
Interest expense		(377)	(1,718)	(9,188)	(8,563)	(6,938)
Change in fair value of warrant liability		(107)	1,119	(755)	(505)	(12,833)
Other financing income	582	906				
Other income (expense)		25	63	(416)	(350)	(113)
Total other income (expense)	977	1,374	160	(10,349)	(9,411)	(19,880)
Net loss	(5,399)	(27,680)	(45,570)	(45,889)	(39,743)	(71,429)
Deemed dividend for the beneficial conversion on Series A-1 and Series A-2 convertible preferred stock		(18,360)				
Net loss applicable to common stockholders	$ (5,399)	$ (46,040)	$ (45,570)	$ (45,889)	$ (39,743)	$ (71,429)
Net loss per share, basic and diluted(1)	$ (13.60)	$ (80.77)	$ (52.68)	$ (40.97)	$ (36.43)	$ (53.31)
Weighted average shares outstanding, basic and diluted(1)	397	570	865	1,120	1,091	1,340
Pro forma net loss per share, basic and diluted (unaudited)(1)				$ (4.49)		$ (3.47)
Weighted average pro forma shares outstanding, basic and diluted (unaudited)(1)				10,057		16,810

(1) See Note 2 of Notes to Financial Statements for an explanation of the method used to calculate net loss per share and the number of shares used in the computation of the per share amounts.

	As of December 31,				As of September 30,
	2006	2007	2008	2009	2010
			(In Thousands)		
Balance Sheet Data:					
Cash and cash equivalents and investment securities, available for sale	$ 22,103	$ 43,255	$ 14,225	$ 44,911	$ 11,673
Working capital	20,035	38,836	3,032	42,102	(920)
Total assets	26,942	53,007	27,625	74,568	55,034
Long-term debt, less current portion		2,870	15,336	8,778	22,390
Convertible preferred stock warrant liability		259	467	5,041	20,301
Convertible preferred stock	27,110	76,955	76,955	149,312	149,312
Accumulated deficit	(5,399)	(33,079)	(78,649)	(124,538)	(195,967)
Total stockholders equity (deficit)	(5,385)	(32,926)	(77,534)	(122,300)	(183,780)

MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with Selected Financial Data and our financial statements and related notes appearing elsewhere in this prospectus. In addition to historical information, this discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of certain factors, including, but not limited, to those set forth under Risk Factors and elsewhere in this prospectus.

Overview

Background

We are a pharmaceutical company commercializing and developing products for the treatment of central nervous system disorders and pain. Our first commercial product, Sumavel DosePro (*sumatriptan* injection) Needle-free Delivery System, offers fast-acting, easy-to-use, needle-free subcutaneous administration of *sumatriptan* for the acute treatment of migraine and cluster headache in a pre-filled, single-use delivery system. We launched the commercial sale of Sumavel DosePro in the United States in January 2010 with our co-promotion partner, Astellas Pharma US, Inc., or Astellas. Our sales and marketing organization is comprised of approximately 100 professionals. Our field sales force of approximately 80 representatives is promoting Sumavel DosePro primarily to neurologists and other key prescribers of migraine medications, including headache clinics and headache specialists. Our promotional efforts are complemented by our collaboration with Astellas and approximately 400 of its sales representatives, who are promoting Sumavel DosePro primarily to primary care physicians, OB/GYNs, emergency medicine physicians and urologists in the United States, or the Astellas Segment. Our lead product candidate, ZX002, is a novel, oral, single-entity controlled-release formulation of *hydrocodone* currently in Phase 3 clinical trials for the treatment of moderate to severe chronic pain in patients requiring around-the-clock opioid therapy. We initiated the Phase 3 clinical development program for ZX002 in March 2010 and, if successful, expect to submit a New Drug Application, or NDA, with the U.S. Food and Drug Administration, or FDA, by early 2012. We in-licensed exclusive U.S. rights to ZX002 from Elan Pharma International Limited, or Elan, in 2007.

We have experienced net losses and negative cash flow from operating activities since inception, and as of September 30, 2010, had an accumulated deficit of $196.0 million. We expect to continue to incur net losses and negative cash flow from operating activities for at least the next several years primarily as a result of the development expenses in connection with clinical trials and pre-clinical studies for ZX002 and the cost of the sales and marketing expenses associated with Sumavel DosePro. As of September 30, 2010, we had cash and cash equivalents of $11.7 million. Although it is difficult to predict future liquidity requirements, we believe that the net proceeds from this offering, together with our existing cash and cash equivalents, future product revenues and borrowings available under our $10.0 million revolving credit facility, will be sufficient to fund our operations for at least the next 12 months. However, successful transition to profitability is dependent upon achieving a level of revenues adequate to support our cost structure. We cannot assure you that we will ever be profitable or generate positive cash flow from operating activities and, unless and until we do, we will need to raise additional capital through debt or equity financings or through collaborations or partnerships with other companies. We may not be able to raise additional capital on terms acceptable to us, or at all, and any failure to raise capital as and when needed would have a negative impact on our results of operations, financial condition and our ability to execute on our business plan. In its report on our financial statements for the year ended December 31, 2009, our independent registered public accounting firm included an explanatory paragraph expressing substantial doubt regarding our ability to continue as a going concern.

Co-Promotion Agreement

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

At the inception of the co-promotion agreement and in exchange for the right to promote Sumavel DosePro, Astellas made a non-refundable up-front payment of $2.0 million to us and agreed to make an additional $18.0 million of payments to us upon the achievement of a series of milestones. As of December 31, 2009, we had received a total of $19.0 million from Astellas. The remaining $1.0 million was paid to us in March 2010. These proceeds are reflected as deferred revenues on our balance sheets at December 31, 2009 and September 30, 2010. Beginning with the launch of Sumavel DosePro in January 2010, we began recognizing these proceeds as contract revenues on a ratable basis over the remaining term of the agreement, which remains in effect through June 30, 2013, subject to extension by one year at Astellas option, contingent upon payment of a predetermined option fee.

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

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

The co-promotion agreement may be terminated by Astellas or us for a number of specified reasons, some of which are beyond our control. In the event Astellas terminates the agreement for specified reasons, including our inability to supply commercial product or a material uncured breach by us of our minimum sales effort obligations, prior to July 31, 2011, we would be required to pay Astellas a specified royalty on net sales of Sumavel DosePro up to an aggregate specified dollar amount. Any such payments would be in lieu of the annual tail payments described above. We depend on Astellas and its sales force to promote Sumavel DosePro to the Astellas Segment and any inability of its sales force to effectively sell the product or any termination of the co-promotion agreement could have a material adverse effect on our results of operations and financial condition.

Revenues

Through the year ended December 31, 2009, we did not generate any product revenues or recognize any contract revenues. During the nine months ended September 30, 2010, we began recognizing product revenues from sales of Sumavel DosePro made by us and Astellas under our co-promotion agreement. During this same period, we began recognizing contract revenues from license and milestone payments received under the Astellas co-promotion agreement. We recognized

$11.8 million in net product revenues since the commercial launch of Sumavel DosePro in January 2010 through September 30, 2010. We recognized $2.8 million in contract revenues associated with license and milestone payments made to us by Astellas under the co-promotion agreement through September 30, 2010.

We sell Sumavel DosePro product in a package of six pre-filled, single-dose units to wholesale pharmaceutical distributors, and on a limited basis to retail pharmacies, or, collectively, our customers, at a wholesale acquisition cost, or gross sales price, of $498 per package as of September 30, 2010. Sales to our customers are subject to specified rights of return. We currently defer recognition of revenue on product shipments of Sumavel DosePro to our customers until the right of return no longer exists, which occurs at the earlier of the time Sumavel DosePro units are dispensed through patient prescriptions or expiration of the right of return. We do not have significant history estimating the number of patient prescriptions dispensed. If we underestimate or overestimate patient prescriptions dispensed for a given period, adjustments to net product revenue may be necessary in future periods.

As a result of this policy, of the $16.4 million in gross product sales of Sumavel DosePro to our customers for the nine months ended September 30, 2010, we recognized $11.8 million in product revenue for the same period, which is net of estimated wholesaler and retail pharmacy discounts, stocking allowances, prompt pay discounts, chargebacks, rebates and patient discount programs. We had a deferred revenue balance of $2.8 million at September 30, 2010 for Sumavel DosePro product shipments, which is net of estimated wholesaler and retail pharmacy discounts, stocking allowances, prompt pay discounts, chargebacks, rebates and patient discount programs.

We will continue to recognize revenue upon the earlier to occur of prescription units dispensed or expiration of the right of return until we can reliably estimate product returns, at which time we will record a one-time increase in net revenue related to the recognition of revenue previously deferred.

Cost of Sales

Cost of sales consist primarily of materials, third-party manufacturing costs, freight and indirect personnel and other overhead costs associated with sales of Sumavel DosePro based on units dispensed through patient prescriptions, as well as reserves for excess, dated or obsolete commercial inventories and production manufacturing variances. For the nine months ended September 30, 2010, our cost of sales was $9.4 million. The cost of sales associated with the deferred product revenues are recorded as deferred costs, which are included in inventory, until such time the deferred revenue is recognized. Deferred cost of sales totaled $0.8 million at September 30, 2010.

Royalty Expense

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

Research and Development Expenses

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

- payments made to third-party contract research organizations, or CROs, and investigational sites, which conduct our trials on our behalf, and consultants;

- expenses associated with regulatory submissions, preclinical development and clinical trials;

payments to third-party manufacturers, which produce our active pharmaceutical ingredient and finished product;

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

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

facility, maintenance, depreciation and other related expenses.

We expense all research and development costs as incurred. Our research and development expenses through December 31, 2009 consisted primarily of costs associated with preclinical testing, clinical development, regulatory activities and the manufacturing development of Sumavel DosePro. These expenses include payments to contract manufacturing organizations. We received FDA approval for Sumavel DosePro in July 2009, after which we began capitalizing costs as inventory related to the production of Sumavel DosePro, including the cost of materials, third-party manufacturing costs, freight and indirect personnel and other overhead costs.

In March 2010, we initiated our Phase 3 clinical development program for ZX002. We utilize CROs, contract laboratories and independent contractors for the conduct of preclinical studies and clinical trials. In 2010, we began tracking third party costs by type of study being conducted. We recognize the expenses associated with the services provided by CROs based on the percentage of each study completed at the end of each reporting period. We coordinate clinical trials through a number of contracted investigational sites and recognize the associated expense based on a number of factors, including actual and estimated subject enrollment and visits, direct pass-through costs and other clinical site fees. For the nine months ended September 30, 2010, we incurred $11.9 million and $1.1 million in third party research and development costs related to ZX002 and Sumavel DosePro, respectively.

We use our employee and infrastructure resources across our product and product candidate development programs. Therefore, we have not tracked salaries, other personnel related expenses, facilities or other related costs to our product development activities on a program-by-program basis. However, we estimate that the majority of our research and development expenses incurred to date are attributable to our Sumavel DosePro program. The following table illustrates, for each period presented, our research and development costs broken down by major categories of the cost:

	Inception (August 25, 2006) through December 31, 2006	Year Ended December 31,			Nine Months Ended September 30,	
		2007	2008	2009	2009	2010
			(In Thousands)			
Research and development expenses:						
Manufacturing development expenses	$ 2,747	$ 13,701	$ 22,381	$ 13,772	$ 17,488	$
Clinical/regulatory expenses	835	10,628	11,529	7,666	4,817	19,394
Purchased in-process research and development(1)	1,320					
Total	$ 4,902	$ 24,329	$ 33,910	$ 21,438	$ 22,305	$ 19,394

(1) This amount represents the value allocated to the DosePro technology in connection with the asset and technology purchased from Aradigm in 2006.

We expect our research and development costs for 2010 will be higher than in 2009 as we progress through the Phase 3 clinical program of ZX002. At this time, due to the inherently unpredictable nature of clinical development we are unable to estimate with any certainty the costs we will incur in the continued development of ZX002. These expenditures are subject to numerous uncertainties regarding timing and cost to completion. Completion of our Phase 3 clinical trials may take longer than currently estimated. The cost of clinical trials may vary significantly over the life of a project as a result of differences arising during clinical development, including, among others:

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

In addition, we may be obligated to pay Elan, from whom we in-licensed exclusive rights to ZX002 in November 2007, up to $4.5 million in total future milestone payments with respect to ZX002 depending upon the achievement of various development and regulatory events. If ZX002 is approved, we are also required to pay a mid single-digit percentage royalty on its net sales for a specified period of time and continue to pay royalties on net sales of the product thereafter at a reduced low single-digit percentage rate in accordance with the terms of the license agreement.

If our Phase 3 clinical trials are successful, we expect to submit an NDA for ZX002 with the FDA by early 2012. However, the successful development and commercialization of ZX002 is highly uncertain. We also expect to incur customary regulatory costs associated with the NDA, if and when submitted, which will be significant. If ZX002 is approved, we also expect to incur significant expenses related to manufacturing and marketing activities. However, at this time, we cannot reasonably estimate or know the nature, specific timing and estimated costs of the efforts that will be necessary to complete the remainder of the development of ZX002, if or when ZX002 will receive regulatory approval and, if approved, if and when material net cash inflows may commence from ZX002 or the amount of any such inflows. This is due to the numerous risks and uncertainties associated with developing and commercializing drugs, including the uncertainty of:

- the costs, timing and outcome of our clinical trials and pre-clinical studies of ZX002;
- the costs, timing and outcome of regulatory review of ZX002;
- the costs of commercialization activities, including product marketing, sales and distribution;
- the potential for future collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development and commercialization plans and capital requirements;
- the costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending intellectual property-related claims;

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

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

our degree of success in commercializing ZX002, if approved.

A change in the outcome of any of these variables with respect to the development of ZX002 could mean a significant change in the costs and timing associated with these efforts.

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

Selling, General and Administrative Expenses

Through the fiscal year ended December 31, 2009, our selling expenses, which include sales and marketing costs, have consisted primarily of salaries, benefits, consulting fees and market research studies related to preparation for the launch of Sumavel DosePro, including shared marketing and advertising costs under our co-promotion agreement with Astellas. In the fourth quarter of 2009 and in the first quarter of 2010, we expanded our commercial infrastructure, including the hiring of sales and marketing management and sales representatives. In addition, in 2010 we began incurring service fee costs for promotional efforts provided by Astellas and sample product costs.

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

Interest Income

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

Interest Expense

Interest expense consists of interest incurred in connection with the $4.5 million borrowed under our loan and security agreement with General Electric Capital Corporation, or GE Capital, entered into in March 2007, our $18.0 million loan and security agreement with Oxford Finance Corporation, or Oxford, and CIT Healthcare LLC, or CIT, entered into in June 2008, non-cash interest expense associated with amortization of debt discount and debt issuance costs and non-cash interest expense associated with the fair value of the beneficial conversion feature on convertible promissory notes we issued to certain investors between February 2009 and July 2009 in an aggregate amount of $14.8 million, or the 2009 Notes.

In July and October 2010, we amended and restated the loan and security agreement with Oxford and CIT, and Oxford and Silicon Valley Bank, or SVB, are now party to that amended and restated agreement, or the amended Oxford loan agreement. The amended Oxford loan agreement consists of a $25.0 million term loan and a $10.0 million revolving credit facility. New warrants were issued to Oxford and SVB in connection with the amended Oxford loan agreement. In connection with the execution of the amended Oxford loan agreement, we repaid the outstanding balance of the Oxford and CIT loan and security agreement totaling $12.8 million at June 30, 2010, which amount was repaid with borrowings under the amended Oxford loan agreement. Consequently, the net proceeds we received upon the execution of the amended Oxford loan agreement totaled $12.2 million. As of September 30, 2010, we had borrowed $2.7 million under the revolving credit facility. Concurrently with the amended Oxford loan agreement, we issued $15.0 million in new convertible promissory notes, or the 2010 Notes, to current investors. As a result of additional borrowings under the amended Oxford loan agreement and the 2010 Notes, interest expense will increase over 2009 levels.

Change in Fair Value of Warrant Liability

Change in fair value of warrant liability represents non-cash (expense) income associated with changes in the fair value of the warrants to purchase preferred stock issued to GE Capital, Oxford, CIT and current investors.

Upon consummation of this offering, the liability reflected on our consolidated balance sheet for convertible preferred stock warrants will be reclassified to stockholders equity (deficit) and we will no longer be required to record the change in fair value of these warrants in the statement of operations.

Other Income (Expense)

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

Net Operating Loss and Tax Credit Carryforwards

As of December 31, 2009, we had federal and state net operating loss carryforwards of approximately $108.4 million and $105.1 million, respectively. If not utilized, the net operating loss carryforwards will begin expiring in 2026 for federal tax purposes and 2016 for state tax purposes. As of December 31, 2009, we had federal and state research and development tax credit carryforwards of approximately $0.9 million and $0.9 million, respectively. The federal tax credits will begin expiring in 2026 unless previously utilized and the state tax credits carry forward indefinitely.

Under Section 382 of the Internal Revenue Code of 1986, as amended, or the Internal Revenue Code, or IRC, substantial changes in our ownership may limit the amount of net operating loss and research and development income tax credit carryforwards that could be utilized annually in the future to offset taxable income. Specifically, this limitation may arise in the event of a cumulative change in ownership of our company of more than 50% within a three-year period. Any such annual limitation may significantly reduce the utilization of the net operating loss carryforwards before they expire. We performed a Section 382 and 383 analysis and determined that we had one ownership change, as defined by IRC Sections 382 and 383, which occurred in August 2006 upon the issuance of Series A-1 preferred shares. As a result of this ownership change, we reduced our net operating loss carryforwards by $1.9 million. The closing of this offering, together with private placements and other transactions that have occurred since our inception, may trigger an ownership change pursuant to Sections 382 and 383, which could further limit the amount of net operating loss carryforwards that could be utilized annually in the future to offset taxable income, if any. Any such limitation, whether as the result of this offering, prior private placements, sales of common stock by our existing stockholders or additional sales of common stock by us after this offering, could have an adverse effect on our results of operations in future years. In each period since our inception, we have recorded a valuation allowance for the full amount of our deferred tax asset, as the realization of the deferred tax asset is uncertain. As a result, we have not recorded any federal or state income tax benefit in our statement of operations.

Internal Control Over Financial Reporting

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

For the year ending December 31, 2011, pursuant to Section 404 of the Sarbanes-Oxley Act, management will be required to deliver a report that assesses the effectiveness of our internal control

over financial reporting. Under current Securities and Exchange Commission, or SEC, rules, our independent registered public accounting firm will also be required to deliver an attestation report on the effectiveness of our internal control over financial reporting beginning with the year ending December 31, 2011, unless we qualify for an exemption as a non-accelerated filer under the Dodd-Frank Wall Street Reform and Consumer Protection Act, enacted on July 21, 2010. Although we may qualify for an exemption from the requirements of Section 404 of the Sarbanes-Oxley Act, as a result of provisions in the Dodd-Frank Wall Street Reform and Protection Act, we currently do not intend to take advantage of the exception even if it is available to us.

Critical Accounting Policies and Estimates

Our management s discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in conformity with generally accepted accounting principles in the United States, or GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, expenses and related disclosures. Actual results could differ from those estimates.

While our significant accounting policies are more fully described in Note 2 to our financial statements appearing elsewhere in this prospectus, we believe the following accounting policies to be critical to the judgments and estimates used in the preparation of our financial statements.

Revenue Recognition

We recognize revenues from the sale of Sumavel DosePro and from license fees and milestones earned on collaborative arrangements. Revenue is recognized when there is persuasive evidence that an arrangement exists, delivery has occurred and title has passed, the price is fixed or determinable and we are reasonably assured of collecting the resulting receivable.

Product Revenue

Sales of Sumavel DosePro to our customers are subject to rights of return within a period beginning six months prior to, and ending 12 months following, product expiration. Given the limited sales history of Sumavel DosePro, we currently cannot reliably estimate expected returns of the product at the time of shipment. Accordingly, we defer recognition of revenue on product shipments of Sumavel DosePro until the right of return no longer exists, which occurs at the earlier of the time Sumavel DosePro units are dispensed through patient prescriptions or expiration of the right of return. Units dispensed are not generally subject to return. We estimate patient prescriptions dispensed using an analysis of third-party information, including third-party market research data, information obtained from certain wholesalers with respect to inventory levels and inventory movement and retail pharmacy re-stocking activity. Sumavel DosePro was launched in January 2010 and, accordingly, we do not have significant history estimating the number of patient prescriptions dispensed. If we underestimate or overestimate patient prescriptions dispensed for a given period, adjustments to revenue may be necessary in future periods.

As a result of this policy, we recognized $11.8 million in Sumavel DosePro product revenue for the nine months ended September 30, 2010, which is net of estimated wholesaler and retail pharmacy discounts, stocking allowances, prompt pay discounts, chargebacks, rebates and patient discount programs. We had a deferred revenue balance of $2.8 million at September 30, 2010 for Sumavel DosePro product shipments, which is net of estimated wholesaler and retail pharmacy discounts, stocking allowances, prompt pay discounts, chargebacks, rebates and patient discount programs.

We will continue to recognize revenue upon the earlier to occur of prescription units dispensed or expiration of the right of return until we can reliably estimate product returns, at which time we will record a one-time increase in net revenue related to the recognition of revenue previously deferred. In addition, the costs of manufacturing Sumavel DosePro associated with the deferred revenue are recorded as deferred costs, which are included in inventory, until such time the deferred revenue is recognized.

Product Sales Allowances

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

Wholesaler and Retail Pharmacy Discounts. We offer discounts to certain wholesale distributors and retail pharmacies based on contractually determined rates. We accrue the discount on shipment to the respective wholesale distributors and retail pharmacies and recognize the discount as a reduction of revenue in the same period the related revenue is recognized.

Prompt Pay Discounts. We offer cash discounts to our customers, generally 2% of the sales price, as an incentive for prompt payment. We account for cash discounts by reducing accounts receivable by the full amount and recognize the discount as a reduction of revenue in the same period the related revenue is recognized.

Chargebacks. We provide discounts to authorized users of the Federal Supply Schedule, or FSS, of the General Services Administration under an FSS contract negotiated by the Department of Veterans Affairs. These federal entities purchase products from the wholesale distributors at a discounted price, and the wholesale distributors then charge back to us the difference between the current retail price and the price the federal entity paid for the product. We estimate and accrue chargebacks based on estimated wholesaler inventory levels, current contract prices and historical chargeback activity.

Rebates. We participate in certain rebate programs, which provide discounted prescriptions to qualified insured patients. Under these rebate programs, we pay a rebate to the third-party administrator of the program, generally two to three months after the quarter in which prescriptions subject to the rebate are filled. We estimate and accrue these rebates based on current contract prices, historical and estimated future percentages of product sold to qualified patients and estimated levels of inventory in the distribution channel.

Patient Discount Programs. We offer discount card programs to patients for Sumavel DosePro in which patients receive discounts on their prescriptions that are reimbursed by us. We estimate the total amount that will be redeemed based on levels of inventory in the distribution and retail channels.

Stocking Allowances. We may offer discounts and extended payment terms, generally in the month of the initial commercial launch of a new product, on the first order made by certain wholesale distributors and retail pharmacies based on contractually determined rates. We accrue the discount on shipment to the respective wholesale distributors and retail pharmacies and recognize the discount as a reduction of revenue in the same period the related revenue is recognized. Revenue is deferred until the later of expiration of recourse terms under these stocking allowance incentive programs or when prescriptions are filled for these shipments determined based on a first-in, first-out basis.

In the first quarter of 2010, we provided stocking allowances on initial orders placed by our customers in connection with the launch of Sumavel DosePro. In accordance with our accounting policy for stocking allowances as disclosed, the allowance provided was accrued at the time of shipment to our customers and recognized as a reduction to revenue in the same period the related revenue was recognized. There have been no additional orders placed with stocking allowances. The amounts accrued for wholesaler and retail pharmacy discounts and prompt pay discounts were $0.3 million at September 30, 2010 and none at both December 31, 2009 and 2008. We recognized $0.8 million in reductions to product revenues related to these discounts for the nine months ended September 30, 2010. Contractually agreed upon discounts with our wholesale and retail customers are typically paid to

our customers on a quarterly basis one to two months after the quarter in which product was shipped to the customer. Based on our experience, our customers generally comply with our payment terms to earn prompt pay discounts. These discounts are measureable at the time of shipment of product to our customers and generally do not vary materially from our estimates.

The amounts accrued for rebates, chargebacks and other incentive programs were $0.3 million at September 30, 2010 and none at both December 31, 2009 and 2008. We recognized $0.6 million in reductions to product revenues related to these sales allowances for the nine months ended September 30, 2010. Our procedures for estimating amounts accrued for rebates, chargebacks and other incentive programs at the end of any period are based on available quantitative data and are supplemented by management s judgment with respect to many factors, including but not limited to, current market dynamics, changes in contract terms, impact of new contractual arrangements and changes in sales trends. Quantitatively, we use historical sales, inventory movement through commercial channels, product utilization and rebate data and apply forecasting techniques in order to estimate our liability amounts. Qualitatively, management s judgment is applied to these items to modify, if appropriate, the estimated liability amounts. There are inherent risks in this process. For example, patients may not achieve assumed utilization levels; third parties may misreport their utilization to us; and discounts determined under federal guidelines, which affect our rebate programs with U.S. federal government agencies, may differ from those estimated. On a quarterly basis, we analyze our estimates against actual rebate, chargeback and incentive program activity and adjust our estimates as necessary. Given our limited history with the commercialization of Sumavel DosePro, we may experience variability in our provisions for these sales allowances as we continue to initiate new sales initiatives and/or managed care programs in connection with the commercialization of our product. An adjustment to our estimated liabilities for rebates, chargebacks and other incentive programs of 5% of net product sales on a quarterly basis, based on operating results for the three months ended September 30, 2010, would have resulted in an increase or decrease to net sales for that quarter of approximately $0.2 million to $0.3 million. The sensitivity of our estimates can vary by program and type of customer. Additionally, there is a time lag between the date we determine the estimated liability and when we actually pay the liability. Due to this time lag, we may record adjustments to our estimated liabilities over several reporting periods, which can result in a net increase to net revenues or a net decrease to net revenues in those periods. Material differences may result in the amount of revenue we recognize from product sales if the actual amount of rebates, chargebacks and incentives differ materially from the amounts estimated by management. To date, there have been no material differences between the amount booked in a period and actual charges incurred.

Contract Revenue

We recognize revenues related to license fees and milestone payments received under our co-promotion agreement with Astellas. Revenue arrangements with multiple deliverables are divided into separate units of accounting if criteria are met, including whether the deliverable has stand-alone value to the customer and the customer has a general right of return relative to the delivered item and delivery or performance of the undelivered item is probable and substantially within the vendor s control. Arrangement consideration is allocated at the inception of the arrangement to all deliverables on the basis of their relative selling price.

In connection with the co-promotion agreement, Astellas made a non-refundable up-front payment of $2.0 million and agreed to make an additional $18.0 million of payments to us upon the achievement of a series of milestones. As of December 31, 2009, Astellas paid a total of $19.0 million to us. The remaining $1.0 million was paid to us in March 2010.

We identified the deliverables in the co-promotion agreement and divided them into separate units of accounting as follows: (1) co-exclusive right to promote Sumavel DosePro combined with the manufacturing and supply of commercial and sample product; and (2) sales support of Sumavel DosePro. We concluded both units of accounting require recognition ratably through the term of the

co-promotion agreement, which began with the date of the launch of Sumavel DosePro (January 2010) and ends June 30, 2013, subject to a one-year extension at Astellas option upon Astellas payment of a pre-determined fee to us, and therefore, the allocation of the upfront and milestone financial consideration is not necessary. Consequently, we recorded the $19.0 million in upfront and milestone payments received from Astellas as deferred revenue in the balance sheet at December 31, 2009. The final $1.0 million milestone payment was recorded as deferred revenue when received in March 2010. Beginning with the launch of Sumavel DosePro in January 2010, we began amortizing the license fees and milestone payments as contract revenue in the statement of operations over the term of the co-promotion agreement. Amounts received from Astellas for shared marketing costs are reflected as a reduction of selling, general and administrative expenses, and amounts payable to Astellas for shared marketing expenses and service fees are reflected as selling, general and administrative expenses.

Inventories and Related Reserves

Inventories are stated at the lower of cost (FIFO) or market and consist of finished goods, work in progress and raw materials used in the manufacture of Sumavel DosePro. We have significant lead times for the procurement and manufacture of our finished goods and we therefore order goods from our suppliers and manufacturers based on our forecasts of future demand. To the extent we procure component materials or produce finished goods in excess of actual future demand, we may be required to provide reserves for potentially excess or dated inventories. We provide such reserves based on an analysis of inventory on hand and on firm purchase commitments compared to forecasts of future sales.

Clinical Trial Expenses

Our expense accruals for clinical trials are based on estimates of the services received from clinical trial investigational sites and CROs. Payments under some of the contracts we have with such parties depend on factors such as the milestones accomplished, successful enrollment of certain numbers of patients, site initiation and the completion of clinical trial milestones. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If possible, we obtain information regarding unbilled services directly from these service providers. However, we may be required to estimate these services based on information available to our product development or administrative staff. If we underestimate or overestimate the activity associated with a study or service at a given point in time, adjustments to research and development expenses may be necessary in future periods. Historically, our estimated accrued liabilities have approximated actual expense incurred. Subsequent changes in estimates may result in a material change in our accruals.

Stock-Based Compensation

Stock-based compensation expense is measured at the grant date, based on the estimated fair value of the award, and is recognized as expense over the employee s requisite service period, or vesting period, on a straight-line basis. Equity awards issued to non-employees are recorded at their fair value on the grant date and are periodically re-measured as the underlying awards vest unless the instruments are fully vested, immediately exercisable and nonforfeitable on the date of grant. Expense recognized for consultant stock options was immaterial for the years ended December 31, 2007, 2008 and 2009 and the nine months ended September 30, 2010.

We utilize the Black-Scholes option-pricing model for determining the estimated fair value of stock-based compensation for stock-based awards to employees and the board of directors. The assumptions used in the Black-Scholes option-pricing model are as follows:

	Year Ended December 31,			Nine Months Ended September 30,	
	2007	2008	2009	2009	2010
Risk free interest rate	3.5% to 4.8%	2.7% to 3.2%	2.3% to 2.8%	2.3% to 2.8%	1.8% to 2.3%
Expected term	1.0 to 6.1 years	5.0 to 6.1 years	5.0 to 6.1 years	5.0 to 6.1 years	5.0 to 6.1 years
Expected volatility	64.4% to 78.1%	80.6% to 86.0%	105.6% to 107.6%	102.7% to 107.6%	94.2% to 95.7%
Expected dividend yield	0.0%	0.0%	0.0%	0.0%	0.0%
Fair value of underlying stock	$0.50 to $16.00	$3.50 to $19.10	$3.20 to $3.60	$3.20	$13.00 to $13.50

The risk-free interest rate assumption was based on the rates for U.S. Treasury zero-coupon bonds with maturities similar to those of the expected term of the award being valued. The assumed dividend yield was based on our expectation of not paying dividends in the foreseeable future. The weighted average expected term of options was calculated using the simplified method as prescribed by accounting guidance for stock-based compensation. This decision was based on the lack of relevant historical data due to our limited historical experience. In addition, due to our limited historical data, the estimated volatility was calculated based upon the historical volatility of comparable companies whose share prices are publicly available. As a result of our use of estimates, if factors cause our assumptions to change, the amount of our stock-based compensation expense could be materially different in the future.

Common Stock Valuation

From inception through September 30, 2010, due to the absence of an active market for our common stock, the exercise prices for all options granted were at the estimated fair value as determined contemporaneously on the date of grant by our board of directors prepared in accordance with methodologies outlined in the *AICPA Practice Aid Valuation of Privately-Held-Company Equity Securities Issued as Compensation*. Our board of directors, which includes members who are experienced in valuing the securities of biotechnology/pharmaceutical companies, considered a number of subjective and objective factors including:

- the prices of our convertible preferred stock sold to outside investors in arms-length transactions, and the rights, preferences and privileges of our convertible preferred stock as compared to those of our common stock, including the liquidation preference of our convertible preferred stock;
- our results of operations and financial position, including the first commercial sale of Sumavel DosePro in the United States in January 2010 and the progression of ZX002 into Phase 3 clinical trials in March 2010;
- our stage of development and business strategy;
- the market value of a comparison group of publicly held biotechnology/pharmaceutical companies that are in a stage of development similar to ours;
- the lack of liquidity of our common stock as a private company;
- contemporaneous valuation data provided by management;
- the likelihood and timing of achieving a liquidity event for the shares of our common stock, such as an initial public offering, given prevailing market conditions; and

the material risks related to our business.

Based on these factors, our board of directors granted options at exercise prices ranging from $0.50 per share in February 2007 to $6.20 per share in August 2010.

During 2009 and 2010, the valuation methodologies employed by us in the contemporaneous determination of fair value of our common stock were based on three primary factors: (i) market approach using comparable publicly traded companies, (ii) income approach using discounted cash flow analysis, and (iii) cost approach. The market approach using publicly traded companies is based on the market value of the invested capital (less cash) derived from already public companies that are in the biotechnology/pharmaceutical industry and have other characteristics similar to us, including size and business model. The income approach using a discounted cash flow analysis is based on the residual value and debt-free cash flow from our multi-year forecast discounted to present value based on our calculated weighted average cost of capital, or WACC. The cost approach using estimated cost of replicating or reproducing the development efforts involved in the development of Sumavel DosePro and ZX002, including applicable selling, general and administrative costs. Each of the above approaches was weighted in the determination of our equity value for each period based on the then current status of our business model and anticipated liquidity events. Once our equity value was estimated, the option pricing method estimated the value of the common stock by creating a series of call options with exercise prices based on the liquidation preference of our preferred stock. The estimated value of the common stock was inferred by analyzing these options. In general, after the equity value of the business enterprise was determined, the next step was analyzing any stock options and warrants outstanding and using the common stock value on a converted basis to see if the options and warrants were in-the-money. Next, the option pricing method was used to allocate the full equity value (inclusive of any cash infusion from the assumed exercise of in-the-money options and warrants) to our common stock.

In August 2010, we commenced the initial public offering process. In connection with the preparation of the financial statements necessary for inclusion in the registration statement related to this offering, we reassessed the estimated fair value of our common stock for financial reporting purposes for each quarter in 2009 and 2010. The reassessment included both the determination of the appropriate valuation models and related inputs. For the reassessed periods prior to 2010, we did not forecast or anticipate a liquidity event in the near term and, as such, utilized the option pricing method. The option pricing method does not utilize a specific probability of completing an initial public offering but instead utilizes a market approach using comparable publicly traded companies. These reassessments did not result in any significant difference in the estimated fair value of our common stock from those estimated by our contemporaneous valuations.

As a result of the greater clarity available to us to define likely outcomes and the proximity to a liquidity event (i.e., this offering), we concluded that the probability weighted expected return method, or PWERM, was more appropriate than our previously used option pricing model and provided a more refined estimate of the likely value of our common stock as of June 30 and September 30, 2010. The type and timing of each potential liquidity event for the June 30 and September 30, 2010 valuations were heavily influenced by the commencement of the initial public offering process while each prior reassessed valuation was based on our best estimate of type and timing of liquidity event at that time.

In our application of the PWERM, our timing and aggregate enterprise value was estimated for various potential liquidity scenarios:

three initial public offering scenarios;

merger and acquisition, or M&A; and

private company.

The enterprise values estimated for these scenarios were based on income and market approaches. Due to our newly launched product and lack of the comparability of revenue multiples within our potential guideline public companies, we utilized a discounted cash flow analysis to determine our

enterprise value in our three initial public offering scenarios. The M&A scenario is based on the value of recently completed M&A activity in our industry. In the stay private scenario we utilized a less optimistic revenue forecast assuming capital constraints in a private company setting and limiting our ability to launch secondary products. Depending on the value, expected timing and likelihood of a given liquidity scenario, the models could result in a significant differential between the value of the common stock and preferred stock. In general, there is a greater differential in the value of common stock and preferred stock when a company s enterprise value is not significantly higher than the aggregate liquidation preferences of its preferred stock.

Once our equity value was estimated for each scenario, we then allocated a portion of the enterprise value to our common stock based on a best economic outcome model. For the initial public offering scenarios, the value assigned to the common stock was estimated using a fully diluted outstanding share analysis based on the conversion of all preferred equity instruments into common stock. For M&A and private company scenarios, the model uses a break point analysis to estimate the various enterprise values at which holders of each series of preferred stock would elect to convert to common stock and the points at which the holders of options and warrants would exercise as a result of the value of the common stock exceeding the exercise price. Each scenario was assigned a weighting factor based on the probability of occurrence.

The resulting proceeds to the common stockholders were then discounted to present value using our WACC. In each scenario, we estimated a likely discount for lack of liquidity as a private company and removed this amount from the value available to common stockholders. An at-the-money put option model was used to determine the discount for lack of liquidity at each valuation date based on the average liquidity date of the various liquidity scenarios. We relied on the Black-Scholes option pricing model framework to estimate the theoretical value of an at-the-money put option on our common stock which could be exercised in a liquidity event occurring at a future estimated date. The per share value derived from this analysis was then divided by the common share price derived from the PWERM to estimate the percentage discount that could be inferred using this model.

The following tables summarize the significant assumptions utilized in the PWERM and option pricing models used to determine the reassessed fair value of our common stock as of the dates indicated. In both the PWERM and option pricing models, where discounted cash flow analyses was used, our revenue forecasts were based on key inputs into statistical algorithms and historical trends rather than the use of year-over-year growth rates. Our key inputs include competitive product launch curves, penetration levels by type of competitive product (i.e. nasal, melt, tablets and injectables) and market research data such as estimated migraines treated, expected patient and physician acceptance rates and seasonality. These estimates are modified to take into account our most recent historical sales activity and the experience of our senior management team. From September 2009 to December 2009, our revenue forecasts showed significant improvement due to closer proximity to the commercial launch of Sumavel DosePro and refinement of underlying assumptions, such as consideration of the new co-promotion agreement with Astellas entered into in the third quarter of 2009. From December 2009 to September 2010, we experienced improvement in our enterprise value within our initial public offering scenarios, which were weighted at a 70% probability, due to the significant impact on revenues and related discounted cash flows associated with the initiation of our Phase 3 clinical program for ZX002 in the first quarter of 2010 and the assumed commercial launch in subsequent years. In addition, our re-assessed valuations in 2009 take into consideration the implied value of our common stock based on the sales price of our Series B convertible preferred stock sold with over 25% participation from new investors. However, these forecasts and projections are subject to numerous estimates, assumptions and uncertainties and were prepared solely for purposes of determining the fair value of our common stock for accounting purposes and our actual operating results and enterprise value, and ability to commercialize our product candidates may differ materially from those expressed or implied by this data.

	September 30, 2009		
Key Assumptions	**Market Approach**	**Income Approach**	**Implied Value Based on Series B Financing**
Weighting	30%	30%	40%
Liquidity date	12/1/2010	N/A	N/A
Present value factor	69%	Various	100%
Weighted average cost of capital	N/A	36%	N/A
Discount for lack of marketability	36%	36%	36%

	December 31, 2009		
Key Assumptions	**Market Approach**	**Income Approach**	**Implied Value Based on Series B Financing**
Weighting	30%	30%	40%
Liquidity date	12/1/2010	N/A	N/A
Present value factor	84%	Various	100%
Weighted average cost of capital	N/A	37%	N/A
Discount for lack of marketability	27%	27%	27%

Key Assumptions	Initial Public Offering (November 2010)	Initial Public Offering (December 2010)	June 30, 2010 Initial Public Offering (March 2011)	Stay Private	Merger or Acquisition
Weighting	20%	35%	15%	15%	15%
Liquidity date	11/1/2010	12/15/2010	3/31/2011	7/1/2010	10/15/2011
Present value factor	Various	Various	Various	Various	Various
Weighted average cost of capital	30%	30%	30%	36%	N/A
Discount for lack of marketability	14%	16%	20%	14%	13%

Key Assumptions	Initial Public Offering (November 2010)	Initial Public Offering (December 2010)	September 30, 2010 Initial Public Offering (March 2011)	Stay Private	Merger or Sale
Weighting	35%	20%	15%	15%	15%
Liquidity date	11/30/2010	12/15/2010	3/31/2011	10/1/2010	10/15/2011
Present value factor	Various	Various	Various	Various	0.99
Weighted average cost of capital	29%	29%	29%	35%	N/A
Discount for lack of marketability	8%	9%	16%	8%	3%

The following is a summary of the weighted average enterprise values (less debt plus cash) used to determine the reassessed values of our common stock (in millions). However, these enterprise values are based on forecasts and projections and are subject to numerous estimates, assumptions and uncertainties and were prepared solely for purposes of determining the reassessed values of our common stock for accounting purposes and our actual enterprise value may differ materially from that expressed or implied by this data:

September 30, 2009	$ 136
December 31, 2009	$ 197
June 30, 2010	$ 325
September 30, 2010	$ 301

Determining the fair market value of our common stock involves complex and subjective judgments including estimates of revenue, assumed market growth rates and estimated costs, as well as appropriate discount rates. At the time of each valuation, the significant estimates used in the discounted cash flow approach included estimates of our revenue and revenue growth rates for several years into the future. Although each time we prepared such forecasts for use in the preparation of a valuation report, we did so based on assumptions that we believed to be reasonable and appropriate, there can be no assurance that any such estimates for earlier periods or for future periods will prove to be accurate.

The following is a summary of our stock option activity during the year ended December 31, 2009 and the nine months ended September 30, 2010:

Grant Date	Number of Options Granted	Exercise Price per Share	Fair Market Value per Share	Intrinsic Value per Share
September 1, 2009	222,000	$ 2.50	$ 3.20	$ 0.70
September 17, 2009	64,500	$ 2.50	$ 3.20	$ 0.70
December 9, 2009	59,500	$ 2.50	$ 3.60	$ 1.10
May 25, 2010	670,050	$ 4.00	$ 13.50	$ 9.50
May 30, 2010	12,250	$ 4.00	$ 13.50	$ 9.50
August 17, 2010	10,500	$ 6.20	$ 13.00	$ 6.80
August 23, 2010	10,000	$ 6.20	$ 13.00	$ 6.80
August 25, 2010	7,500	$ 6.20	$ 13.00	$ 6.80

We recognized stock-based compensation expense in the statements of operations as follows (in thousands):

	Year Ended December 31,			Nine Months Ended September 30,	
	2007	2008	2009	2009	2010
Cost of sales	$	$	$	$	$ 73
Research and development	45	227	310	228	262
Selling, general and administrative	86	692	716	512	1,377
Total	$ 131	$ 919	$ 1,026	$ 740	$ 1,712

The total stock-based compensation expense related to unvested stock option grants not yet recognized as of September 30, 2010 was $9.3 million and the weighted average period over which these grants are expected to vest is 2.93 years.

Based on the initial public offering price of $4.00 per share, the intrinsic value of stock options outstanding at September 30, 2010 would have been $1.1 million, of which $0.7 million and $0.4 million would have been related to stock options that were vested and unvested, respectively, at that date.

Our 2006 Equity Incentive Plan, 2010 Equity Incentive Award Plan and 2010 Employee Stock Purchase Plan, are considered compensatory plans and compensation expense will depend on the level of enrollment in these plans and assumptions used in the determination of the fair market value of the awards at date of grant.

Preferred Stock Warrant Liability

We have estimated the fair value of all outstanding convertible preferred stock warrants. The warrant obligation is adjusted to fair value at the end of each reporting period. Such fair values were estimated using either the Black-Scholes option-pricing model or a binomial model depending on the characteristics of the warrants and an estimated term equal to each warrant s contractual life, which ranges from seven to 10 years. We will continue to adjust the warrant liability for changes in fair value until the earlier of the exercise of the warrants or the completion of a liquidation event, including the completion of this offering, at which time the liability will be reclassified to stockholders equity (deficit).

Results of Operations

Comparison of nine months ended September 30, 2010 and 2009

Revenue. Revenue for the nine months ended September 30, 2010 was $14.6 million and zero for the nine months ended September 30, 2009. Revenue for the nine months ended September 30, 2010 consists of $11.8 million of product revenue and $2.8 million of contract revenue. Product revenue in the current period consists of Sumavel DosePro dispensed to patients, which is net of estimated wholesaler and retail pharmacy discounts, stocking allowances, prompt pay discounts, chargebacks, rebates and patient discount programs. We began selling Sumavel DosePro in January 2010 and therefore had no product revenue prior to that time. Contract revenue represents amortization of license fee payments and milestone payments we received in connection with the co-promotion agreement we entered into with Astellas in July 2009 and which we began recognizing upon the commencement of sales of Sumavel DosePro.

Cost of Sales. Cost of sales for the nine months ended September 30, 2010 was $9.4 million and zero for the nine months ended September 30, 2009. Cost of sales for the nine months ended September 30, 2010 represents the cost of Sumavel DosePro units dispensed to patients and the impact of excess capacity caused by production underruns and other manufacturing variances. We began selling Sumavel DosePro in January 2010 and therefore had no cost of sales prior to that time. Prior to regulatory approval of Sumavel DosePro, costs of prototypes, testing and process refinement were charged to research and development. Beginning in the second half of 2009, we began capitalizing manufacturing cost of inventories.

Royalty Expense. Royalty expense was $0.6 million for the nine months ended September 30, 2010 and zero for the nine months ended September 30, 2009. Royalty expense for the nine months ended September 30, 2010 represents the amortization of a $4.0 million milestone payment we made in connection with the asset purchase agreement with Aradigm payable on the first commercial sale of Sumavel DosePro, which occurred in January 2010, as well as royalties payable to Aradigm from net sales of Sumavel DosePro during the period.

Research and Development Expenses. Research and development expenses decreased to $19.4 million for the nine months ended September 30, 2010 compared to $22.3 million for the nine months ended September 30, 2009. This decrease of $2.9 million primarily was due to:

- a decrease of $17.5 million due to the capitalization of third-party direct labor, materials and internal overhead costs related to the manufacturing of Sumavel DosePro commercial product, inclusive of related salaries and personnel costs, subsequent to the FDA approval of Sumavel DosePro in July 2009. Prior to FDA approval, these costs were recognized as research and development expenses; offset by

- an increase of $14.6 million in research and development costs primarily as a result of the initiation of our Phase 3 clinical trials for ZX002 and a Phase 4 clinical trial for Sumavel DosePro which was initiated in late 2009.

Selling, General and Administrative Expenses. Selling, general and administrative expenses increased to $36.8 million for the nine months ended September 30, 2010 compared to $8.0 million for the nine months ended September 30, 2009. Selling expenses were $30.6 million for the nine months ended September 30, 2010 compared to $3.1 million for the nine months ended September 30, 2009. General and administrative expenses were $6.2 million for the nine months ended September 30, 2010 compared to $4.9 million for the nine months ended September 30, 2009. The increase of $28.8 million in selling, general and administrative expenses primarily was due to:

- an increase of $27.5 million in sales and marketing expense as a result of the expansion of our commercial infrastructure, which included the hiring of approximately 80 sales representatives, and the commercial launch of Sumavel DosePro; and

an increase of $1.3 million of general and administrative expenses due to an increase in salaries and related benefits.

Interest Income. Interest income decreased to $4,000 for the nine months ended September 30, 2010 compared to $7,000 for the nine months ended September 30, 2009. This decrease of $3,000 was due primarily to the decrease in average cash and investment balances.

Interest Expense. Interest expense decreased to $6.9 million for the nine months ended September 30, 2010 compared to $8.6 million for the nine months ended September 30, 2009. This decrease of $1.7 million was primarily due to:

a decrease of $3.0 million in debt discount costs in connection with the $14.8 million borrowed under the 2009 Notes. These notes were converted in September 2009, and the amortization of the related discount was accelerated.

an increase of $0.3 million in interest expense in connection with (1) the early settlement of our outstanding principal balance on our $18.0 million loan and security agreement with Oxford and CIT entered into in June 2008 and amended in July and October 2010 and (2) the 2010 Notes; and

an increase of $1.0 million in the amortization of debt issuance and debt discount costs in connection with (1) the $18.0 million loan and security agreement with Oxford and CIT entered into in June 2008 and amended in July and October 2010 and (2) the 2010 Notes.

Change in Fair Value of Warrant Liability. Change in the fair value of warrant liability increased by $12.3 million to $12.8 million in expense for the nine months ended September 30, 2010 compared to $0.5 million in expense for the nine months ended September 30, 2009 due to the increase in fair value of the Series A-1, Series A-2 and Series B convertible preferred stock. This increase in the fair value of the warrants is primarily the result of the recognition of the value of the warrants to purchase Series B convertible preferred stock.

Other Income (Expense). Other income (expense) decreased to $0.1 million of expense for the nine months ended September 30, 2010 compared to $0.4 million of expense for the nine months ended September 30, 2009. This decrease was due to foreign currency transaction gains which primarily related to the settlement of our liabilities payable in Euro and U.K. pounds sterling.

Comparison of year ended December 31, 2009 and 2008

Research and Development Expenses. Research and development expenses decreased to $21.4 million for the year ended December 31, 2009 compared to $33.9 million for the year ended December 31, 2008. This decrease of $12.5 million primarily was due to:

a decrease of approximately $13.2 million due to the capitalization of third-party direct labor, materials and internal overhead costs related to the manufacturing of Sumavel DosePro commercial product, inclusive of related salaries and personnel costs;

a decrease of approximately $2.0 million in expenses associated with consulting services, $0.4 million in travel-related expenses, and $0.4 million of salaries and personnel related costs;

a decrease of $1.6 million for ZX002 clinical trial expenses, as the Phase 3 clinical trials for this program were temporarily delayed, and a $0.2 million reduction in clinical trial expenses for Sumavel DosePro; and

an increase of $5.3 million in manufacturing costs related to services and supplies in the testing and manufacturing development of Sumavel DosePro prior to the production of commercial inventories.

Selling, General and Administrative Expenses. Selling, general and administrative expenses increased to $14.1 million for the year ended December 31, 2009 compared to $11.8 million for the year ended December 31, 2008. This increase of $2.3 million primarily was due to:

- an increase of $2.7 million in salaries and personnel costs as we expanded our commercial and administrative infrastructure, including the hiring of approximately 20 sales representatives, in preparation for the January 2010 commercial launch of Sumavel DosePro, $0.2 million in travel related expenses and $0.2 million in facilities costs; offset by

- a decrease of $0.8 million of expenses associated with consulting and professional services.

Interest Income. Interest income decreased to $10,000 for the year ended December 31, 2009 compared to $696,000 for the year ended December 31, 2008. This decrease of $686,000 was due primarily to the decrease in average cash and investment balances as a result of investing the proceeds received from our Series B preferred stock financing and Astellas in lower yielding instruments.

Interest Expense. Interest expense increased to $9.2 million for the year ended December 31, 2009 compared to $1.7 million for the year ended December 31, 2008. This increase of $7.5 million was primarily due to:

- an increase of $1.0 million in the amortization of debt issuance, debt discount costs and interest expense in connection with the loan and security agreement with GE Capital entered into in March 2007 and the $18.0 million loan and security agreement with Oxford and CIT entered into in June 2008;

- an increase of $3.5 million in interest and the amortization of debt discount costs in connection with the $14.8 million borrowed under the 2009 Notes; and

- recognition of $3.0 million in fair value of the right to convert the outstanding principal and interest under the 2009 Notes to convertible preferred stock.

Change in Fair Value of Warrant Liability. Change in the fair value of warrant liability decreased by $1.9 million to $0.8 million in expense for the year ended December 31, 2009 compared to $1.1 million in income for the year ending December 31, 2008 due to the increase in fair value of the Series A-1, Series A-2 and Series B convertible preferred stock.

Other Income (Expense). Other expense was $0.4 million for the year ended December 31, 2009 compared to other income of $0.1 million for the year ended December 31, 2008. This $0.5 million increase in expense was due to foreign currency transaction losses which primarily related to the settlement of our liabilities payable in Euro and U.K. pounds sterling.

Comparison of year ended December 31, 2008 and 2007

Research and Development Expenses. Research and development expenses increased to $33.9 million for the year ended December 31, 2008 compared to $24.3 million for the year ended December 31, 2007. This increase of $9.6 million primarily was due to:

- an increase of approximately $8.7 million resulting from manufacturing costs related to services and supplies in the testing and manufacturing development of Sumavel DosePro, inclusive of related salaries, personnel costs and travel; and

- an increase of approximately $0.9 million in expenses associated with consulting services, clinical supplies and costs incurred in preparation for the Phase 3 clinical trials of ZX002, including related salaries and personnel costs.

Selling, General and Administrative Expenses. Selling, general and administrative expenses increased to $11.8 million for the year ended December 31, 2008 compared to $4.7 million for the year ended December 31, 2007. This increase of $7.1 million primarily was due to:

- an increase of $4.0 million in market research, branding and sales and marketing personnel costs; and
- an increase of $1.7 million of expenses associated with professional fees for legal, consulting and accounting services from the initiation in 2008 of our registration process with the SEC for a proposed initial public offering and an increase of $1.4 million of facilities cost and expenses associated with administrative salaries and related personnel costs.

Interest Income. Interest income decreased to $0.7 million for the year ended December 31, 2008 compared to $0.9 million for the year ended December 31, 2007. This decrease of $0.2 million was due primarily to the decrease in average cash and investment balances as a result of the use of cash for operating purposes.

Interest Expense. Interest expense increased to $1.7 million for the year ended December 31, 2008 compared to $0.4 million for the year ended December 31, 2007. This increase of $1.3 million was primarily due to an increase of $1.3 million in interest and amortization of debt issuance and debt discount costs in connection with the loan and security agreements with GE Capital and Oxford /CIT and interest on additional borrowings.

Change in Fair Value of Warrant Liability. Change in the fair value of warrant liability increased by $1.2 million to $1.1 million in income for the year ended December 31, 2008 compared to $0.1 million in expense for the year ending December 31, 2007 due to the decrease in fair value of the Series A-1 and Series A-2 convertible preferred stock.

Other Financing Income. Other financing income decreased to zero for the year ended December 31, 2008 compared to $0.9 million for the year ended December 31, 2007. The amount recognized in 2007 relates to the change in the estimated fair value of our investors right to purchase additional shares of Series A-1 convertible preferred stock.

Other Income. Other income increased to $63,000 for the year ended December 31, 2008 compared to $25,000 for the year ended December 31, 2007. This net increase of $38,000 was due to foreign currency transaction gains which primarily related to the settlement of our liabilities payable in Euro and U.K. pounds sterling.

Liquidity and Capital Resources

We have experienced net losses and negative cash flow from operations since inception, and as of September 30, 2010, had an accumulated deficit of $196.0 million, and expect to continue to incur net losses and negative cash flow from operations for at least the next several years primarily as a result of, among other things, the development expenses in connection with our clinical trials and pre-clinical studies for ZX002 and the cost of the sales and marketing expenses associated with Sumavel DosePro.

In its report accompanying our audited financial statements for the year ended December 31, 2009, included elsewhere in this prospectus, our independent registered public accounting firm included an explanatory paragraph stating that our recurring losses from operations and lack of sufficient working capital raise substantial doubt as to our ability to continue as a going concern. A going concern opinion means, in general, that our independent registered public accounting firm has substantial doubt about our ability to continue our operations without continuing infusions of capital from external sources and could impair our ability to finance our operations through the sale of debt or equity securities or commercial bank loans. Our ability to continue as a going concern will depend, in large part, on our ability to generate positive cash flow from operations and obtain additional financing, if necessary, neither of which is certain, as well as the continued availability of borrowings under our amended Oxford loan agreement. If we are unable to achieve these goals, our business would be jeopardized and

we may not be able to continue operations and may have to liquidate our assets and may receive less than the value at which those assets are carried on our financial statements, and it is likely that investors will lose all or a part of their investment.

Since inception, our operations have been financed primarily through equity and debt financings, the issuance of convertible notes and payments received from Astellas under our co-promotion agreement. Through December 31, 2009, we received aggregate net cash proceeds of approximately $148.3 million from the sale of shares of our preferred and common stock as follows:

- from August 25, 2006 (inception) to December 31, 2009, we issued and sold a total of 1,444,468 shares of common stock for aggregate net cash proceeds of $0.2 million;
- in August 2006, we issued and sold a total of 30,775,000 shares of Series A-1 convertible preferred stock for aggregate net cash proceeds of $30.5 million;
- in September 2007 and December 2007, we issued and sold an additional 38,025,000 shares of Series A-1 convertible preferred stock for aggregate net cash proceeds of $38.0 million; in December 2007, we issued and sold a total of 9,090,909 shares of Series A-2 convertible preferred stock for aggregate net cash proceeds of $9.9 million;
- in September 2009, we issued and sold 32,689,062 shares of Series B convertible preferred stock for aggregate net cash proceeds of $34.8 million (inclusive of $14.8 million of outstanding principal of convertible notes held by certain investors that we issued earlier in 2009 and that were converted into Series B convertible preferred stock in connection with the financing) and warrants to purchase up to 3,363,619 shares of Series B convertible preferred stock ; and
- in December 2009, we issued and sold an additional 31,818,171 shares of Series B convertible preferred stock and warrants to purchase up to 9,545,447 shares of Series B convertible preferred stock for aggregate net cash proceeds of $34.9 million.

In March 2007, we entered into a loan and security agreement with GE Capital for the purpose of financing our capital equipment costs. Under the agreement, we were allowed to borrow up to $10.0 million based on purchases of property and equipment at a fixed interest rate determined at the time of borrowing. Pursuant to the loan and security agreement, we borrowed approximately $4.5 million under two promissory notes during the year ended December 31, 2007. Monthly payments of principal and interest are required to be made over a 48 month period beginning on the date of the advance. The outstanding balance is collateralized by specific manufacturing equipment owned by us. There are no financial covenants in connection with the loan and security agreement. The loan and security agreement permits the lender to demand the immediate repayment of all borrowings and other amounts thereunder if, among other customary events of default, the lender determines, in its sole discretion, that a material adverse change with respect to us has occurred. As of September 30, 2010, there are no further amounts available under this credit facility as our ability to borrow additional amounts expired on December 21, 2007. As of September 30, 2010, $1.0 million in aggregate principal amount of borrowings were outstanding under the GE Capital agreement, which we are required to repay, together with accrued interest, in monthly installments ending on January 1, 2012. We have the option to repay outstanding borrowings under the GE Capital agreement, subject to prepayment fees.

In June 2008, we entered into an $18.0 million loan and security agreement with Oxford and CIT for the purpose of financing our operating expenses, which agreement was amended and restated in July and October 2010 as described below. The borrowings under the Oxford and CIT agreement bore an interest rate of 9.76%. Payments consisted of interest-only payments for the first 10 months followed by principal and interest payments for the subsequent 36 months. The agreement required a final payment of $1.0 million, in addition to principal repayments, at final maturity, which was May 1, 2012. As described below, we amended and restated this loan and security agreement in July and October 2010.

In July 2009, we entered into the co-promotion agreement with Astellas. In connection with this co-promotion agreement, Astellas made a non-refundable up-front payment to us of $2.0 million and

agreed to make an additional $18.0 million of payments to us upon the achievement of a series of milestones. As of December 31, 2009, we received a total of $19.0 million from Astellas. The remaining $1.0 million was paid to us in March 2010.

In July and October 2010, we amended and restated the loan and security agreement with Oxford and CIT, and Oxford and SVB are now party to the amended Oxford loan agreement. The amended Oxford loan agreement consists of a $25.0 million term loan and a $10.0 million revolving credit facility. The obligations under the amended Oxford loan agreement are collateralized by our personal property (including, among other things, accounts receivable, equipment, inventory, contract rights, rights to payment of money, license agreements, general intangibles and cash) but excluding, among other things, copyrights, patents, patent applications, trademarks, service marks, trade secret rights and equipment pledged to secure the GE loan facility described above.

The amended Oxford loan agreement includes financial covenants requiring that (1) we achieve, as of the last day of each month measured on a trailing three-month basis, actual revenue of at least a specified percentage of our projected revenue as provided to Oxford and SVB in the event we fail to maintain a liquidity ratio (defined, in general, as the ratio of (a) cash and cash equivalents deposited with Silicon Valley Bank plus unused borrowing capacity under that agreement to (b) all debt, capital lease obligations and contingent obligations owed to the lenders) of 1.25 to 1.00 and (2) we complete an equity or subordinated debt financing of at least $10.0 million prior to November 30, 2010. The agreement also includes a covenant that the audit report accompanying our year-end financial statements for fiscal year 2010 and thereafter not include a going concern qualification. As discussed under Risk Factors Our independent registered public accounting firm has expressed substantial doubt as to our ability to continue as a going concern, the audit report accompanying our 2009 financial statements includes a going concern qualification and, as a result, our results of operations and financial condition will have to improve to a point where our auditors can deliver their audit report without this qualification in order to avoid a breach of this covenant. In addition, the amended Oxford loan agreement prohibits us from (1) incurring any debt other than, among other things, debt under the amended Oxford loan agreement or under the GE Capital agreement, subordinated debt and purchase money debt and refinancings of that permitted debt, (2) entering into sale and leaseback transactions and (3) entering into mergers with, or acquisitions of all or substantially all the assets of, another entity with a value in excess of $100,000, and also prohibits the occurrence of a change in control of our company. Under the amended Oxford loan agreement, a change in control will be deemed to occur if, among other things, our stockholders prior to this offering cease to hold (a) at least 60% of our capital stock or (b) capital stock having a majority of the ordinary voting power in the election of our directors. The amended Oxford loan agreement also prohibits a change in our management such that our Chief Executive Officer, Chief Financial Officer or President resigns, is terminated or is no longer actively involved in our management in his or her current position and is not replaced with a person acceptable to our board of directors within 120 days.

The $25.0 million term loan bears an interest rate of 12.06% per annum. Payments consist of monthly interest only payments for the first 12 months followed by principal and interest payments for the subsequent 30 months. The term loan requires a final payment of $1.2 million, in addition to the repayment of unpaid principal, at the loan maturity date, which is January 1, 2014. We have the option to prepay the outstanding balance of the term loan in full subject to a prepayment fee of either 2% or 3% of the principal amount being prepaid depending upon when the prepayment occurs as well as the $1.2 million final payment. Under the terms of the revolving credit facility, we may borrow up to $10.0 million, but not more than a specified percentage of our eligible accounts receivable and inventory balances (as defined in the agreement). Amounts outstanding under the revolving credit facility accrue interest payable monthly at a floating rate per annum equal to the greater of 3.29% above SVB s prime rate or 7.29%. In addition, we pay a monthly fee equal to 0.5% per annum of the average unused portion of the revolving credit facility. If the revolving credit facility is terminated, a final payment is required in the amount of $0.1 million, $0.2 million or $0.3 million depending upon when the termination occurs. The amended Oxford loan agreement matures on the earliest of January 1, 2014, the occurrence of an event

of default resulting in our obligations becoming due and payable in accordance with the amended Oxford loan agreement or the date of any prepayment of all outstanding obligations under the amended Oxford loan agreement, at which time a final payment of $0.1 million, plus all unpaid principal, must be paid in full. In connection with the execution of the amended Oxford loan agreement, we repaid the outstanding balance of the Oxford and CIT loan and security agreement totaling $12.8 million at June 30, 2010, which amount was repaid with borrowings under the amended loan and security agreement. Consequently, the net proceeds we received upon the execution of the amended Oxford loan agreement totaled $12.2 million. As of September 30, 2010, we had borrowed $2.7 million under the revolving credit facility.

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

Concurrently with and as required by the amended Oxford loan agreement, we entered into a note purchase agreement with certain existing investors pursuant to which we borrowed an aggregate of $15.0 million. We issued convertible promissory notes, or the 2010 Notes, for the amount borrowed which accrue interest at a rate of 8.00% per annum and become due and payable in July 2011. The principal amount of the 2010 Notes and accrued interest thereon will automatically convert into shares of our common stock upon completion of this offering at a conversion price equal to the initial public offering price per share of our common stock. If a deemed liquidation event (as defined in our certificate of incorporation) occurs prior to the completion of this offering, the holders of the 2010 Notes may elect to (1) receive the repayment of the notes or (2) convert the notes into shares of Series B convertible preferred stock at a conversion rate of $1.10 per share.

Cash and Cash Equivalents. Cash and cash equivalents totaled $11.7 million and $44.9 million at September 30, 2010 and December 31, 2009, respectively.

The following table summarizes our cash flows from (used in) operating, investing and financing activities for the years ended December 31, 2007, 2008 and 2009 and the nine months ended September 30, 2009 and 2010:

	Year Ended December 31,			Nine Months Ended September 30,	
	2007	2008	2009	2009	2010
			(In Thousands)		
Statement of Cash Flows Data:					
Total cash provided by (used in):					
Operating activities	$ (26,800)	$ (41,288)	$ (32,361)	$ (20,071)	$ (58,492)
Investing activities	1,005	(2,793)	(2,057)	(1,203)	(2,084)
Financing activities	51,972	16,798	65,104	31,833	27,338
Increase (decrease) in cash and cash equivalents	$ 26,177	$ (27,283)	$ 30,686	$ 10,559	$ (33,238)

Operating Activities. Net cash used in operating activities was $58.5 million and $20.1 million for the nine months ended September 30, 2010 and 2009, respectively. Net cash used for the nine months ended September 30, 2010 primarily reflects the use of $51.7 million for operations (excluding non-cash items), payment of a $4.0 million milestone obligation to Aradigm as a result of the first commercial sale of Sumavel DosePro, and investments of $4.8 million in commercial inventory of Sumavel DosePro, partially offset by $2.0 million provided by other working capital sources. Net cash used for the nine months ended September 30, 2009 primarily reflects expenditures related to testing and manufacturing development of Sumavel DosePro, personnel-related costs, third-party supplier expenses and professional fees.

Net cash used in operating activities was $32.4 million and $41.3 million for the years ended December 31, 2009 and 2008, respectively. Net cash used in 2009 primarily reflects the use of $33.3 million for operations, an investment of $15.7 million in commercial inventory of Sumavel DosePro and $2.4 million in other working capital requirements, offset by $19.0 million of proceeds provided by our co-promotion partner, Astellas, for Sumavel DosePro. Net cash used in 2008 primarily reflects expenditures related to external research and product development, clinical trial costs, personnel-related costs, third-party supplier expenses and professional fees. Net cash of $26.8 million used in operating activities in 2007 primarily reflects expenditures related to external research and product development, clinical trial costs, personnel-related costs, third-party supplier expenses and professional fees.

Investing Activities. Net cash used in investing activities was $2.1 million and $1.2 million for the nine months ended September 30, 2010 and 2009, respectively. These amounts are the result of the purchase of property and equipment primarily for use in manufacturing Sumavel DosePro.

Net cash used in investing activities was $2.1 million and $2.8 million for the years ended December 31, 2009 and 2008, respectively. These amounts are the result of the purchase of property and equipment and in 2008 inclusive of the net purchases, sales and maturities of investment securities. Net cash provided by investing activities of $1.0 million in 2007 primarily relates to proceeds from sales and maturities of investment securities, net of purchases of investment securities and property and equipment.

We incurred capital expenditures of $2.1 million during the nine months ended September 30, 2010 and expect to incur approximately $1.0 million to $1.2 million during the fourth quarter of 2010. These capital expenditures primarily relate to further investments in our manufacturing operations toward increasing production capacity.

Financing Activities. Net cash provided by financing activities was $27.3 million for the nine months ended September 30, 2010 compared to net cash provided by financing activities of $31.8 million for the nine months ended September 30, 2009. Net cash provided by financing activities for the nine months ended September 30, 2010 relates to $27.7 million in proceeds received in connection with the amended Oxford loan agreement, $15.0 million in proceeds received in connection with the 2010 Notes, offset by principal repayments made of $15.4 million on our outstanding debt facilities. Net cash provided by financing activities for the nine months ended September 30, 2009 relates to $14.8 million in proceeds received in connection with the 2009 Notes and $20.0 million in net proceeds received in connection with the initial closing of our Series B convertible preferred stock financing offset by $3.0 million in principal repayments on our outstanding debt facilities.

Net cash provided by financing activities was $65.1 million and $16.8 million for the years ended December 31, 2009 and 2008, respectively. In 2009 we received net proceeds of $69.7 million from our Series B convertible preferred stock financing, inclusive of $14.8 million of proceeds from the issuance of convertible promissory notes between February and July 2009 that converted into Series B convertible preferred stock, and made principal repayments on our outstanding debt facilities totaling $4.7 million. In 2008, we received net proceeds of $17.8 million from the Oxford and CIT loan and security agreement and made principal repayments on our outstanding debt facilities totaling $1.0 million. Net cash provided by financing activities was $52.0 million for 2007. In 2007, we received net proceeds of $47.9 million from the issuance of Series A convertible preferred shares and $4.4 million from the GE Capital debt facility net of $0.5 million of proceeds used for principal repayments on our outstanding debt facilities.

Future Financing Activities. We cannot be certain if or when we will generate sufficient cash flows from sales of Sumavel DosePro to finance our operating expenses, nor can we predict the amount of cash that may be necessary for clinical trials and pre-clinical studies of ZX002 or any of our other product candidates. Likewise, we expect to make additional investments in equipment and other production capacity to manufacture sufficient quantities of Sumavel DosePro. In addition, if we or

Astellas are not successful in the promotion of Sumavel DosePro we may require additional financing resources to finance our operations and meet our promotion and inventory commitments under our co-promotion arrangement.

As described above, under our amended Oxford loan agreement, we are subject to financial covenants that require us to achieve certain revenue targets in the event we fail to maintain a liquidity ratio (defined, in general, as the ratio of (a) cash and cash equivalents deposited with Silicon Valley Bank plus unused borrowing capacity under that agreement to (b) all debt, capital lease obligations and contingent obligations owed to the lenders) of 1.25 to 1.00 and generate $10.0 million of proceeds through additional equity or subordinated debt financing by November 30, 2010, and we are also subject to other covenants and obligations under that agreement. Likewise, both the amended Oxford loan agreement and our GE Capital loan agreement permit the lenders to demand immediate repayment of all borrowings upon the occurrence of specified events of default. If we fail to pay amounts owing under either of these loan agreements when due, if we breach our other covenants or obligations under either of these agreements, or if other events of default under either of these credit agreements occur, the applicable lenders would be entitled to demand immediate repayment of all borrowings and other obligations thereunder and to seize and sell the collateral pledged as security under that agreement to satisfy those obligations. If we were to breach our covenants and obligations and we were unable to obtain a waiver or amendment from the lender, we would be required to seek additional equity or debt financing to refinance our obligations under the agreement. Additional debt or equity financing may not be available to us in amounts or on terms we consider acceptable, or at all. In that regard, we have from time to time been required to obtain waivers and amendments under our debt instruments in order to avoid breaches or other defaults. For example, in both 2009 and 2010 we were required to obtain amendments or waivers under our credit facilities.

We cannot be certain if, when and to what extent we will generate positive cash flow from operations from the commercialization of our product and, if approved, product candidates. We expect our development and commercialization expenses to be substantial and to increase over the next few years as we continue to grow the Sumavel DosePro brand and continue to advance our ZX002 product through Phase 3 clinical trials.

To the extent that funds generated by this offering, together with existing cash and cash equivalents, net revenue, and borrowings available under our $10.0 million revolving credit facility, are insufficient to fund our future activities, capital expenditures and other cash needs, we will need to raise additional funds through public or private equity or debt financings. Although we are currently not a party to any agreement or letter of intent with respect to potential investments in, or acquisitions of, businesses, services or technologies, we may enter into these types of arrangements in the future, which could also require us to seek additional equity or debt financing. There can be no assurance that we will be able to raise additional funds from any of these sources on terms we deem acceptable, or at all. In addition, future issuance of equity, convertible or other equity-linked securities could materially dilute the ownership interests of holders of our common stock and additional debt financing could result in a material increase in the amount of cash necessary to fund debt service payments and also could require that we comply with financial and other covenants that limit our flexibility and operations. In addition, the fact that we have pledged substantially all of our assets to secure our existing loan facilities will likely increase the cost, perhaps substantially, of any additional debt financing we may obtain or prevent us from obtaining additional debt financing altogether. Although it is difficult to predict future liquidity requirements, we believe that the net proceeds from this offering, together with our existing cash and cash equivalents, future product revenues and borrowings available under our $10.0 million revolving credit facility, will be sufficient to fund our operations for at least the next 12 months.

Contractual Obligations and Commitments

The following table describes our long-term contractual obligations and commitments as of December 31, 2009:

	Payments Due by Period				
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
			(In Thousands)		
Debt obligations(1)	$ 16,366	$ 7,041	$ 9,325	$	$
Debt interest(2)	2,918	1,291	1,627		
Operating lease obligations(3)	5,675	1,463	2,620	1,178	414
Co-Promotion marketing & promotional expenses(4)	5,502	5,502			
Purchase obligations(5)	26,664	9,933	11,577	5,154	
Total	$ 57,125	$ 25,230	$ 25,149	$ 6,332	$ 414

(1) Represents principal payments due in each period on our loan and security agreement with GE Capital and our loan and security agreement with Oxford Finance Corporation and CIT Healthcare LLC.

(2) Includes the interest on regular scheduled debt payments to GE Capital at an annual rate of 10.08% on the initial borrowing of $3.5 million made in March 2007 and at an annual rate of 9.91% on the second borrowing of $1.0 million made in December 2007. Also includes the interest on regular scheduled debt payments to Oxford Finance Corporation and CIT Healthcare LLC at an annual rate of 9.76%.

(3) Includes the minimum rental payments for our San Diego, California office pursuant to a lease entered into in October 2009 and expiring, as extended, in July 2011, which office houses our general and administrative, sales and marketing operations. Also includes the minimum rental payments for our Emeryville, California office pursuant to a lease entered into in July 2007 and expiring, as extended, in September 2015, which office houses our supply chain and inventory management and research and development operations. The rent for our Emeryville facility includes a 3.0% annual increase for the duration of the lease. Also includes the rental payments for a fleet of up to 95 vehicles pursuant to a lease entered into in August 2009. Each vehicle has a lease term of 36 months.

(4) Represents our portion of the shared marketing and promotional costs as agreed between us and Astellas for 2010 joint promotional efforts for Sumavel DosePro. These obligations are determined on an annual basis through the term of the agreement.

(5) Primarily represents non-cancellable purchase orders for the production of key components of Sumavel DosePro and a minimum manufacturing fee payable to Patheon UK Limited, our contract manufacturing organization.

Under our co-promotion agreement with Astellas, we are required to pay Astellas a service fee on a quarterly basis that represents a fixed percentage of between 45% and 55% of Sumavel DosePro net sales to the Astellas Segment. Under our asset purchase agreement with Aradigm, we are required to pay a 3% royalty on global net sales of Sumavel DosePro by us or one of our licensees and, in the event that we or one of our future licensees, if any, commercializes a non-*sumatriptan* product in the DosePro delivery system, we are required to pay Aradigm, at our election, either a 3% royalty on net sales of each non-*sumatriptan* product commercialized or a fixed low-twenties percentage of royalty revenue received by us from the licensee. In addition, under our license agreement with Elan we may be required to pay up to $4.5 million in total future milestone payments with respect to ZX002 depending upon the achievement of various development and regulatory events and, if ZX002 is approved, to pay a

mid single-digit percentage royalty on its net sales for a specified period of time and continue to pay royalties on net sales of the product thereafter at a reduced low single-digit percentage rate in accordance with the terms of the license agreement. We also maintain agreements with third parties to manufacture our product, conduct our clinical trials and perform data collection and analysis. Our payment obligations under these agreements will likely depend upon the progress of our development programs and commercialization efforts. Therefore, we are unable at this time to estimate with certainty the future costs we will incur under these agreements.

Recent Accounting Pronouncements

Effective July 1, 2009, the Financial Accounting Standards Board, or the FASB, Accounting Standards Codification, or ASC or Codification, became the authoritative source of GAAP. All existing FASB accounting standards and guidance were superseded by the ASC. Instead of issuing new accounting standards in the form of statements, staff positions and Emerging Issues Task Force abstracts, the FASB now issues Accounting Standards Updates that update the Codification. Rules and interpretive releases of the SEC under authority of federal securities laws continue to be additional sources of authoritative GAAP for SEC registrants.

In August 2009, the FASB ratified a new accounting standard for the fair value measurement of liabilities when a quoted price in an active market is not available. The new guidance is effective for reporting periods beginning after August 28, 2009, which means that it became effective for the fourth quarter beginning October 1, 2009. We adopted this guidance in relation to our existing warrants for convertible preferred stock as more fully described in Note 2 to our financial statements (Fair Value) appearing elsewhere in this prospectus.

In January 2010, the FASB issued a new accounting standard which amends guidance on fair value measurements and disclosures. The new guidance requires disclosure of transfers into and out of Level 1 and Level 2 fair value measurements, and also requires more detailed disclosure about the activity within Level 3 fair value measurements. This standard is effective for annual and interim reporting periods beginning after December 15, 2009, except for the requirements related to Level 3 disclosures, which are effective for annual and interim reporting periods beginning after December 15, 2010. We adopted the relevant provisions of this guidance, and the adoption did not have a material impact on our financial statements.

In February 2010, the FASB issued a new accounting standard which amends guidance on subsequent events. The new guidance requires evaluation of subsequent events through the date the financial statements are issued for SEC filers, amends the definition of SEC filer, and changes required disclosures. This standard is effective on February 24, 2010 and did not have a material impact on our financial statements upon adoption.

In March 2010, the FASB Emerging Issues Task Force, or EITF, ratified a new accounting standard which amends guidance on the milestone method of revenue recognition. The EITF concluded that the milestone method is a valid application of the proportional performance model when applied to research or development arrangements. This guidance eliminates the requirement to establish the fair value of undelivered products and services and instead provides for separate revenue recognition based upon management s estimate of the selling price for an undelivered item when there is no other means to determine the fair value of that undelivered item. This standard allows an entity to make an accounting policy election to recognize a payment that is contingent upon the achievement of a substantive milestone in its entirety in the period in which the milestone is achieved. This standard is effective for fiscal years beginning on or after June 15, 2010 with early adoption permitted. The guidance may be applied prospectively for milestones achieved after the adoption date or retrospectively for all periods presented. We do not expect this guidance to have a material impact on our financial position, results of operations or cash flows.

Off-Balance Sheet Arrangements

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

Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk

Our cash and cash equivalents as of September 30, 2010 consisted primarily of cash and money market funds. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates. The primary objective of our investment activities is to preserve principal while at the same time maximizing the income we receive without significantly increasing risk. Instruments that meet this objective include commercial paper, money market funds and government and non-government debt securities. Some of the investment securities available-for-sale that we invest in may be subject to market risk. This means that a change in prevailing interest rates may cause the value of the investment securities available-for-sale to fluctuate. To minimize this risk, we intend to continue to maintain our portfolio of cash and money market funds. Due to the short-term nature of our investments and our ability to hold them to maturity, we believe that there is no material exposure to interest rate risk.

Our $10.0 million revolving credit facility with Oxford and SVB bears interest at the greater of 3.29% above SVB s prime rate or 7.29%. As of September 30, 2010, we had $2.7 million outstanding on this revolving credit facility.

Foreign Exchange Risk

All of the revenues we have generated to date have been paid in U.S. dollars and we expect that our revenues will continue to be generated primarily in U.S. dollars for at least the next several years. Payments to our material suppliers and contract manufactures are denominated in the Euro and U.K. pounds sterling, thereby increasing our exposure to exchange rate gains and losses on non-U.S. currency transactions. Foreign currency gains and losses associated with these expenditures have not been significant to date. However, fluctuations in the rate of exchange between the U.S. dollar and these or other foreign currencies could adversely affect our financial results in the future, particularly to the extent we increase production to support Sumavel DosePro sales demands. For the nine months ended September 30, 2010, approximately $25.4 million (based on exchange rates as of September 30, 2010) of our materials and contract manufacturing costs were denominated in foreign currencies. We do not currently hedge our foreign currency exchange rate risk. We intend to evaluate various options to mitigate the risk of financial exposure from transacting in foreign currencies in the future.

BUSINESS

Overview

We are a pharmaceutical company commercializing and developing products for the treatment of central nervous system disorders and pain. Our first commercial product, Sumavel DosePro (*sumatriptan* injection) Needle-free Delivery System, was launched in January 2010. Sumavel DosePro offers fast-acting, easy-to-use, needle-free subcutaneous administration of *sumatriptan* for the acute treatment of migraine and cluster headache in a pre-filled, single-use delivery system. Sumavel DosePro is the first drug product approved by the U.S. Food and Drug Administration, or FDA, that allows for the needle-free, subcutaneous delivery of medication. Sumavel DosePro may offer a faster-acting and more efficacious treatment alternative to oral and nasal triptans and simple, convenient administration when compared to traditional, needle-based *sumatriptan* injection. As a result, we believe that Sumavel DosePro has the potential to be prescribed by a broad physician audience, especially for difficult to treat migraine episodes.

Migraine is a syndrome that affects approximately 30 million people in the United States, according to a 2010 National Headache Foundation, or NHF, press release. Triptans are the class of drugs most often prescribed for treating migraines. In the United States in the 12 months ended June 2010, triptans generated sales of approximately $3.45 billion and s*umatriptan*, including branded and generic forms, represented the biggest market share of the seven approved triptans, with sales of approximately $1.97 billion, according to Wolters Kluwer Pharma Solutions (Source® PHAST Institution/Retail).

We launched the commercial sale of Sumavel DosePro in the United States in January 2010 with our co-promotion partner, Astellas Pharma US, Inc., or Astellas. Our sales and marketing organization is comprised of approximately 100 professionals. Our field sales force of approximately 80 representatives is promoting Sumavel DosePro primarily to neurologists and other key prescribers of migraine medications, including headache clinics and headache specialists. Our promotional efforts are complemented by our collaboration with Astellas and approximately 400 of its sales representatives, who are promoting Sumavel DosePro primarily to primary care physicians, OB/GYNs, emergency medicine physicians and urologists in the United States. We also have entered into a partnership for Sumavel DosePro with Desitin Arzneimittel GmbH, or Desitin, to accelerate development and regulatory approvals in Europe and further enhance the global commercial potential of Sumavel DosePro.

Sumavel DosePro has demonstrated consistent monthly growth in total prescriptions since its launch in January 2010. The product continues to add new and repeat prescribers in both the neurology and primary care settings, including a significant number of prescribers who had not prescribed needle-based *sumatriptan* injection in the prior 12 months. The product is gaining use from a range of patient segments, including new triptan users, patients being converted to the product from other migraine drugs and patients who have been prescribed Sumavel DosePro and also have other triptan prescriptions. Since its launch, 77% of all patient conversions to Sumavel DosePro have come from patients with prescriptions for oral triptans, including tablets and melt formulations. (Source® Lx PTA January 2010 August 2010). Through our ongoing efforts with the largest commercial health plans, Sumavel DosePro is achieving broad coverage in the United States, with a reimbursement claims approval rate of approximately 78% since launch (Source® Dynamic Claims January 2010 August 2010). Total gross sales of Sumavel DosePro through September 30, 2010 were $16.4 million. For the same period, we recognized $11.8 million in net product revenue from these sales, represented by more than 21,800 aggregate dispensed prescriptions. Weekly prescribing data shows that more than 5,600 physicians have prescribed Sumavel DosePro. (Source® PHAST Retail January 2010 - September 2010 and Source® LaunchTrac week ended January 15, 2010 - week ended October 1, 2010)

Our lead product candidate, ZX002, is a novel, oral, single-entity controlled-release formulation of *hydrocodone* currently in Phase 3 clinical trials for the treatment of moderate to severe chronic pain in patients requiring around-the-clock opioid therapy. ZX002 utilizes Elan Pharma International Limited s, or Elan s, proprietary Spheroidal Oral Drug Absorption System, or SODAS® technology, which serves to

enhance the release profile of *hydrocodone* to provide consistent 12-hour pain relief relative to existing immediate-release combination formulations. Most marketed *hydrocodone* products contain the analgesic combination ingredient *acetaminophen,* which if taken in high quantities over time can cause liver toxicity. ZX002, if approved, may represent the first available controlled-release version of *hydrocodone* and also the first *hydrocodone* product that is not combined with another analgesic. As a result, we believe ZX002 could generate sales from both patients who are using immediate-release opioid products on a chronic basis and patients already using extended-release opioids. We initiated the Phase 3 clinical development program for ZX002 in March 2010 and, if successful, expect to submit a New Drug Application, or NDA, with the FDA by early 2012. We in-licensed exclusive U.S. rights to ZX002 from Elan in 2007.

The American Pain Society estimated in 1999 that 9% of the U.S. adult population suffers from moderate to severe non-cancer related chronic pain. Chronic pain can be treated with both immediate-release and extended-release opioids. We define our target market for ZX002 as prescription, non-injectable *codeine*-based and extended-release *morphine*-based pain products. This market generated U.S. sales of approximately $13.0 billion for the 12 months ended June 2010, based on average wholesale price, on approximately 202 million prescriptions. During the same period, existing *hydrocodone* products, the most commonly prescribed pharmaceutical products in the United States, generated $3.1 billion in sales on approximately 126 million prescriptions. (Source® PHAST Retail). We believe ZX002 has the potential to be an important therapeutic alternative to existing *hydrocodone* products, including the branded product Vicodin and its generic equivalents.

Our DosePro technology is a novel, patent-protected, needle-free drug delivery system designed for self-administration of a pre-filled, single dose of liquid drug. We believe the FDA s approval of Sumavel DosePro represents an important validation of the technology. Results from our pre-clinical and clinical studies demonstrate that DosePro can be used successfully with small molecules and biological products, including protein therapeutics and monoclonal antibodies. We are building our internal product pipeline by investigating proven drugs that can be paired with DosePro to enhance their benefits and commercial attractiveness. Specifically, we have initiated pre-clinical development on a proprietary long-acting formulation of an injectable central nervous system, or CNS, drug product and are also evaluating the market potential, formulation requirements and clinical development pathway of an additional CNS compound that could be paired with DosePro to enhance its commercial attractiveness. If these efforts are successful, we may be able to submit an Investigational New Drug Application, or IND, for one or both product candidates in 2011. We are also seeking to capitalize on our DosePro technology by out-licensing it to potential partners enabling them to enhance, differentiate or extend the life cycle of their proprietary injectable products.

Investment Highlights

We believe we are differentiated by the unique characteristics of our marketed product and late stage product candidate, each of which addresses large market opportunities, as well as our established commercial infrastructure, our innovative technology and the depth of experience of our management team. The following represents the key attributes that help differentiate our company:

Fully-integrated pharmaceutical company with established commercial infrastructure. We have a sophisticated and robust commercial infrastructure relative to many companies of similar size and stage of development in the pharmaceuticals industry. Our sales and marketing organization is comprised of approximately 100 professionals, including a field sales force of approximately 80 representatives who are focused exclusively on the promotion of Sumavel DosePro. Our field sales representatives have an average of 12 years of prior experience promoting pharmaceutical products and most have prior experience in the neurology and/or migraine space. In addition, our sales managers have on average 19 years of pharmaceutical industry experience, including an average of eight years of sales management experience.

Sumavel DosePro, a differentiated new entrant in the migraine market that has demonstrated consistent monthly prescription growth since its launch. Our first commercial product, Sumavel DosePro, was launched in January 2010. We believe it represents a valuable new migraine treatment option that will address the significant unmet medical needs of patients and physicians. Through our own sales force and our collaboration with Astellas, we have a combined network of more than 475 sales representatives detailing both primary care physicians and specialists who are key prescribers of migraine therapeutics. To date, we have seen consistent growth in adoption of Sumavel DosePro by physicians and patients alike, with more than 5,600 prescribing physicians as of the week ended October 1, 2010, of whom a growing proportion are now repeat-prescribers. Monthly prescriptions of Sumavel DosePro have grown from less than 250 in January 2010 to more than 3,500 in September 2010. (Source® PHAST Retail January 2010 September 2010 and Source® LaunchTrac week ended January 15, 2010 week ended October 1, 2010). Sumavel DosePro s initial acceptance by third-party payors has also been encouraging, with approximately 78% of reimbursement claims submitted for Sumavel DosePro being approved since its launch (Source® Dynamic Claims January 2010 August 2010).

ZX002, a novel, controlled-release chronic pain therapy in Phase 3 clinical development. ZX002 has the potential to be the first approved single-entity, controlled-release formulation of *hydrocodone*, the most widely prescribed pharmaceutical product in the United States. ZX002 utilizes Elan s proprietary SODAS delivery system, which serves to enhance the release profile of *hydrocodone* to provide consistent 12-hour pain relief relative to existing immediate-release formulations. In March 2010, we initiated our Phase 3 development program for ZX002 and expect to begin to receive top-line data from our Phase 3 clinical trials in the second half of 2011.

Validated, proprietary DosePro technology with broad range of potential applications. Sumavel DosePro, which utilizes our DosePro technology, is the first drug product approved by the FDA which allows for the needle-free, subcutaneous delivery of medication. We believe that DosePro has the potential to become a preferred delivery option for patients and physicians for many medications beyond *sumatriptan*, including small molecules and biologics, and are evaluating further internal development candidates and technology out-licensing opportunities. We and the predecessor owners of the DosePro technology have invested significant resources over a 10 year period in evaluating potential applications of DosePro and optimizing the design, manufacturing and versatility of this technology. Our DosePro technology is covered by 61 issued U.S. and foreign patents, which are expected to expire on various dates from 2014 through 2023, and 31 pending patent applications.

Experienced management team with unique commercial and development expertise, including CNS sales and marketing experience. Our management team has a proven clinical, regulatory, business development and commercialization track record at Zogenix and prior organizations, as well as significant expertise in CNS disorders and pain. Our executive officers and key employees have an average of 20 years of experience in the pharmaceutical, financial and commercial sectors. Prior to Zogenix, members of our management team had success in developing, achieving regulatory approval for and commercializing multiple product candidates at their former employers. In particular, our CEO and our Vice President of Sales and Managed Markets participated in the successful launch and market defense of GlaxoSmithKline s, or GSK s, Imitrex, the first triptan to be commercialized in the United States. At Zogenix, our team has successfully acquired, developed, obtained regulatory approval for and launched the commercial sale of Sumavel DosePro and completed a significant primary care co-promotion agreement in the United States for the product. It also completed an in-licensing transaction and initiated Phase 3 development for our ZX002 product candidate.

Our Strategy

Our core strategy is to commercialize and develop differentiated CNS and pain therapeutics that can address significant unmet medical needs and overcome limitations of existing products. Key elements of our strategy include:

Increasing sales and continuing to drive patient and physician adoption of Sumavel DosePro in the United States. Sumavel DosePro has demonstrated consistent monthly growth since its launch in January 2010. We are leveraging our established commercial infrastructure, our collaboration with Astellas and our investment in sales and marketing programs to increase awareness and adoption of, and access to, Sumavel DosePro with prescribers, patients, third-party payors, pharmacists and employers.

Developing and commercializing ZX002 for the treatment of moderate to severe chronic pain. Our ongoing Phase 3 clinical program for ZX002 is focused on establishing safety and efficacy of controlled-release single-entity *hydrocodone* to treat moderate to severe chronic pain in patients requiring around-the-clock opioid therapy. If our clinical program is successful and we receive FDA approval, we intend to expand our sales and marketing infrastructure, including expanding our field sales force to 250 or more representatives, to allow us to reach a broad range of opioid prescribers in our target market.

Expanding our product pipeline in CNS disorders and/or pain. We are utilizing our proprietary DosePro technology to add to our internal product pipeline. We have initiated pre-clinical development work on a proprietary long-acting formulation of an injectable CNS drug product and are also evaluating the market potential, formulation requirements and clinical development pathway of an additional CNS compound that could be paired with DosePro to enhance its commercial attractiveness. If these efforts are successful, we may be able to submit an IND for one or both product candidates in 2011.

Obtaining regulatory approvals for Sumavel DosePro outside of the United States. We have a partnership for Sumavel DosePro with Desitin in order to accelerate development and regulatory approvals in Europe and enhance the global commercial potential of Sumavel DosePro. We also continue to evaluate potential partnerships to commercialize Sumavel DosePro in additional markets outside of Europe and the United States.

Out-licensing our proprietary DosePro technology. We are evaluating opportunities to out-license the DosePro needle-free drug delivery technology to partners seeking to enhance, differentiate or extend the life-cycle of their injectable products. These opportunities include biologics and small molecules that are both currently marketed products and development stage product candidates.

Securing rights to complementary products and product candidates that address CNS disorders and/or pain. To strategically leverage our commercial resources and generate additional revenue, we are seeking third-party co-promotion opportunities. In the future, we will also consider in-licensing or acquisition opportunities with a focus on product candidates that utilize novel technologies to improve the profile of existing compounds for CNS disorders and/or pain.

Our Product and Product Candidates

Sumavel DosePro for the Acute Treatment of Migraine and Cluster Headache

We launched the commercial sale of Sumavel DosePro in the United States in January 2010 with our co-promotion partner, Astellas. Our Sumavel DosePro (*sumatriptan* injection) Needle-free Delivery System offers fast-acting, easy-to-use subcutaneous administration of *sumatriptan* for the acute treatment of migraine and cluster headache. Sumavel DosePro utilizes our proprietary DosePro system which enables patients to self-administer subcutaneous *sumatriptan* in three easy steps. Sumavel DosePro may offer a faster-acting and more efficacious treatment alternative to oral and nasal triptans and simple, convenient administration when compared to traditional, needle-based *sumatriptan* injection. As a result, we believe that Sumavel DosePro has the potential to be prescribed by a broad physician audience, especially for difficult to treat migraine episodes.

Migraine Market

Migraine is a chronic neurovascular disorder characterized by episodic attacks. According to a 2007 press release from the NHF, approximately 30 million people in the United States suffer from migraines, with women three times more likely to suffer migraines than men. Migraine attacks typically manifest themselves as moderate to severe headache pain, with symptoms that often include nausea and/or vomiting and abnormal sensitivity to light and sound. Migraines can severely limit the normal daily functioning of patients, who may seek dark, quiet surroundings until the episode has passed. According to the International Headache Society, the duration of untreated or unsuccessfully treated migraine episodes ranges from four to 72 hours. According to data published in the March 2002 issue of Neurology, 63% of patients suffer one or more attacks per month, 25% of patients have one or more attacks per week and the median duration of an untreated migraine is approximately 24 hours. Overall, the cost burden of migraine in the United States was estimated by Thomson Medstat in June 2006 to approach $25 billion annually, including $12.7 billion in direct medical costs and $12 billion in indirect costs related to employee absenteeism, short-term disability and workers compensation costs to employers.

Cluster headaches are characterized by groups or clusters of debilitating headaches lasting weeks or months, then disappearing for months or years. This type of headache affects an estimated one million sufferers in the United States, and approximately 90% of these sufferers are male, according to the NHF website. Due to the severe nature of cluster headache, patients are commonly treated with prescription medication.

Acute therapies dominate the prescription migraine and cluster headache market and are used during intermittent attacks. The goals of acute therapy are to stop the attack quickly and consistently, minimize the use of backup and rescue medications, enhance self-care and restore the patient s ability to function, use the least amount of medication and limit adverse side effects.

A major advancement in the acute treatment of migraine began in 1993 with the launch of the first triptan, *sumatriptan* injection (Imitrex), in the United States. All triptans are selective agonists for the 5-HT_{1B} and 5-HT_{1D} receptors. Triptans presumably exert their antimigrainous effect through binding to vascular 5-HT_1 receptors, which have been shown to be present on both the human basilar artery, one of the major arteries that supplies blood to the brain, and the outer most membrane covering the brain. Triptans activate these receptors to cause vasoconstriction, an action in humans correlated with the relief of migraine and cluster headache. *Sumatriptan* was subsequently joined by other drugs in the triptan class. By the year 2003, there were seven approved triptans in the United States with a focus on oral delivery forms to offer convenience of dosing for migraine patients. *Sumatriptan* is the only triptan available in oral, nasal and subcutaneous forms, each of which has different pharmacokinetic properties.

Triptans remain the drugs of choice and the most often prescribed therapy for the acute treatment of migraine and cluster headache. The following table provides a breakdown of the U.S. triptan market, including sales and doses prescribed for oral (tablets and melts), nasal and injectable forms of triptan for the 12 months ended June 2010.

U.S. Triptan Market

(12 months ended June 2010)

Triptan Form	Sales (millions)	$ Share	Doses (millions)	Dose Share
Oral Tablet	$ 2,680	77.6%	111.1	84.7%
Oral Melt	352	10.2	13.8	10.6
Nasal	116	3.3	3.1	2.3
Injectable	305	8.8	3.2	2.4
Total	$ 3,453	100%	131.2	100%

Source® PHAST Institution/Retail.

As indicated in the prior table, the triptan market is dominated by oral dosage forms (tablets and melts), with approximately 95% of U.S. triptan doses taken as oral formulations and the remaining 5% split between injectable and nasal formulations. Branded and generic *sumatriptan*, in all dosage forms, remains the most prescribed triptan molecule with sales of approximately $1.97 billion (57% dollar share of the triptan market). Of that amount, the injectable forms of *sumatriptan* accounted for $305 million. By comparison, ergotamine agents, another class of drugs used for the acute treatment of migraine, including injectable DHE and Migranal, accounted for $54.7 million in sales in the United States during the same 12-month period. (Source® PHAST Institution/Retail). *Sumatriptan* is the only triptan available to patients in the injectable form and, with the exception of Sumavel DosePro, all other forms of injectable *sumatriptan* make use of needle-based injections for their administration.

In five major European countries (France, Germany, Italy, Spain and the United Kingdom), triptans generated total sales of approximately $550 million for the 12 months ended June 2007, according to average wholesale price data published by IMS Health MIDAS. Of that $550 million, the European equivalent of Imitrex, Imigran, represented sales of approximately $148 million, of which the injectable form accounted for approximately $35 million.

Migraine Market Dynamics

The type of migraine treatment utilized by patients often depends on the frequency and severity of the headache, its speed of onset and previous response to medication. In published studies, migraine sufferers most often cite faster onset of pain relief as a key therapeutic attribute they would like from their migraine medication. Patients with more frequent or severe migraines or those who do not respond to simple analgesics may seek medical attention with a primary care physician initially and then with a headache clinic or neurology specialist if needed. Once a physician makes a diagnosis of migraine, oral triptans are generally prescribed as first-line therapy.

If a patient does not respond to one triptan product, the physician may switch to another triptan or dosage form or add another triptan or dosage form to a patient s treatment armamentarium. Market research conducted on our behalf by Boston Healthcare Associates, Inc. indicates that it is common for a migraine patient to be offered several different oral triptan options before being offered a nasal or injectable product. In addition, the same market research indicates that approximately 25% of migraine patients had two or more active prescriptions for different brands and/or forms of triptan therapy. We believe these patients maintain multiple prescriptions because they have found that certain medications or dosage forms work better for certain types of migraines and choose which medication to use based on the type of migraine episode they are experiencing.

Clinical research has substantiated that the nature of migraine episodes varies widely. In some episodes, patients can sense a migraine coming and take their medication accordingly. In other episodes, patients may wake up with a migraine already in progress or the migraine may come on suddenly. An estimated 48% of migraines occur between the hours of 4:00 a.m. and 9:00 a.m., according to an article published in the June 1998 issue of Headache. Migraines may also be associated with nausea and/or vomiting. Twenty-nine percent of patients reported vomiting as a symptom of migraine attacks, according to the American Migraine Study II, and epidemiological studies in migraine reveal that the vast majority of patients (more than 90%) have experienced nausea during a migraine attack and more than 50% have nausea with the majority of attacks, according to an article published in Drugs in 2003 (Volume 63, Issue 21). Depending on the type of migraine episode, a treatment may be more or less effective. For example, oral treatments may be of little value in a patient who is vomiting or who is experiencing migraine-associated gastric stasis. There is also clinical evidence that oral agents may be less effective when taken at a later stage of a migraine attack, rather than at an earlier stage. Consequently, rapid onset migraine and waking with a migraine attack may reduce the benefits to patients of oral triptans, because both represent fully-developed attacks.

The following table compares the time to maximum drug concentration in blood, or Tmax, and pain relief of oral forms, including melts and tablets, and nasal forms of marketed triptans to *sumatriptan* injection. The data are derived from Prescribing Information for the different formulations of these marketed triptans:

Triptan Prescribing Information Data

Form/Product (API)	Tmax	Relief at 1 hour(1)(2)	Relief at 2 hours(2)
Subcutaneous			
Sumavel DosePro (*sumatriptan* injection)	12 minutes	70%	81-82%
Nasal			
Imitrex (*sumatriptan*)	Not provided	38-46%	43-64%
Zomig (*zolmitriptan*)	3.0 hrs	60%	69-70%
Oral Melt			
Zomig-ZMT (*zolmitriptan*)	3.0 hrs	33-43%	63%
Maxalt-MLT (*rizatriptan*)	1.6-2.5 hrs	38-43%	59-74%
Oral Tablets			
Imitrex (*sumatriptan*)	2.0-2.5 hrs	28-36%	50-62%
Treximet (*sumatriptan/naproxen sodium*)	1.0 hrs	28%	57-65%
Zomig (*zolmitriptan*)	1.5 hrs	35-45%	59-67%
Maxalt (*rizatriptan*)	1.0-1.5 hrs	38-43%	60-77%
Amerge (*naratriptan*)	2.0-3.0 hrs	19-21%	50-66%(3)
Axert (*almotriptan*)	1.0-3.0 hrs	32-36%	55-65%
Frova (*frovatriptan*)	2.0-4.0 hrs	12%	37-46%
Relpax (*eletriptan*)	1.5 hrs	20-30%	47-77%

(1) Other than Sumavel DosePro (*sumatriptan* injection), we have estimated one-hour pain relief data for all forms/products based on Kaplan-Meier plots included in each product s Prescribing Information of the probability over time of obtaining headache response following treatment.

(2) Range reflects headache relief data obtained in placebo controlled clinical studies, which include different doses of the same triptan.

(3) Represents pain relief at four hours.

Tmax closely correlates to speed of onset of pain relief, and has also been shown to be correlated with completeness of pain relief and pain freedom over time. Relief at two hours is the standard endpoint used in migraine studies and represents the percentage of patients reporting a reduction of

migraine symptoms from a classification of severe or moderate to mild or none within two hours after taking the medication. As indicated in the prior table, *sumatriptan* injection has the earliest Tmax, reaching maximum blood concentration in 12 minutes, as compared with one or more hours for the other marketed triptan products, and exhibits the highest percentage of patients reporting pain relief at two hours (81%-82%) as compared to all other marketed oral and nasal triptan products (37-77%). *Sumatriptan* injection is the only migraine product that explicitly reports pain relief at one hour in its Prescribing Information. The efficacy profile of *sumatriptan* injection has been suggested to be related to its faster rate (not extent) of drug absorption compared to oral and nasal forms of triptans. Nasal forms, while claimed by some to be fast-acting, have drug absorption profiles similar to oral forms because a large portion of the administered dose is usually swallowed prior to absorption.

Unmet Needs in Acute Migraine Therapy

Triptans have been widely used in clinical practice for more than 15 years and are generally considered to be safe and effective for many patients during their migraine episodes. However, more than half of all patients are unsatisfied with their current migraine therapy, as reported from a national survey of 500 migraine sufferers published by the NHF in June 2010 and supported by a grant from us and Astellas. Specifically, the NHF survey results indicate that three in four migraine sufferers said that their current medication did not work fast enough to get them back to their life when a migraine strikes suddenly or upon waking, and a majority of migraine sufferers said their prescription oral migraine medication was not useful for every migraine attack. Limitations of oral and nasal triptan formulations include:

Slower onset of pain relief. As shown in the prior table, compared to Sumavel DosePro, each oral and nasal triptan has a longer Tmax, which is correlated with a slower onset of pain relief.

Lower degree of pain relief. As shown in the prior table, oral and nasal triptans may have a lower percentage of patients reporting pain relief at one and two hours following treatment as compared to Sumavel DosePro.

Significant numbers of non-responders. According to our market research with physicians and patients, approximately 30% of migraine patients fail to respond to an oral or nasal triptan.

Nasal route unpleasant. The nasal route is an alternative to oral delivery; however, nasal spray can be unpleasant in taste.

Some of these limitations are more pronounced depending on the type of migraine episode the patient is suffering. For example, when waking with a migraine already in progress, speed to onset of pain relief is important. In migraines with nausea and/or vomiting, a patient may not be able to ingest an oral treatment.

Despite its speed of onset and completeness of pain relief advantages over oral and nasal triptans, needle-based *sumatriptan* injection has been limited to less than 10% of the U.S. triptan market on a dollar basis and less than 3% on a total dose basis (Source® PHAST Institution/Retail) July 2009 June 2010). We believe this is largely due to limitations related to its delivery system which include:

Needle-based. Approximately 50% of patients refuse to use a needle-based injectable product for migraine because of needle anxiety or fear, or a lack of confidence in their ability to administer an injection correctly, according to physician market research conducted in 2006 by Palace Healthcare Group, Inc. on our behalf.

Cumbersome to use. The Imitrex STATdose System, or Imitrex STATdose, GSK s autoinjector for delivering *sumatriptan* with a needle, and its generic equivalents require more than 15 steps per their published instructions to prepare, administer and reload for its next use. This multi-step process, which patients have to complete during a migraine episode, is prone to error. Further, market research conducted by Palace Healthcare Group on our behalf finds that physicians report that the training required for Imitrex STATdose is a barrier to prescribing.

Needlestick risk. Needle-based systems may require special handling and needle disposal, or sharps, containers to avoid needlestick injuries.

Due to these limitations, there has historically been a limited prescriber base for injectable delivery forms of *sumatriptan*. Of an aggregate of over 347,000 prescribers of triptans in the United States, only an approximate 65,000 had written a prescription for *sumatriptan* injection (including Sumavel DosePro) in the 12 months ended June 2010 (Source® Prescriber July 2009 June 2010). As a result, a limited number of patients are offered injectable delivery forms. Only 54% of migraine patients had ever been offered *sumatriptan* injection according to patient market research conducted by Boston Healthcare Associates, Inc. on our behalf.

Our Solution: Sumavel DosePro

Sumavel DosePro is a pre-filled, single-use disposable, needle-free drug delivery system that subcutaneously delivers 6 mg of *sumatriptan* in 0.5 mL of sterile liquid. Sumavel DosePro was designed to be portable, intuitive and easy-to-use. To use, the patient simply snaps off a plastic tip, flips back a lever and presses the end of the delivery system to the skin of the abdomen or thigh. Under the force of a small amount of compressed nitrogen gas, the liquid form of *sumatriptan* is expelled out of the device as a thin jet of medication, which pierces the skin and selectively deposits into the subcutaneous tissue. This process occurs in less than 1/10th of a second.

Due to its unique attributes, Sumavel DosePro has the potential to expand the dosage share for injectable *sumatriptan* beyond the traditional needle-based forms because it reduces the barriers inherent in needle-based delivery systems to being prescribed by physicians and accepted by patients. Sumavel DosePro may provide patients with the following benefits when compared to alternative triptan formulations:

Rapid, more complete, migraine pain relief. Sumavel DosePro can provide onset of migraine pain relief in as little as ten minutes for some patients, according to its Prescribing Information, which is faster than onset of pain relief for oral and nasal triptans. The Prescribing Information for the product indicates that an average of 81% (vs. an average of 34% for placebo) of patients show pain relief at two hours following administration of Sumavel DosePro and that 49% of patients were pain free within 1 hour (vs. 9% for placebo) and 64% were pain free within two hours (vs. 15% for placebo) following administration.

Help for sufferers of morning migraines, fast onset migraine and migraines with vomiting. According to two studies published in the October 2006 issue of Clinical Therapeutics, 48% and 57% of patients with waking migraines were pain free at two hours (vs. 18% and 19% for placebo) following administration of *sumatriptan* injection. Subcutaneous *sumatriptan* is also as efficacious when administered early during a migraine attack as when the attack is full-blown. In addition, the pharmacokinetics of subcutaneously delivered *sumatriptan* is not affected by gastric stasis, nausea and/or vomiting.

Help for triptan tablet non-responders. Clinical research published in the January 2007 issue of Journal of Headache and Pain suggests injectable *sumatriptan* provides relief in up to 90% of migraine patients who have not responded to oral tablet triptans in at least two of their last three migraines. In this study, 43 patients who had failed to respond to oral triptans in at least two of their last three migraines were given *sumatriptan* injection for their next migraine. Of these patients, 91% reported pain relief at two hours, 56% reported being pain free at two hours and 32% reported sustained pain freedom through 24 hours following treatment of their first headache.

Simplicity, through a new, convenient and easy-to-use option. Sumavel DosePro is based on our unique delivery system which was designed to be portable, intuitive and easy-to-use, and can be

disposed following use without the need of a sharps container. We believe healthcare providers appreciate the simplicity of DosePro because it is easy to train patients to use properly. Our usability study for Sumavel DosePro showed 98% of patients were able to self-administer Sumavel DosePro in the home during an acute migraine attack, without clinical supervision and with minimal prior training.

Needle-free, eliminating needle-based issues. Because it is needle-free, we believe Sumavel DosePro may eliminate the basis for patient needle phobia and fear. Additionally, it removes the risks of needlestick injury, the cost and inconvenience of needle disposal, issues resulting from poor injection technique and costs associated with professionally administered needle-based injections. Studies show when a choice between needle-based and needle-free injection is available, the majority of patients prefer needle-free injection. More specifically, in a head-to-head study conducted by GSK of Sumavel DosePro versus the European branded version of Imitrex STATdose, a needle-based delivery system, 61% of migraine patients preferred using Sumavel DosePro while only 18% preferred using the European branded version of Imitrex STATdose, with the remaining patients expressing no preference.

In addition, we believe that the unique attributes of Sumavel DosePro have the potential to reduce productivity loss in the workplace for patients suffering from migraine. According to a study published in the May 1998 issue of Archives of Internal Medicine, results from a placebo-controlled clinical study of 135 patients having migraine indicated that use of *sumatriptan* injection may reduce migraine-associated productivity loss. This decrease is a function of both a reduction in time lost due to reduced effectiveness while working and a reduction in time lost due to missing work altogether. Moreover, 52% of patients using *sumatriptan* injection (vs. 9% for placebo) returned to normal work performance within two hours after dosing.

Sumavel DosePro Launch

Working in collaboration with our co-promotion partner, Astellas, as well as third-party advertising and market research organizations, we developed and are executing a sophisticated and comprehensive commercialization strategy for Sumavel DosePro supported by a range of marketing programs. This strategy and tactical plan was built taking into consideration the unmet needs in the migraine market in conjunction with the unique product attributes of Sumavel DosePro. Key objectives of our launch strategy are to:

validate the unmet needs of patients during challenging migraine episodes and position Sumavel DosePro as an effective treatment solution with key prescribers;

build awareness of Sumavel DosePro with migraine sufferers in order to drive patient requests;

enhance speed of physician adoption by focusing promotional efforts on key prescribers of migraine medications across specialties;

ensure a positive first-dose experience for patients; and

achieve broad patient access to Sumavel DosePro by ensuring nationwide retail distribution and adequate third-party payor reimbursement status.

In support of these strategic objectives, we and Astellas are executing a variety of marketing programs to educate customers, which include direct-to-physician promotional materials, speaker programs, direct-to-patient programs, digital media, participation in selected medical conventions and reimbursement support programs. In addition, we and Astellas provide product samples to physicians so that their patients may try Sumavel DosePro during an acute migraine attack before filling their first prescription.

Sumavel DosePro Market Experience to Date

Sumavel DosePro has demonstrated consistent monthly growth in total prescriptions since its launch in January 2010. We continue to add new and repeat prescribers in both the neurology and primary care settings, including a significant number of prescribers who had not prescribed *sumatriptan* injection in the prior 12 months. The product is gaining use from a range of patient segments including new triptan users, patients being converted to the product from other migraine drugs and patients with prescriptions for other triptans. Since its launch, 77% of all patient conversions to Sumavel DosePro have come from oral triptans, including tablets and melt formulations (Source® Lx PTA January 2010 August 2010). Total gross sales of Sumavel DosePro through September 30, 2010 in the United States were $16.4 million, and we recognized $11.8 million in net product revenue from these sales. The wholesale acquisition cost for a six-pack of Sumavel DosePro was $498 as of September 30, 2010.

Selected market highlights since we launched Sumavel DosePro in January 2010 include:

Prescription Trends. Monthly prescription data shows that more than 21,800 aggregate prescriptions of Sumavel DosePro have been dispensed and that monthly total prescriptions have increased in each month since launch, as illustrated in the following table. In September 2010, more than 3,500 total prescriptions were dispensed and nearly 31% of total prescriptions were classified as refill prescriptions. (Source® PHAST Retail January 2010 September 2010)

(1) TRx is total prescriptions dispensed, including new prescriptions (NRx) and refill prescriptions.

Prescriber Base. Weekly prescribing data shows that more than 5,600 physicians have prescribed Sumavel DosePro, of whom a growing proportion are now repeat prescribers. Fifty-five percent of prescribers are primary care physicians (including internal medicine, family practice and general practice), 31% are neurologists, pain management specialists and psychiatrists and the remaining 14% are from a wide range of other specialties. (Source LaunchTrac week ended January 15, 2010 week ended October 1, 2010). In addition, 32% of Sumavel DosePro prescribers had not written a prescription for needle-based *sumatriptan* injection in the previous 12 months and an additional 35% of prescribers had written, on average, less than one prescription per month for needle-based *sumatriptan* injection. (Source® LaunchTrac week ended January 15, 2010 week ended July 30, 2010)

Patient Dynamics. Analysis of patient data indicates that approximately 34% of patients filling a Sumavel DosePro prescription were new to the triptan market (i.e., had not filled a triptan prescription in the prior 18 months), approximately 34% had active prescriptions for Sumavel DosePro and at least one additional triptan and approximately 16% of patients had converted to Sumavel DosePro from another triptan. The remaining approximately 16% of patients were continuing users of Sumavel DosePro. Importantly, of the patients who converted from another triptan, 77% converted from oral triptans, including tablets and melt formulations. (Source® Lx PTA January 2010 August 2010)

Patients Experience. Patients experience with Sumavel DosePro has been positive based on their feedback provided via the Connects Program from Infomedics. This internet-based program invites patients that received a Sumavel DosePro prescription to register online at the time of their prescription and then provide feedback after they have used the product to treat a migraine episode. Through September 11, 2010, 1,071 patient respondents who had used Sumavel DosePro have rated their satisfaction with Sumavel DosePro at an average score of 7.1 versus 5.5 for their prior migraine medication (9-point satisfaction scale, with 9 being very satisfied).

Third-party Payor Coverage. Through our ongoing efforts with the largest commercial health plans, Sumavel DosePro is achieving broad coverage in the United States. In many of these plans, Sumavel DosePro is categorized as a Tier 3 drug. For certain of these plans, Sumavel DosePro is on Tier 3/ restricted reimbursement status, which means that some additional prior authorization or step-edit is required prior to a claims approval. Approximately 78% of reimbursement claims submitted for Sumavel DosePro have been approved since its launch (Source® Dynamic Claims January 2010 August 2010). We are currently in discussions to further expand coverage and improve patient access for Sumavel DosePro with additional third-party payors.

Sumavel DosePro Regulatory Approval

We sought and received FDA marketing approval of Sumavel DosePro under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, or the FFDCA, utilizing Imitrex *sumatriptan* injection as the reference listed product. Section 505(b)(2) of the FFDCA provides an alternate path to FDA approval for modifications to formulations or new dosing of products previously approved by the FDA. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. This expedited the development program for Sumavel DosePro by decreasing the overall scope of clinical and pre-clinical work required to be completed by us.

The clinical efficacy of subcutaneous injectable *sumatriptan* for migraine and cluster headache has been established by the reference listed product, Imitrex *sumatriptan* injection, which was approved in 1992. Based on our clinical bioequivalence studies, the FDA concluded that Sumavel DosePro is bioequivalent to injectable *sumatriptan* administered to the thigh or abdomen using Imitrex STATdose and is well tolerated when compared to this reference listed product. Our Sumavel DosePro NDA was approved by the FDA on July 15, 2009, and the Sumavel DosePro Prescribing Information includes the historical efficacy data of *sumatriptan* injection.

Sumavel DosePro Pivotal Clinical Program

Based on discussions with the FDA, and due to the existing body of data on injectable *sumatriptan*, our pivotal clinical program evaluated Sumavel DosePro in studies for pharmacokinetics, bioequivalence, safety, local injection site signs and reactions, and usability by patients with migraine. We conducted a single pivotal pharmacokinetics and bioequivalence clinical trial for the purpose of providing evidence of bioequivalence and safety of Sumavel DosePro as compared to Imitrex STATdose. This study, completed in April 2007, was a randomized, open-label, cross-over trial comparing safety, tolerability and pharmacokinetics in 54 subjects. The primary endpoint of bioequivalence was demonstrated in the commonly used abdomen and thigh injection sites. A separate 52-patient usability study was conducted in the second half of 2007 to evaluate the usability of Sumavel

DosePro in patients during acute migraine attacks in an outpatient setting. In this study, 98% were able to use Sumavel DosePro correctly during a migraine attack on their first attempt, thus confirming the product candidate s ease of use. Further use of Sumavel DosePro by the same patients in their treatment of subsequent migraine attacks provided consistent evidence of usability in the outpatient setting. In addition, we concluded a successful safety trial with Sumavel DosePro in December 2007 to study the effect of repeat dosing and multiple injections. Adverse events seen in our clinical studies were consistent with previously reported adverse events for *sumatriptan* injection. The most common treatment-emergent adverse reactions (reported by at least 5% of patients) for *sumatriptan* injection as described in the Sumavel DosePro Prescribing Information summarizing two large placebo-controlled clinical trials were injection site reaction (59%), atypical sensations (42%), dizziness (12%), flushing (7%), chest discomfort (5%), weakness (5%), and neck pain/stiffness (5%).

Desitin submitted a Marketing Authorization Application for Sumavel DosePro to the Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM)) in Germany, the reference member state, through the Decentralized Procedure in October 2009, following completion of a European pivotal bioequivalence trial comparing needle-free Sumavel DosePro to a traditional needle-based autoinjector, Imigran-Inject, the European brand of Imitrex STATdose.

Sumavel DosePro Post-Approval Clinical Program

In addition to the clinical program completed in support of product approval, we recently completed a Phase 4 open-label, multicenter study in the United States to evaluate treatment satisfaction, treatment confidence and subject preference for Sumavel DosePro in adult subjects diagnosed with migraine and currently treated with triptans. More than 200 subjects, who were predominantly taking oral triptan therapy, tried Sumavel DosePro to treat up to four migraines over a 60-day period. The study utilized the Patient Perception of Migraine Questionnaire-Revised, or PPMQ-R, to evaluate patient satisfaction with migraine treatment through analysis of efficacy, functionality, ease of use and tolerability/side effects. The primary endpoint PPMQ-R Overall Satisfaction score increased significantly from baseline to end of treatment ($p<0.001$), an improvement that met the criterion for clinical significance, due to significant increases in the PPMQ-R scores for efficacy ($p<0.0001$) and functionality ($p<0.0001$). We intend to disclose additional analyses of study results at relevant clinical symposia and via peer-review publications in 2011.

DosePro and Sumavel DosePro Clinical Experience

The DosePro drug delivery system has been in development for more than ten years. During this time, more than 9,000 injections have been administered in multiple clinical studies to assure the proper functioning of the system and to establish the safety and tolerability of needle-free administration by DosePro. While our experience indicates that some patients will experience pain upon injection with the DosePro technology, this pain sensation is consistent with the pain sensation associated with injection with a fine gauge needle and can be generally characterized as transient mild discomfort.

ZX002 for the Treatment of Moderate to Severe Chronic Pain

Our lead product candidate, ZX002, is a novel, oral, single-entity controlled-release formulation of *hydrocodone* currently in Phase 3 clinical trials for the treatment of moderate to severe chronic pain in patients requiring around-the-clock opioid therapy. We believe ZX002 has the potential to be an important therapeutic alternative to existing *hydrocodone* products, including the branded products Vicodin, Lortab and their generic equivalents, which contain the analgesic combination ingredient *acetaminophen* and, if taken in high quantities over time, can lead to serious side effects such as liver toxicity. ZX002 utilizes the SODAS Technology, Elan s proprietary multiparticulate drug delivery system that allows the development of customized controlled-release profiles and serves to enhance the release profile of *hydrocodone* in ZX002 to provide constant 12-hour pain relief. We believe these release properties have the potential to provide longer lasting and more consistent pain relief with fewer daily

doses than the commercially available formulations of *hydrocodone*. As a result of its unique single-entity controlled-release profile, we believe ZX002 will generate sales from both patients who use immediate-release products on a chronic basis and patients already using extended-release products in the prescription opioid market.

The Chronic Pain Market

Pain is a worldwide problem with serious health and economic consequences. The American Pain Society estimated in 1999 that 9% of the U.S. adult population suffers from moderate to severe non-cancer related chronic pain. Chronic pain may be defined as pain that lasts beyond the healing of an injury or that persists beyond three months. Common types of chronic pain include lower back pain, arthritis, headache and face and jaw pain. While mild pain does not typically stop an individual from participating in his or her daily activities, moderate pain may prevent an individual from participating in his or her daily activities and severe pain typically stops an individual from participating in his or her daily activities and induces a patient to exhibit pain avoidance behaviors.

Chronic pain treatment depends on the individual patients, their diagnosis and their pain severity. Chronic pain patients typically first attempt to self-medicate with over-the-counter drugs such as *acetaminophen*, aspirin or another non-steroidal anti-inflammatory drug, or NSAID. Patients with more constant and/or moderate to severe pain typically seek medical attention and prescription pain medication from a primary care physician and, if necessary, are referred to a neurologist or a physical medicine or pain specialist. Physicians generally assess the patient and, if appropriate, start treatment with a trial of opioid therapy to determine the optimal opioid regimen. At this point, physicians commonly prescribe opioids, including products from the *codeine* and *morphine* classes. The general objective of the physician is to safely achieve adequate control of pain.

Physicians generally prefer to start patients on less potent opioids where possible. A trial of opioid therapy usually begins with short-acting doses taken on an as-needed basis. This allows the clinician and patient to assess the total opioid requirement. Patients taking substantial doses of short-acting opioids multiple times per day may find substitution of an extended-release agent, taken one to two times per day, extremely helpful to provide more constant pain relief. In theory, the more constant opioid blood levels of extended-release products may provide better pain relief and better sleep quality. Dosing intervals less frequent than every four to six hours may also provide improved patient adherence to the prescribed regimen and improved patient convenience. Finally, individual patients may do poorly on one opioid, but better after switching to another. This practice is called opioid rotation and is regularly employed in chronic pain management. Opioids, while generally effective for pain treatment, are associated with numerous potential adverse effects, including opioid induced bowel dysfunction, sedation, nausea, vomiting, decreased respiratory function, addiction and, in some instances, death.

Hydrocodone is often used as a starter opioid to initiate opioid therapy because it is viewed by many physicians as a less potent opioid. Historically, *hydrocodone* preparations in the United States have been utilized primarily for treatment of acute pain following surgery or injury. For this purpose, they were combined with analgesics, including *acetaminophen* or an NSAID, which treat the acute inflammatory component of the pain. These analgesics are generally safe when used at lower doses or for short periods of time. However, at higher doses or over extended periods of time, they may significantly increase patient risk for gastrointestinal, liver and kidney damage.

As the practice of pain management has broadened to include chronic therapy for moderate to severe pain, physicians continue to broadly use *hydrocodone* combinations. In the United States, market research conducted by bioStrategies Group on our behalf indicates that approximately 50% of the use of immediate-release combination products that include *hydrocodone*, *codeine* or *oxycodone* is for the treatment of chronic pain. However, physicians sometimes find the non-opioid analgesic component in combination *hydrocodone* products creates a ceiling effect when they wish to escalate doses. For

example, the most commonly prescribed dose of Vicodin (5mg *hydrocodone*/500 mg *acetaminophen*) given at a maximum dose of eight tablets per day delivers 4 g of *acetaminophen*, which approaches or exceeds recommended *acetaminophen* dosing, while only delivering 40 mg of *hydrocodone*, based on the Vicodin Prescribing Information. If a further increase in opioid dose is warranted, a physician is compelled to transition to an opioid not in combination, such as *oxycodone*, or more potent opioids such as *fentanyl* or *oxymorphone*.

In the 12 months ended June 2010, our target market, which we define as prescription non-injectable *codeine*-based and extended-release *morphine*-based pain products, generated sales of approximately $13.0 billion in the United States on approximately 202 million prescriptions. Of the $13.0 billion, *hydrocodone* products, the most commonly prescribed opioid and the most commonly prescribed pharmaceutical products in the United States, generated $3.1 billion in sales on approximately 126 million prescriptions. (Source® PHAST Retail).

In June 2009, the FDA organized a joint meeting of the Drug Safety and Risk Management Advisory Committee, Nonprescription Drugs Advisory Committee, and the Anesthetic and Life Support Advisory Committee to discuss how to address the public health problem of liver injury related to the use of *acetaminophen* in both over-the-counter and prescription products. The expert panel specifically considered the elimination of combination prescription products containing *acetaminophen* (including Vicodin and its generics) from the U.S. market. Twenty of the 37 working group members (10 saying this was a high priority) voted in favor of removing such products from the market. The working group ultimately did not recommend withdrawal of these products stating that the benefits of access to Schedule III *acetaminophen*/*hydrocodone* combination products over Schedule II opioids outweighed the risk of removing the combinations from the market. The working group also noted that the logical choice to substitute for the combination products would be a single-entity formulation of *hydrocodone.* There are currently no approved products formulated with *hydrocodone* alone, and we believe ZX002 has the potential to fill this treatment gap.

Limitations of Current Opioid Pain Therapies

While *hydrocodone* in combination products remains the most commonly prescribed opioid, currently available *hydrocodone* formulations have several major limitations, including:

Hydrocodone only available in short-acting/immediate-release form. There are currently no extended-release *hydrocodone* formulations on the market.

Adherence dependent. Because *hydrocodone* is available only in immediate-release formulations that are dosed every four to six hours, its around-the-clock efficacy is dependent on diligent adherence by the patient. Published studies across therapeutic categories, including the treatment of diabetes, hypertension and infectious disease, demonstrate that patient adherence to drug regimens declines as the number of daily drug doses increases.

Inconsistent pain relief. Because of the dosing issues noted above, many patients experience suboptimal pain relief due to variable opioid blood levels, particularly towards the end of dosing intervals.

Opioid dose is limited by combination analgesics. The overwhelming majority of currently approved *hydrocodone* products include *acetaminophen* in their formulation. Because of the potential side effects of chronic increasing *acetaminophen* doses, the *acetaminophen* component of these combination products can become a dose limiting factor. When this occurs, patients must limit their total *hydrocodone* dose to avoid potential liver and other side effects of *acetaminophen* and thus may receive a sub-optimal daily dose of *hydrocodone,* or they must switch to other single-entity opioids, such as *oxycodone. Hydrocodone* combinations with NSAIDs have similar dose limitations due to the gastrointestinal side effects associated with NSAIDs.

While extended-release, single-entity opioids exist, published study reports indicate that patients are regularly taking more daily doses of extended-release opioids than the recommended labeled

dose, suggesting that not all of them provide true 12- or 24-hour dosing. For example, results from a study of 437 patients published in the May/June 2003 issue of the Journal of Managed Care Pharmacy indicated that despite the every 12-hours dosing regimen recommended in its Prescribing Information, patients taking extended-release *oxycodone* on average took 4.6 tablets per day, at an average dosing interval of only 7.8 hours. In the same study, among extended-release *oxycodone* patients, only 1.9% reported the duration of pain relief as 12 or more hours. A separate study published in the September/October 2004 issue of The Clinical Journal of Pain indicated that the prescribed frequency of dosing extended-release *oxycodone* determined through clinical practice was twice daily for 33% of patients, with 67% of patients requiring greater than twice daily dosing.

Our Solution: ZX002

We believe that ZX002, if approved, may provide patients and physicians with the following benefits when compared to existing opioid pain medications:

Single-entity hydrocodone. ZX002, if successfully developed and approved by the FDA, is expected to be the first non-combination, controlled-release *hydrocodone* product to be commercialized in the United States, giving physicians and patients a *hydrocodone* option unencumbered with *acetaminophen* or NSAIDs and their potential adverse effects.

Twice daily dosing provides true around-the-clock relief. ZX002, via its unique controlled-release profile, is designed to provide consistent relief of moderate to severe chronic pain over a 12-hour period per dose. Clinical studies have shown a pharmacokinetic profile that supports the expected extended relief profile of ZX002.

Easier adherence/greater patient convenience. Because of its twice daily dosing regimen, ZX002 requires fewer daily doses than currently available *hydrocodone* formulations, thereby increasing the likelihood of patient adherence and convenience.

Another opioid option for chronic medication rotation. The unique profile of ZX002 provides another option for physicians investigating new alternatives to offer patients who require medication rotation due to tolerance, side effects or poor pain control.

ZX002 Phase 3 Clinical Development Program

We initiated a single pivotal Phase 3 efficacy trial (Study 801) in March 2010. This trial is a randomized, 12-week, double-blind, placebo-controlled trial to evaluate the safety and efficacy of ZX002 for the treatment of moderate to severe chronic lower back pain in opioid-experienced adult subjects. Our trial utilizes a protocol design that has been used successfully to demonstrate the efficacy of other controlled-release opioid therapies for chronic pain. The primary efficacy endpoint in this trial is the mean change in average daily pain intensity scores between ZX002 and placebo. We confirmed the FDA s agreement on the trial design for Study 801 and the overall safety database requirements for an NDA submission at our End of Phase 2 meeting with the FDA conducted in June 2008. We did not seek a Special Protocol Assessment, or SPA, from the FDA for Study 801.

To further assess the safety and tolerability of ZX002 as a chronic pain therapy, we have also initiated an open-label Phase 3 trial in opioid-experienced adult subjects with any indication appropriate for continuous, around-the-clock opioid therapy for an extended period of time (Study 802). The goal of this trial is to evaluate the safety and tolerability of ZX002 for up to 12 months of treatment. We expect to begin to receive top-line data from both our Phase 3 trials in the second half of 2011.

Based upon feedback from the FDA at our End of Phase 2 meeting, and assuming positive outcomes from the studies described above, we do not believe that additional Phase 3 safety and efficacy trials will be required to support our proposed label. Concurrent with our Phase 3 program, we will be conducting a small number of additional single-dose pharmacokinetic and clinical pharmacology trials and pre-clinical studies required for submission of the NDA and approval of this product candidate. If

the Phase 3 clinical development program for ZX002 is successful, we expect to submit an NDA with the FDA by early 2012.

Prior Clinical Development of ZX002

Our licensor for ZX002, Elan, conducted pre-clinical and clinical studies of ZX002 under an IND initiated in 2002.

Phase 1 and Phase 2 Clinical Development. In single and multiple dose pharmacokinetic evaluations, ZX002 demonstrated detectable plasma concentrations of *hydrocodone* within 15 minutes of administration. ZX002 also demonstrated a sustained release effect significantly longer than currently available *hydrocodone* combination products such as Vicodin, as well as dose proportional pharmacokinetics. Consistent, steady-state plasma levels, which are believed to be desirable for chronic pain patients who require around-the-clock opioid therapy, were achieved within one week of the initiation of dosing. In addition, ZX002 has been tested under both fed and fasted conditions and the amount of drug exposure was not affected by food, which we believe provides the basis for a flexible administration regimen for chronic pain. We believe that these prior pharmacokinetic studies demonstrate that ZX002 displays a consistent, controlled-release profile, dose-proportional pharmacokinetics and an acceptable safety profile.

ZX002 has also been evaluated in two separate Phase 2 pain studies. The first study was a randomized, single-dose, parallel group, placebo-controlled, active-comparator study to evaluate the safety, efficacy and pharmacokinetics of increasing doses of ZX002 in opioid-naive adults immediately following bunion removal surgery. This study was designed to evaluate pain prevention rather than pain treatment. In this 241-patient study, patients were treated with either one of four doses of ZX002 (10, 20, 30 or 40 mg controlled-release *hydrocodone bitartrate*), an active immediate-release comparator consisting of 10 mg *hydrocodone bitartrate* plus 325 mg *acetaminophen*, or placebo. The primary efficacy measurement was the visual analog scale of pain intensity from 0 to 12 hours after dosing. The 40 mg dose of ZX002 was significantly more effective ($p<0.05$) versus placebo in controlling postoperative pain. In addition, efficacy of the 40 mg dose did not significantly differ from the *hydrocodone bitartrate/acetaminophen* active comparator in any of the efficacy outcome measures. None of the three lower doses of ZX002 were superior to placebo in the primary efficacy measurements. All four doses were found to be safe and well-tolerated. We believe this efficacy and safety information is useful in establishing proof-of-concept for ZX002.

The second Phase 2 study was a four week, multiple-dose, safety, tolerability and pharmacokinetic dose-escalation study of ZX002 in opioid-experienced adults with chronic, moderate to severe osteoarthritis pain. The primary objective was to assess the safety, tolerability and pharmacokinetics of ZX002 at steady state over a range of escalating daily doses. Thirty-seven patients in two dosing cohorts received escalating doses of ZX002 over three weeks. This study demonstrated a clinically acceptable safety profile and a reduction in pain intensity for chronic moderate to severe osteoarthritis pain patients across multiple dosage strengths. We believe that the study also demonstrated a steady-state pharmacokinetic profile that is appropriate for the management of chronic pain. In both Phase 2 studies, patients experienced mild to moderate adverse events, such as nausea, vomiting, headache, dizziness, sweating, constipation and drowsiness, which are similar to the reported effects of opioids currently prescribed for chronic pain.

The data from these Phase 1 and Phase 2 studies were submitted to the FDA under our IND and were summarized in our End of Phase 2 meeting briefing package in support of progressing ZX002 into pivotal Phase 3 clinical studies.

Our DosePro Technology and Pre-clinical Pipeline

Our proprietary DosePro technology is a first-in-class, easy-to-use drug delivery system designed for self-administration of a pre-filled, single dose of liquid drug, subcutaneously, without a needle. The DosePro technology (formerly known as Intraject) has undergone more than ten years of design,

process engineering, clinical evaluation and development work, including significant capital investment by the predecessor owners of the technology, Weston Medical Group, plc and Aradigm Corporation, or Aradigm. We believe the approval and launch of Sumavel DosePro in the United Sates validates the technology s commercial viability and readiness for other potential drug applications.

We believe that DosePro offers several benefits to patients compared to other subcutaneous delivery methods, and that it has the potential to become a preferred delivery option for patients and physicians for many injected medicines beyond *sumatriptan*, particularly those that are self-administered. These benefits include less anxiety or fear due to the lack of a needle, easier disposal without the need for a sharps container, no risk of needlestick injury or contamination, an easy-to-use three step process, no need to fill or manipulate the device, reliable performance, discreet use and portability. In several clinical trials and market research studies, DosePro has been shown to be preferred by patients over conventional needle-based systems. For example, in a head-to-head study conducted by GSK of Sumavel DosePro versus the European branded version of Imitrex STATdose, a needle-based delivery system, 61% of migraine patients preferred using Sumavel DosePro while only 18% preferred using the European branded version of Imitrex STATdose, with the remaining patients expressing no preference. In addition, in a market study conducted on our behalf by Boston Healthcare Associates, Inc., 76% of patients preferred Sumavel DosePro as a delivery method over Imitrex STATdose. In addition, DosePro requires less time from physicians and other caregivers to train patients to use the device. Physician preference for DosePro as a needle-free alternative to conventional needle-based injections has also been demonstrated in market research studies. For example, in a study conducted by Palace Healthcare Group, Inc. on our behalf, 94% of primary care physicians and 98% of neurologists indicated they would be more willing to prescribe an injectable migraine product if it were needle-free.

Clinical studies suggest that DosePro will have significant versatility in its ability to deliver various types of therapeutic compounds, including both small molecules and biologic products where the dose volume is 0.5 mL or less. In addition to positive results using DosePro in clinical studies performed with saline and *sumatriptan*, there have been three positive single-dose human pilot studies conducted with a combination of a protein pharmaceutical and DosePro. These studies include pharmacokinetic bioequivalence studies comparing DosePro to a conventional needle injection for human growth hormone and erythropoietin, or EPO, and pharmacodynamic equivalence study using granulocyte colony-stimulating factor, or GCSF. Pre-clinical work with monoclonal antibodies evaluating bioavailability, pharmacokinetics and a lack of immunogenicity has also been conducted. *In vitro* studies with DosePro technology have demonstrated the potential to allow the subcutaneous delivery of highly viscous formulations, which can be a limiting factor for use of traditional needle-based delivery systems. As a result of the versatility of DosePro to deliver various types of drug products, this technology may have significant market potential across a broad range of therapeutic areas, including those typically treated with small volume injectable products, such as hepatitis, infertility, multiple sclerosis and rheumatoid arthritis.

Since some drug formulations cannot be accommodated in a 0.5 mL dose volume, we have initiated early stage design and development of a larger volume, second generation version of our DosePro technology, which if successfully developed, would allow for a broader range of potential applications for our technology. However, the full development of such technology will require substantial investment and we may consider entering into a third-party collaboration in order to fully-develop such technology. There is no guarantee that we or any potential future third-party collaborator will be able to successfully develop such a device technology, whether for financial or technical reasons or otherwise.

Given its multiple benefits and therapeutic versatility, we believe the DosePro technology provides us with an opportunity to develop our own product candidates by pairing DosePro with proven drugs to enhance their commercial attractiveness. We have initiated pre-clinical development work on a proprietary long-acting formulation of an injectable CNS drug product and are also evaluating the market potential, formulation requirements and clinical development pathway of an additional CNS

compound that could be paired with DosePro to enhance its commercial attractiveness. If these efforts are successful, we may be able to submit an IND for one or both product candidates in 2011. We also believe DosePro provides an attractive licensing option for other pharmaceutical and biotech companies seeking to enhance, differentiate or extend the life-cycle of their own injectable products, and we are continuing to explore such arrangements with several established pharmaceutical companies. These opportunities include both currently marketed products as well as development stage product candidates.

Sales and Marketing

We have built a highly experienced sales and marketing organization in the United States focused on marketing and selling Sumavel DosePro to physicians, nurses and other healthcare professionals. Our sales and marketing organization is comprised of approximately 100 professionals. Our field sales force of approximately 80 representatives is promoting Sumavel DosePro primarily to neurologists and other key prescribers of migraine medications, including headache clinics and headache specialists. We believe the key factors in the continued successful adoption of Sumavel DosePro will include expanding its use as an alternative to oral and nasal triptan therapy, converting current *sumatriptan* injectable users to Sumavel DosePro and building patient awareness and trial. We are specifically positioning Sumavel DosePro as a therapeutic alternative for oral triptan non-responders and dissatisfied patients, including those with morning migraines, fast progressing migraines and migraines accompanied by nausea and/or vomiting.

We believe our sales force is differentiated by its level of experience and background in the industry and accountability for sales results. Our field sales representatives have an average of 12 years of prior experience promoting pharmaceutical products and most have prior experience in the neurology and/or migraine space. In addition, our sales management team has on average 19 years of pharmaceutical industry experience, including an average of eight years of sales management experience. Each of our sales representatives and regional business directors undergoes a formal training program focused on disease background, our product, competitive products and territory management, as well as compliance with applicable laws. Our training program also includes significant ongoing and field-based learning to provide a comprehensive understanding and perspective as to our markets and disease states and the needs of both physicians and patients.

In addition to our field sales team, we also have an experienced team of field-based managed markets and trade directors. This team works closely with our regional business directors to engage with third-party payors to ensure and expand reimbursement coverage and patient access for our product and implement pharmacy based educational programs. To date, we have entered into a limited number of contracts with private health insurers, managed care organizations, government entities and other third-party payors that provide coverage for our products.

We are supporting this field based organization with an internal team which includes product management, communications, commercial analytics and sales operations staff. This team is focused on the implementation of a variety of marketing programs to educate customers, which include direct-to-physician promotional materials, speaker programs, direct-to-patient programs, digital media, participation in selected medical conventions and reimbursement support programs.

In addition, in July 2009, we entered into an exclusive agreement with Astellas under which Sumavel DosePro is currently being marketed by Astellas in the United States and promoted primarily to primary care physicians, OB/GYNs, emergency medicine physicians and urologists by approximately 400 Astellas sales representatives. This allows us to effectively market and sell to a broader physician audience than could be reached by our sales force alone.

In March 2008, we entered into a licensing and distribution agreement with Desitin, a private German pharmaceutical company focused on the development, manufacturing and distribution of products for the treatment of CNS disorders. Under the terms of the agreement, we licensed to Desitin

the exclusive development and commercialization rights to Sumavel DosePro for the European Union, Norway, Switzerland and Turkey. Desitin will oversee, and be responsible for the expenses related to, all clinical development, regulatory approval and commercialization efforts required to market Sumavel DosePro in Germany and any other territories in which Desitin elects to develop and market Sumavel DosePro. We have agreed to manufacture and supply the product to Desitin for commercial sale. Desitin has agreed to pay us a specified transfer price for commercial product and a low single-digit percentage royalty on net sales of the product. We retain full commercial rights to Sumavel DosePro in all other countries not licensed under the Desitin agreement, including the United States, Canada and the countries in Asia. We continue to evaluate potential partnerships to expand the future sale of Sumavel DosePro to additional markets outside of Europe and the United States.

For the launch of ZX002, if approved, we intend to expand our sales and marketing infrastructure, including expanding our field sales force to 250 or more representatives to allow us to reach a broad range of opioid prescribers in our target market and continue to support Sumavel DosePro. We expect our primary target audiences may expand to include anesthesiologists, pain specialists, physical medicine specialists and additional primary care physicians. In addition, we expect that we will also consider opportunities to partner ZX002 to reach a broader physician audience. We will also evaluate third-party co-promotion opportunities that would allow us to strategically leverage our commercial resources and generate additional revenue in the United States.

Competition

The pharmaceutical industry is characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary therapeutics. We face competition from a number of sources which may target the same indications as our product or product candidates, including large pharmaceutical companies, smaller pharmaceutical companies, biotechnology companies, academic institutions, government agencies and private and public research institutions, many of which have greater financial resources, sales and marketing capabilities, manufacturing capabilities, experience in obtaining regulatory approvals for product candidates and other resources than us. We face competition not only in the commercialization of Sumavel DosePro or any product candidates for which we obtain marketing approval from the FDA or other regulatory authorities, but also for the in-licensing or acquisition of additional product candidates, and the out-licensing of our DosePro drug delivery technology.

Sumavel DosePro

Sumavel DosePro competes against other marketed migraine therapeutics. The largest class of marketed prescription products for treatment of migraine is the triptan class. The largest selling triptan is *sumatriptan*, with the branded products Imitrex and Treximet marketed by GSK and Sumavel DosePro marketed by us. There are six other branded triptan therapies being sold by pharmaceutical companies including AstraZeneca PLC, Endo Pharmaceuticals Holdings Inc., Johnson & Johnson, Merck, and Pfizer in the United States.

We also face competition from generic *sumatriptan* injectable, now marketed in the United States as an authorized generic of the autoinjector system by Par Pharmaceutical Companies and Sandoz Inc. (a Novartis AG company). In addition, the FDA recently approved Alsuma (*sumatriptan* injection), a needle-based autoinjector which was developed and is manufactured by Meridian Medical Technologies, a subsidiary of King Pharmaceuticals, Inc., or King, and will be distributed by US WorldMeds, LLC. Finally, generic injectable *sumatriptan* in the form of vials and prefilled syringes is available from the following nine companies: APP Pharma (Fresenius Kabi), Bedford Laboratories, Cura Pharmaceutical Co., Inc., JHP Pharmaceuticals, LLC, Par Pharmaceutical, Sagent Pharmaceuticals, Inc./ Strides Arcolab Limited, Sandoz Inc., Teva Pharmaceutical Industries Limited, and Wockhardt Limited. Although these products and alternative autoinjector forms of *sumatriptan* injection may not be directly substituted for Sumavel DosePro, generic versions of injectable *sumatriptan* may reduce the future

adoption of our Sumavel DosePro by health insurers and consumers, as financial pressure to use generic products may encourage the use of a generic product over Sumavel DosePro. Presently, however, we are seeing little impact from substitution on the uptake of Sumavel DosePro.

In addition to these migraine therapeutics, there are other marketed non-triptan migraine therapeutics, such as Cambia sold by Nautilus Neurosciences, Inc. and Migranal sold by Valeant Pharmaceuticals International. Moreover, there are several product candidates under development that could potentially be used to treat migraines and compete with Sumavel DosePro, including products under development by large pharmaceutical companies such as GSK and Merck and smaller companies such as NuPathe, Inc. and MAP Pharmaceuticals, Inc. In addition, Allergan, Inc. is developing BOTOX botulinum toxin for the potential treatment of chronic migraine.

ZX002

If approved for the treatment of moderate to severe chronic pain, ZX002 will compete against other marketed branded and generic pain therapeutics and may compete with additional product candidates currently under development or developed in the future. Current competitors in the opioid pain therapeutics space include, but are not limited to, Abbott Laboratories, Cephalon, Inc., Endo Pharmaceuticals Holdings Inc., Johnson & Johnson, King, Mallinckrodt Inc., Purdue Pharma L.P., Teva Pharmaceutical Industries Limited and Watson Pharmaceuticals, Inc. There are at least 15 opioid product candidates, including abuse and diversion resistant formulations of currently available opioids, novel opioids and alternative delivery forms of various opioids under development at other pharmaceutical companies, including single-entity extended-release *hydrocodone* product candidates being developed by Cephalon, Inc., Egalet A/S and King. ZX002 may also face competition from non-opioid products, as well as alternative delivery forms of NSAIDs. In addition to the previously named companies, a number of pharmaceutical companies are developing new product candidates for pain including, but not limited to, Acura Pharmaceuticals, Inc., Altea Therapeutics Corporation, Collegium Pharmaceutical, Inc., Eli Lilly and Company, Elite Pharmaceuticals, Inc., Hospira, Inc., Inspirion Delivery Technologies, LLC, Intellipharmaceutics International Inc., Pfizer and QRxPharma Ltd.

DosePro Technology

Traditional needle and syringe remain the primary method for administering intramuscular and subcutaneous injections. The injectable drug market is increasingly adopting new injection systems including pre-filled syringes, pen injectors and autoinjector devices. The majority of these devices, however, still employ a needle. We will compete with companies operating in the needle-based drug delivery market. These companies include, but are not limited to, Becton, Dickinson and Company, Owen Mumford Ltd. and Ypsomed. Additional competition may come from companies focused on out-licensing needle-free technology including Antares Pharma Inc. and Bioject Inc., which have both commercialized spring-driven, multiple-use, patient-filled, needle-free injectors, primarily for injecting human growth hormone or insulin for diabetes. We believe that market acceptance of these devices has been limited due to a combination of the cost of the devices, their large size and their complexity of use. Other companies may also be developing single-use, pre-filled, needle-free delivery systems. We also may experience future competition from alternative delivery systems which bypass the need for an injection, including inhaled, nasal, sublingual or transdermal technologies.

Distribution

We primarily sell Sumavel DosePro to wholesale pharmaceutical distributors, who, in turn, sell the products to pharmacies, hospitals and other customers. Three wholesale pharmaceutical distributors, Cardinal Health, Inc., McKesson Corporation and AmerisourceBergen Corporation, individually comprised 48.2%, 37.2% and 10.2%, respectively, of our total gross sales of Sumavel DosePro for the nine months ended September 30, 2010.

We use a third-party logistics provider, Cardinal Health 105, Inc. (a/k/a Specialty Pharmaceutical Services), for key services related to logistics, warehousing and inventory management, distribution, contract administration and chargeback processing, accounts receivable management and call center management. In addition, we utilize third parties to perform various other services for us relating to sample accountability and regulatory monitoring, including adverse event reporting, safety database management and other product maintenance services.

The following are distribution agreements that we believe are material to the ongoing operation of our business.

Cardinal Health Inc.

In December 2009 and January 2010, we entered into a wholesale purchase agreement and distribution services agreement, respectively, with Cardinal Health, Inc. and its affiliates, or collectively Cardinal Health, pursuant to which it provides us with distribution and inventory management services for Sumavel DosePro. The wholesale purchase agreement covers general terms related to the distribution and inventory management services provided by Cardinal Health, including with respect to the purchase of Sumavel DosePro from us and chargebacks and returns related to such purchases. The distribution services agreement covers the fees payable by us to Cardinal Health for the performance of such services. Under the distribution services agreement, we pay Cardinal Health a quarterly fee based on the volume of Sumavel DosePro purchased by Cardinal Health from us during that quarter.

The distribution services agreement has an initial three-year term, which expires in January 2013, and the wholesale purchase agreement has an initial one-year term, which expires in December 2010. Following the initial term, each agreement automatically renews for successive one-year periods unless either party provides the other party with written notice of non-renewal within a specified period prior to the expiration of the then-current term. Either party may terminate either agreement (1) upon mutual written agreement of the parties, (2) upon written notice if the other party has failed to cure a breach of any of the terms of the agreement within a specified period following receipt of written notice of such breach, or (3) upon institution (whether voluntary or involuntary) of bankruptcy, insolvency, liquidation or similar proceedings by or against the other party or the assignment of the other party s assets for the benefit of creditors. In addition, either party may terminate the distribution services agreement 60 days following termination of the agreement pursuant to which an affiliate of Cardinal Health, Cardinal Health 105, Inc. (a/k/a Specialty Pharmaceutical Services) provides third-party logistics services for us. Cardinal Health may also terminate the distribution services agreement following a change of control of our company if Cardinal Health determines that the transaction gives rise to credit or financial risks. Either party may also terminate the wholesale purchase agreement for any reason by giving the other party specified written notice.

McKesson Corporation

In December 2009, we entered into a strategic redistribution center and core distribution agreement with McKesson Corporation, or McKesson, pursuant to which McKesson provides us with distribution and inventory management services for Sumavel DosePro. We pay McKesson a quarterly fee based on the volume of Sumavel DosePro purchased by McKesson from us during that quarter. The agreement remains in effect unless terminated by either party upon specified written notice to the other party.

Manufacturing

Sumavel DosePro and our DosePro technology are manufactured by contract manufacturers, component fabricators and secondary service providers. Suppliers of components, subassemblies and other materials are located in the United Kingdom, Germany, Ireland and the United States. All contract manufacturers and component suppliers have been selected for their specific competencies in the manufacturing processes and materials that make up the DosePro system. FDA regulations require that

materials be produced under current Good Manufacturing Practices, or cGMPs, or Quality System Regulations, or QSR, as required for the respective unit operation within the manufacturing process. Manufacturing equipment specific to the production of critical DosePro components and assemblies was developed and purchased by us and the prior owners of the DosePro technology and is currently owned by us.

We manage the supply chain for Sumavel DosePro, consisting of the DosePro system and the active pharmaceutical ingredient, or API, internally with experienced operations professionals, including employees residing in the United Kingdom who oversee European contract manufacturing operations. We have entered into long-term supply agreements relating to Sumavel DosePro with our critical contract manufacturers, most component fabricators and secondary service providers to secure long-term commercial supply for Sumavel DosePro and expect manufacturing capacity to adequately support our projected Sumavel DosePro demand through 2011. Each of these manufacturers and each other company that supplies, fabricates or manufactures any component used in our DosePro device is currently the sole qualified source of their respective components. In order to support projected demand after 2011, or if demand exceeds our expectation before then, we will be required to expand the capacity of some of our existing contract manufacturers and suppliers or qualify new manufacturers or suppliers.

DosePro systems intended for clinical trials of DosePro-based products other than Sumavel DosePro are provided by using the existing manufacturing infrastructure, supplemented with clinical scale aseptic fill/finish as appropriate for the stage and scale of the product under clinical development.

Clinical materials for our ZX002 clinical program are manufactured by Elan Drug Delivery, Inc. under the terms of our license agreement with Elan described under Collaborations, Commercial and License Agreements below.

The following are manufacturing and supply arrangements and agreements that we believe are material to the ongoing operation of our business.

Patheon UK Limited

In November 2008, we entered into a manufacturing services agreement with Patheon UK Limited, or Patheon, located in Swindon, United Kingdom, a specialist in the aseptic fill/finish of injectables and other sterile pharmaceutical products. Under the terms of the agreement, Patheon serves as our exclusive manufacturer for the aseptic capsule assembly, filling and inspection, final device assembly and packaging of Sumavel DosePro, as well as other manufacturing and support services. Although we are not required to have any minimum quantity of Sumavel DosePro manufactured under the agreement, we have agreed to provide Patheon with forecasts of the required volumes of Sumavel DosePro we need, and we are required to pay Patheon a monthly manufacturing fee of £283,000, or approximately $448,000 (based on the exchange rate as of September 30, 2010), over the remaining term of the agreement, aggregating to £10,483,000, or approximately $16,569,000. Under the agreement, we are also required to pay support and service fees, with the level of service fees increasing if annual production exceeds a specified volume. The agreement has an initial five-year term, which expires October 31, 2013. The parties may mutually agree in writing to renew the term for additional terms prior to the expiration of the then-current term. Either party may terminate the agreement (1) upon specified written notice to the other party, (2) upon written notice if the other party has failed to remedy a material breach of any of its representations, warranties or other obligations under the agreement within a specified period following receipt of written notice of such breach, and (3) immediately upon written notice to the other party in the event that the other party is declared insolvent or bankrupt by a court of competent jurisdiction, a voluntary petition of bankruptcy is filed in any court of competent jurisdiction by such other party or the agreement is assigned by such other party for the benefit of creditors. Patheon may also terminate the agreement upon specified written notice if we assign the agreement to certain specified parties.

Nypro Limited

Nypro Limited, located in Bray, Ireland, manufactures the actuator assemblies and injection molded components for our DosePro device pursuant to purchase orders. We do not currently have a long-term commercial supply agreement with Nypro.

MGlas AG

In May 2009, we entered into a commercial manufacturing and supply agreement with MGlas AG, located in Schweinfurt, Germany. Under the terms of the agreement, MGlas is our exclusive supplier of the glass capsule that houses the *sumatriptan* API in Sumavel DosePro (and will be the exclusive supplier of glass capsules for any future 0.5 mL DosePro product candidates or products). The agreement has an initial three-year term, which expires in May 2012. Either party may terminate the agreement by providing the other party with specified written notice. In addition, either party may terminate the agreement immediately by written notice if the other party commits a material breach of its obligations which is either incapable of remedy or is not remedied within a specified period following receipt of written notice of such breach, or in the event the other party becomes insolvent or is subject to insolvency-related proceedings.

Dr. Reddy s Laboratories, Inc.

We are party to a supply agreement with Dr. Reddy s Laboratories, Inc., or Dr. Reddy s, which was originally entered into between Aradigm and Dr. Reddy s in September 2004. Under the terms of the agreement, Dr. Reddy s, a global pharmaceutical company and supplier of bulk API located in India, agreed to supply us with the *sumatriptan* API for Sumavel DosePro at a specified price. Dr. Reddy s has agreed to sell to us, and we agreed to purchase on a non-exclusive basis from Dr. Reddy s, not less than 50% of our quarterly requirements for *sumatriptan* in the United States, Canada and the European Union. The initial term of the agreement expires in 2020. The term of the agreement may be extended by us for successive one-year periods by written notice to Dr. Reddy s, unless Dr. Reddy s gives written notice to us that it does not wish to extend the term. We may terminate the agreement upon written notice if Dr. Reddy s is unable to deliver sufficient amounts of *sumatriptan* over a specified period of time. We may also terminate the agreement if we are negotiating an agreement with a third party to commercialize such third party s formulation of *sumatriptan* and such agreement would preclude us from sourcing *sumatriptan* from any party other than such third party. Either party may terminate the agreement upon written notice if the other party commits a material breach of its obligations and fails to remedy the breach within a specified time period, if the other party becomes insolvent or subject to bankruptcy proceedings, or where a force majeure event continues for a specified period of time.

Collaborations, Commercial and License Agreements

Astellas Co-Promotion Agreement

In July 2009, we entered into a co-promotion agreement with Astellas. Under the terms of the agreement, we granted Astellas the co-exclusive right (with us) to market and sell Sumavel DosePro in the United States (excluding Puerto Rico and the other territories and possessions of the United States) until June 30, 2013. Astellas has the option to extend the term of the agreement by an additional year in its sole discretion (and contingent upon Astellas payment to us of a predetermined option fee). In addition, Astellas has a right to opt-in to the commercialization of potential line extensions of Sumavel DosePro. Under the agreement, both Astellas and we are obligated to collaborate and fund the marketing of Sumavel DosePro and to provide annual minimum levels of sales effort directed at Sumavel DosePro during the term. In 2011 and throughout the remainder of the term, these minimum sales efforts are set forth as a minimum number of annual primary detail equivalents. We are responsible for the manufacture, supply, and distribution of commercial product for sale in the United States. In addition, we will supply product samples to Astellas, and Astellas will pay us for such samples, at an agreed upon transfer price.

The target audience for Astellas sales efforts is primarily comprised of prescribers classified as primary care physicians (including internal medicine, family practice and general practice), OB/GYNs, emergency medicine physicians and urologists, or collectively the Astellas Segment. The target audience for our sales effort is primarily comprised of neurologists and other prescribers of migraine medicines who fall outside the Astellas Segment. In addition, our representatives have the right to call upon a specified number of key prescribers within the Astellas Segment; conversely Astellas representatives have the right to call upon a specified number of neurologists.

Under the agreement, Astellas has paid us upfront and milestone payments in an aggregate amount of $20.0 million through September 30, 2010. Astellas is not obligated to pay us any additional milestone payments. In consideration for Astellas performance of its commercial efforts, we are required to pay Astellas a service fee on a quarterly basis that represents a fixed percentage of between 45% and 55% of Sumavel DosePro net sales to the Astellas Segment. Astellas is not compensated for Sumavel DosePro sales to neurologists, any other prescribers not included in the Astellas Segment or for non-retail sales. In addition, upon completion of the co-promotion term, Astellas will be eligible to receive two additional annual tail payments calculated as decreasing fixed percentages (ranging from a mid-twenties down to a mid-teen percentage) of net sales in the Astellas Segment in the last 12 months of its active promotion.

Astellas may terminate the agreement for any reason or no reason upon 180-days written notice to us after September 30, 2010 or at any time in the event we undergo a change of control (as defined in the agreement). In addition, Astellas may terminate the agreement if a governmental authority takes action that prevents or makes it unlawful for Astellas to perform its obligations under the agreement, in the event of our inability to supply commercial product, under certain circumstances where a third party asserts that the making or selling of Sumavel DosePro infringes the intellectual property rights of a third party, or if we materially breach our minimum sales effort obligations and do not cure such breach within a specified period. In the event a termination pursuant to the reasons set forth in the previous sentence takes place prior to July 31, 2011, we would be required to pay Astellas a specified royalty on net sales of Sumavel DosePro up to an aggregate specified dollar amount. Any such payments would be in lieu of the annual tail payments described above. We may terminate the agreement in the event that Astellas materially breaches its minimum sales effort obligations and does not cure such breach within a specified period. Either party may terminate the agreement upon the occurrence of a large scale recall or market withdrawal of Sumavel DosePro, a failure of the Sumavel DosePro brand to achieve certain minimum sales levels in 2010 or 2011, a material uncured breach by the other party, insolvency or bankruptcy of the other party, or other event which affects the other party s ability to perform its obligations under the agreement.

Desitin License and Distribution Agreement

In March 2008, we entered into a licensing and distribution agreement with Desitin. Under the terms of the agreement, we granted Desitin the exclusive right under our intellectual property rights related to Sumavel DosePro to develop, use, distribute, sell, offer for sale, and import Sumavel DosePro and any potential modified versions of Sumavel DosePro in the European Union, Norway, Switzerland and Turkey. Under the agreement, Desitin has the right, but with the exception of Germany not the obligation, at its own expense, to develop, obtain marketing approval and commercialize Sumavel DosePro in these territories. In addition, Desitin has a right of first refusal on the commercialization of any potential line extensions of Sumavel DosePro. We will manufacture and supply the product to Desitin for commercial sale in the licensed territories. Desitin will pay us a specified transfer price for commercial product and a low single-digit percentage royalty on net sales of the product for an initial term, on a country to country basis until the greater of ten years after the first commercial sale in that country or the expiration, in such country, of the last patent right to expire under the licensed technology. After the initial term, in countries where the product has had commercial sales, the agreement will be automatically renewed on a country-by-country basis by additional successive specified periods unless it is terminated by either party giving a specified prior written notice.

Either party may terminate the agreement upon a material uncured breach, insolvency or bankruptcy, adverse event which affects the other party s ability to perform its obligations under the agreement or upon the enactment of any law, decree or regulation which would impair or restrict either our right, title or interest in the intellectual property, or Desitin s right to market or distribute the product in accordance with the agreement, either party s right to terminate or elect not to renew the agreement as provided therein, or our right to collect the purchase price or royalties under the agreement. Either party may also terminate the agreement by giving 90 days prior written notice if continued marketing in the relevant territories is no longer possible due to advice from a relevant regulatory authority or clinical review board in such countries or due to serious adverse events caused by Sumavel DosePro anywhere in the world. Desitin may terminate the agreement upon a competent regulatory authority in the territories either imposing therapeutic indications not acceptable to Desitin or requiring the product to be marketed as a generic drug. Desitin also may terminate the agreement if more than one study regarding bioequivalence is required to obtain marketing authorization. We may terminate the agreement upon a specified prior written notice if in each of a specified number of consecutive calendar years Desitin fails to meet a specified percentage of sales forecasts to be mutually agreed upon under the agreement, if Desitin takes any act impairing our intellectual property rights or if Desitin ceases to carry on business in the marketing of pharmaceutical products in the territories. Desitin may also terminate the agreement, upon written notice, if the price at which we supply our product to Desitin exceeds a specified threshold.

Elan Pharma International Limited License Agreement

In November 2007, we entered into a license agreement with Elan, which was amended in September 2009. Under the terms of this license agreement, Elan granted to us an exclusive license in the United States and its possessions and territories, with defined sub-license rights to third parties other than certain technological competitors of Elan, to certain Elan intellectual property rights related to our ZX002 product candidate. The agreement grants us the exclusive right under certain Elan patents and patent applications to import, use, offer for sale and sell oral controlled-release capsule or tablet formulations of *hydrocodone*, where *hydrocodone* is the sole active ingredient, for oral prescriptions in the treatment or relief of pain, pain syndromes or pain associated with medical conditions or procedures in the United States. This right enables us to exclusively develop and sell ZX002 in the United States. Elan has retained the exclusive right to take action in the event of infringement or threatened infringement by a third party of Elan s intellectual property rights under the agreement. We have the right to pursue an infringement claim against the alleged infringer should Elan decline to take or continue an action.

Under the terms of the agreement, the parties agreed that, subject to the future negotiation of a commercial manufacture and supply agreement, Elan, or an affiliate of Elan, will have the sole and exclusive right to manufacture and supply finished commercial product of ZX002 to us under agreed upon financial terms.

Elan also granted to us, in the event that Elan is unwilling or unable to manufacture or supply commercial product to us, a non-exclusive license to make product under Elan s intellectual property rights. This non-exclusive license also includes the right to sublicense product manufacturing to a third party, other than certain technological competitors of Elan.

Under the license agreement, we paid an upfront fee to Elan of $500,000. We may be obligated to pay Elan up to $4.5 million in total future milestone payments with respect to ZX002 depending upon the achievement of various development and regulatory events. We are also required to pay a mid single-digit percentage royalty on net sales of the product for an initial royalty term equal to the longer of the expiration of Elan s patents covering the product in the United States, or 15 years after commercial launch, if Elan does not have patents covering the product in the United States. After the initial royalty term, the license agreement will continue automatically for three-year rolling periods during which we will continue to pay royalties on net sales of the product at a reduced low single-digit percentage rate in accordance with the terms of the license agreement.

Either party may terminate the agreement upon a material, uncured default or certain insolvency events of the other party or upon 12 months written notice prior to the end of the initial royalty term or any additional three-year rolling period. Elan may terminate the agreement in the event that we fail to meet specified development and commercialization milestones within specified time periods. We may terminate this agreement if the sale of ZX002 is prohibited by regulatory authorities, or if, despite commercially reasonable efforts, we are unable to obtain regulatory approval for ZX002. We may also terminate the agreement, with or without cause, at any time upon six months written notice prior to NDA approval for ZX002 and at any time upon 12 months prior written notice after NDA approval for ZX002.

Aradigm Corporation Asset Purchase Agreement

In August 2006, we entered into an asset purchase agreement with Aradigm. Under the terms of the agreement, Aradigm assigned and transferred to us all of its right, title and interest to tangible assets and intellectual property related to the DosePro (formerly known as Intraject) needle-free drug delivery system. Aradigm also granted to us a non-exclusive, fully paid, worldwide, perpetual, irrevocable, transferable, sublicensable license under all other intellectual property of Aradigm that was owned, controlled or employed by Aradigm prior to the closing of the asset purchase and that is necessary or useful to the development, manufacture or commercialization of the DosePro delivery system. Aradigm also retained a worldwide, royalty-free, non-exclusive license, with a right to sublicense, under all transferred intellectual property rights solely for purposes of the pulmonary field, and we granted Aradigm a license under other intellectual property rights solely for use in the pulmonary field.

At the time of the closing of the asset purchase, we paid to Aradigm a sum of $4.0 million as consideration. Under the agreement, we also paid a subsequent milestone payment to Aradigm of $4.0 million upon the U.S. commercialization of Sumavel DosePro in February 2010. We are also required to pay a 3% royalty on global net sales of Sumavel DosePro, by us or one of our licensees, if any, until the later of January 2020 or the expiration of the last valid claim of the transferred patents covering the manufacture, use, or sale of the product.

In addition, in the event we or one of our future licensees, if any, commercializes a non-*sumatriptan* product in the DosePro delivery system, we will be required to pay Aradigm, at our election, either a 3% royalty on net sales of each non-*sumatriptan* product commercialized, or a fixed low-twenties percentage of the royalty revenues received by us from the licensee, if any, until the later of the ten year anniversary of first commercial sale of the product in the United States or the expiration of the last valid claim of the transferred patents covering the manufacture, use or sale of the product. Royalty revenues under this agreement include, if applicable, running royalties on the net sales of non-*sumatriptan* products, license or milestone fees not allocable to development or other related costs incurred by us, payments in consideration of goods or products in excess of their cost, or payments in consideration for equity in excess of the then fair market value of the equity.

Intellectual Property

Our success will depend to a significant extent on our ability to obtain, expand and protect our intellectual property estate, enforce patents, maintain trade secret and trademark protection and operate without infringing the proprietary rights of other parties.

Needle-free Drug Delivery Technologies

Sumavel DosePro is a new drug-device combination that subcutaneously delivers *sumatriptan* utilizing our proprietary needle-free drug delivery system to treat migraine and cluster headache. Our patent portfolio is directed to various types and components of needle-free and other drug delivery systems. As of September 30, 2010, we have 15 issued U.S. patents, nine pending U.S. patent applications, 46 issued foreign patents and 22 pending foreign patent applications. Of the above, we have seven issued U.S. patents, three pending U.S. patent applications, 28 issued foreign patents and six pending foreign patent applications relating to various aspects of Sumavel DosePro and our DosePro technology.

Our issued U.S. Patent No. 5,891,086 covers a particular activator mechanism forming a part of the needleless injector device, and is expected to expire in 2014. We have a corresponding patent in Canada, and two each in Germany, Spain, France, United Kingdom, Italy and Japan, which are all expected to expire in 2013. Our issued U.S. Patent No. 6,135,979 covers a needleless injector with particular safety mechanisms, and is expected to expire in 2017. We have corresponding patents in Germany, France, United Kingdom and Japan, which are all expected to expire in 2016. Our issued U.S. Patent No. 5,957,886 claims a needleless injector system using a viscous damping medium, and is expected to expire in 2016. We have corresponding patents (one each in Canada, Germany, France, United Kingdom and Japan), which are all expected to expire in 2015. U.S. Patents 5,891,086; 6,135,979; and 5,957,886 are listed in the FDA Orange Book for Sumavel DosePro.

We have two U.S. patents and two pending foreign patent applications in Canada and Europe corresponding to methods of proof testing glass drug containers, such as those used in the manufacture of Sumavel DosePro. These patents, and applications if they issue, are expected to expire in 2023. We also have one U.S. patent and one each in Canada, Germany, France and the United Kingdom corresponding to methods of filling needle-free injector capsules, such as those used in the manufacture of Sumavel DosePro. These patents, and applications if they issue, are expected to expire in 2022.

We also have two pending U.S. patent applications, four foreign patents (one each in Germany, France, Japan and the United Kingdom), and one pending foreign patent application in Canada corresponding to needle-free injector drug capsules and methods for filling capsules with liquid drug, such as those used in the manufacture of Sumavel DosePro. These patents, and applications if they issue, are expected to expire in 2022.

Our remaining issued U.S. patents, pending U.S. patent applications, issued foreign patents, and pending foreign patent applications are not currently used in Sumavel DosePro, but may be used with alternate versions of, or future product candidates utilizing, our DosePro technology.

We do not have patent protection for Sumavel DosePro in a significant number of countries, including large territories such as India, Russia and China, and we will be unable to prevent infringement in those countries. Additionally, the three U.S. patents listed in the FDA Orange Book for Sumavel DosePro expire in 2014, 2016 and 2017. Upon expiration, we will lose certain advantages that come with Orange Book listing of patents and will no longer be able to prevent others in the U.S. from practicing the inventions claimed by the three patents.

ZX002

ZX002 is an oral version of an opioid pain reliever, which is designed to offer a controlled-release profile that utilizes Elan s proprietary SODAS delivery system. Our in-licensed patents from Elan relating to ZX002 include one issued U.S. Patent No. 6,902,742 and a pending U.S. Patent Application No. 11/372,857. The license agreement is described above in further detail. The issued patent is expected to expire in November 2019. Absent any award of patent term extensions, the patent application, if it issues, is not expected to expire later than this date.

Government Regulation

FDA Approval Process

In the United States, pharmaceutical products are subject to extensive regulation by the FDA. The FFDCA and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of pharmaceutical products. Failure to comply with applicable FDA or other requirements may subject a company to a variety of administrative or judicial sanctions, such as the FDA s refusal to approve pending applications, a clinical hold, warning letters, recall or seizure of products, partial or total

suspension of production, withdrawal of the product from the market, injunctions, fines, civil penalties or criminal prosecution.

FDA approval is required before any new unapproved drug or dosage form, including a new use of a previously approved drug, can be marketed in the United States. The process required by the FDA before a drug may be marketed in the United States generally involves:

- completion of pre-clinical laboratory and animal testing and formulation studies in compliance with the FDA s good laboratory practice, or GLP, regulations;
- submission to the FDA of an IND for human clinical testing which must become effective before human clinical trials may begin in the United States;
- approval by an independent institutional review board, or IRB, at each clinical trial site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with good clinical practices, or GCP, to establish the safety and efficacy of the proposed drug product for each intended use;
- satisfactory completion of an FDA pre-approval inspection of the facility or facilities at which the product is manufactured to assess compliance with the FDA s cGMP regulations, and for devices and device components, the QSR, and to assure that the facilities, methods and controls are adequate to preserve the drug s identity, strength, quality and purity;
- submission to the FDA of a new drug application, or NDA;
- satisfactory completion of an FDA advisory committee review, if applicable; and
- FDA review and approval of the NDA.

The pre-clinical and clinical testing and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our product candidates will be granted on a timely basis, if at all. Pre-clinical tests include laboratory evaluation of product chemistry, formulation, stability and toxicity, as well as animal studies to assess the characteristics and potential safety and efficacy of the product. The results of pre-clinical tests, together with manufacturing information, analytical data and a proposed clinical trial protocol and other information, are submitted as part of an IND to the FDA. Some pre-clinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions relating to one or more proposed clinical trials and places the clinical trial on a clinical hold, including concerns that human research subjects will be exposed to unreasonable health risks. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, our submission of an IND may not result in FDA authorization to commence a clinical trial. A separate submission to an existing IND must also be made for each successive clinical trial conducted during product development.

Further, an independent IRB, covering each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and informed consent information for subjects before the trial commences at that site and it must monitor the study until completed. The FDA, the IRB, or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk or for failure to comply with the IRB s requirements, or may impose other conditions.

As a separate amendment to an IND, a sponsor may submit a request for an SPA from the FDA. Under the SPA procedure, a sponsor may seek the FDA s agreement on the proposed design and size of a clinical trial intended to form the primary basis for determining a product s efficacy. Upon specific request by a sponsor, the FDA will evaluate the protocol and respond to a sponsor s questions regarding, among other things, primary efficacy endpoints, trial conduct and data analysis within

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45 days of receipt of the request. The FDA ultimately assesses whether the protocol design and planned analysis of the trial adequately address objectives in support of a regulatory submission. Agreements and disagreements between the FDA and the sponsor regarding an SPA are documented by the FDA in an SPA letter to the sponsor or in the minutes of a meeting between the sponsor and the FDA. Even if the FDA agrees to the design, execution and analyses proposed in protocols reviewed under an SPA, the FDA may revoke or alter its agreement under certain circumstances, including:

public health concerns emerge that were unrecognized at the time of the protocol assessment;

a sponsor fails to follow a protocol that was agreed upon with the FDA;

the relevant data, assumptions, or information provided by the sponsor in a request for an SPA change are found to be false or to omit relevant facts; or

the FDA and the sponsor agree in writing to modify the protocol and such modification is intended to improve the study.

Clinical trials involve the administration of the investigational new drug to human subjects under the supervision of qualified investigators in accordance with GCP requirements, which include the requirement that all research subjects provide their informed consent in writing for their participation in any clinical trial. Sponsors of clinical trials generally must register and report, at the NIH-maintained website ClinicalTrials.gov, key parameters of certain clinical trials. For purposes of an NDA submission and approval, human clinical trials are typically conducted in the following three sequential phases, which may overlap or be combined:

Phase 1: The drug is initially introduced into healthy human subjects or patients and tested for safety, dose tolerance, absorption, metabolism, distribution and excretion and, if possible, to gain an early indication of its effectiveness.

Phase 2: The drug is administered to a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted indications and to determine dose tolerance and optimal dosage. Multiple Phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more extensive Phase 3 clinical trials.

Phase 3: These are commonly referred to as pivotal studies. When Phase 2 evaluations demonstrate that a dose range of the product appears to be effective and has an acceptable safety profile, Phase 3 trials are undertaken in large patient populations to further evaluate dosage, to obtain additional evidence of clinical efficacy and safety in an expanded patient population at multiple, geographically-dispersed clinical trial sites, to establish the overall risk-benefit relationship of the drug and to provide adequate information for the labeling of the drug.

Phase 4: In some cases, the FDA may condition approval of an NDA for a product candidate on the sponsor s agreement to conduct additional clinical trials to further assess the drug s safety and effectiveness after NDA approval. Such post-approval trials are typically referred to as Phase 4 studies.

The results of product development, pre-clinical studies and clinical trials are submitted to the FDA as part of an NDA. NDAs must also contain extensive information relating to the product s pharmacology, chemistry, manufacture, controls and proposed labeling, among other things.

For some drugs, especially controlled substances, the FDA may require a risk evaluation and mitigation strategies, or REMS, which could include measures imposed by the FDA such as prescribing restrictions, requirements for post-marketing studies or certain restrictions on distribution and use. Under federal law, the submission of most NDAs is additionally subject to a substantial application user fee, and the manufacturer and/or sponsor under an approved NDA are also subject to annual product and establishment user fees. The FDA has 60 days from its receipt of an NDA to determine whether the

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application will be accepted for filing based on the agency s threshold determination that it is sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the NDA must be resubmitted with the additional information and is subject to payment of additional user fees. The resubmitted application is also subject to review before the FDA accepts it for filing.

Once the submission has been accepted for filing, the FDA begins an in-depth substantive review. Under the Prescription Drug User Fee Act, or PDUFA, the FDA agrees to specific performance goals for NDA review time through a two-tiered classification system, Standard Review and Priority Review. Standard Review NDAs have a goal of being completed within a ten-month timeframe. A Priority Review designation is given to drugs that offer major advances in treatment, or provide a treatment where no adequate therapy exists. The goal for completing a Priority Review is six months. It is likely that our product candidates will be granted a Standard Review. The review process may be extended by the FDA for three additional months to consider certain information or obtain clarification regarding information already provided in the submission. The FDA may refer applications for novel drug products or drug products which present difficult questions of safety or efficacy to an advisory committee for review, evaluation and recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendation of an advisory committee, but it considers such recommendations carefully when making decisions. In addition, for combination products like Sumavel DosePro or future product candidates utilizing the DosePro technology, the FDA s review may include the participation of both the FDA s Center for Drug Evaluation and Research and the FDA s Center for Devices and Radiological Health, which may complicate or prolong the review.

Before approving an NDA, the FDA may inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP, and if applicable, QSR, requirements and are adequate to assure consistent production of the product within required specifications. Additionally, the FDA will typically inspect one or more clinical sites to assure compliance with GCP before approving an NDA.

After the FDA evaluates the NDA and, in some cases, the related manufacturing facilities, it may issue an approval letter or a Complete Response Letter, or CRL, to indicate that the review cycle for an application is complete and that the application is not ready for approval. CRLs generally outline the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when the deficiencies have been addressed to the FDA s satisfaction, the FDA will typically issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications.

Once issued, the FDA may withdraw product approval if ongoing regulatory requirements are not met or if safety problems are identified after the product reaches the market. In addition, the FDA may require post-approval testing, including Phase 4 studies, and surveillance programs to monitor the effect of approved products which have been commercialized, and the FDA has the power to prevent or limit further marketing of a product based on the results of these post-marketing programs. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved label, and, even if the FDA approves a product, it may limit the approved indications for use for the product or impose other conditions, including labeling or distribution restrictions or other risk-management mechanisms. Further, if there are any modifications to the drug, including changes in indications, labeling, or manufacturing processes or facilities, we may be required to submit and obtain FDA approval of a new or supplemental NDA, which may require us to develop additional data or conduct additional pre-clinical studies and clinical trials.

Post-Approval Requirements

Once an NDA is approved, a product will be subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to drug/device listing, recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. There also are extensive U.S. Drug Enforcement Agency, or DEA, regulations applicable to marketed controlled substances.

In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and state agencies, and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and generally require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. While physicians may prescribe for off label uses, manufacturers may only promote for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off label uses, and a company that is found to have improperly promoted off label uses may be subject to significant liability.

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act, or PDMA, which regulates the distribution of drugs and drug samples at the federal level, and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution, including a drug pedigree which tracks the distribution of prescription drugs.

The FDA may require post-approval studies and clinical trials if the FDA finds that scientific data, including information regarding related drugs, deem it appropriate. The purpose of such studies would be to assess a known serious risk or signals of serious risk related to the drug or to identify an unexpected serious risk when available data indicate the potential for a serious risk. The FDA may also require a labeling change if it becomes aware of new safety information that it believes should be included in the labeling of a drug.

The FDA also has the authority to require a drug-specific risk evaluation and mitigation strategy, or REMS, to ensure the safe use of the drug. In determining whether a REMS is necessary, FDA must consider the size of the population likely to use the drug, the seriousness of the disease or condition to be treated, the expected benefit of the drug, the duration of treatment, the seriousness of known or potential adverse events, and whether the drug is a new molecular entity. If the FDA determines a REMS is necessary, the drug sponsor must agree to the REMS plan at the time of approval. A REMS may be required to include various elements, such as a medication guide or patient package insert, a communication plan to educate health care providers of the drug s risks, limitations on who may prescribe or dispense the drug, or other measures that the FDA deems necessary to assure the safe use of the drug. In addition, the REMS must include a timetable to assess the strategy at 18 months, three years, and seven years after the strategy s approval. The FDA may also impose a REMS requirement on a drug already on the market if the FDA determines, based on new safety information, that a REMS is necessary to ensure that the drug s benefits outweigh its risks.

In February 2009, the FDA informed drug manufacturers that it will require a REMS for sustained release opioid drug products. Subsequently, the FDA initiated efforts to develop a new standardized REMS for these opioid medications to ensure their safe use. A controlled-release formulation of *hydrocodone* would also be required to have a REMS. The FDA s authority to take this action is based on risk management and post market safety provisions within the FDAAA. We intend to submit a REMS at the time of the NDA submission for ZX002.

With respect to post-market product advertising and promotion, the FDA imposes a number of complex regulations on entities that advertise and promote pharmaceuticals, which include, among others, standards for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities, and promotional activities involving the internet. The FDA has very broad enforcement authority under the FFDCA, and failure to abide by these regulations can result in penalties, including the issuance of a warning letter directing entities to correct deviations from FDA standards, a requirement that future advertising and promotional materials be pre-cleared by the FDA, and state and federal civil and criminal investigations and prosecutions.

Section 505(b)(2) New Drug Applications

As an alternate path to FDA approval for modifications to formulations or uses of products previously approved by the FDA, an applicant may submit an NDA under Section 505(b)(2) of the FFDCA. Section 505(b)(2) was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Amendments, and permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The applicant may rely upon published literature and the FDA s findings of safety and effectiveness based on certain pre-clinical or clinical studies conducted for an approved product. The FDA may also require companies to perform additional studies or measurements to support the change from the approved product. The FDA may then approve the new product candidate for all or some of the label indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant.

To the extent that a Section 505(b)(2) NDA relies on studies conducted for a previously approved drug product, the applicant is required to certify to the FDA concerning any patents listed for the approved product in the Orange Book. Specifically, the applicant must certify for each listed patent that (1) the required patent information has not been filed; (2) the listed patent has expired; (3) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (4) the listed patent is invalid, unenforceable or will not be infringed by the new product. A certification that the new product will not infringe the already approved product s listed patent or that such patent is invalid is known as a Paragraph IV certification. If the applicant does not challenge the listed patents through a Paragraph IV certification, the Section 505(b)(2) NDA application will not be

approved until all the listed patents claiming the referenced product have expired. The Section 505(b)(2) NDA application also will not be accepted or approved until any non-patent exclusivity, such as exclusivity for obtaining approval of a New Chemical Entity, listed in the Orange Book for the referenced product, has expired.

If the 505(b)(2) NDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the referenced NDA and patent holders once the 505(b)(2) NDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a legal challenge to the Paragraph IV certification. Under the FFDCA, the filing of a patent infringement lawsuit within 45 days of their receipt of a Paragraph IV certification in most cases automatically prevents the FDA from approving the Section 505(b)(2) NDA for 30 months, or until a court decision or settlement finding that the patent is invalid, unenforceable or not infringed, whichever is earlier. The court also has the ability to shorten or lengthen the 30 month stay if either party is found not to be reasonably cooperating in expediting the litigation. Thus, the Section 505(b)(2) applicant may invest a significant amount of time and expense in the development of its product only to be subject to significant delay and patent litigation before its product may be commercialized.

The 505(b)(2) NDA applicant also may be eligible for its own regulatory exclusivity period, such as three-year exclusivity. The first approved 505(b)(2) applicant for a particular condition of approval, or change to a marketed product, such as a new extended release formulation for a previously approved product, may be granted three-year Hatch-Waxman exclusivity if one or more clinical studies, other than bioavailability or bioequivalence studies, was essential to the approval of the application and was conducted/sponsored by the applicant. Should this occur, the FDA would be precluded from making effective any other application for the same condition of use or for a change to the drug product that was granted exclusivity until after that three-year exclusivity period has run. Additional exclusivities may also apply.

Additionally, the 505(b)(2) NDA applicant may have relevant patents in the Orange Book, and if it does can initiate patent infringement litigation against those applicants that challenge such patents, which could result in a thirty-month stay delaying those applicants.

DEA Regulation

One of our product candidates, ZX002, will be regulated as a controlled substance as defined in the Controlled Substances Act of 1970, or CSA, which establishes registration, security, recordkeeping, reporting, storage, distribution and other requirements administered by the DEA. The DEA is concerned with the control of handlers of controlled substances, and with the equipment and raw materials used in their manufacture and packaging, in order to prevent loss and diversion into illicit channels of commerce.

The DEA regulates controlled substances as Schedule I, II, III, IV or V substances. Schedule I substances by definition have no established medicinal use, and may not be marketed or sold in the United States. A pharmaceutical product may be listed as Schedule II, III, IV or V, with Schedule II substances considered to present the highest risk of abuse and Schedule V substances the lowest relative risk of abuse among such substances. ZX002, our proprietary oral, controlled-release version of *hydrocodone*, is expected to be listed by the DEA as a Schedule II controlled substance under the CSA. Consequently, its manufacture, shipment, storage, sale and use will be subject to a high degree of regulation. For example, all Schedule II drug prescriptions must be signed by a physician, physically presented to a pharmacist and may not be refilled without a new prescription.

Annual registration is required for any facility that manufactures, distributes, dispenses, imports or exports any controlled substance. The registration is specific to the particular location, activity and controlled substance schedule. For example, separate registrations are needed for import and manufacturing, and each registration will specify which schedules of controlled substances are authorized.

The DEA typically inspects a facility to review its security measures prior to issuing a registration. Security requirements vary by controlled substance schedule, with the most stringent requirements applying to Schedule I and Schedule II substances. Required security measures include background checks on employees and physical control of inventory through measures such as cages, surveillance cameras and inventory reconciliations. Records must be maintained for the handling of all controlled substances, and periodic reports made to the DEA, for example distribution reports for Schedule I and II controlled substances, Schedule III substances that are narcotics, and other designated substances. Reports must also be made for thefts or losses of any controlled substance, and to obtain authorization to destroy any controlled substance. In addition, special authorization and notification requirements apply to imports and exports.

In addition, a DEA quota system controls and limits the availability and production of controlled substances in Schedule I or II. Distributions of any Schedule I or II controlled substance must also be accompanied by special order forms, with copies provided to the DEA. Because ZX002, an oral, controlled-release version of *hydrocodone*, is expected to be regulated as a Schedule II controlled substance, it will be subject to the DEA s production and procurement quota scheme. The DEA establishes annually an aggregate quota for how much *hydrocodone* may be produced in total in the United States based on the DEA s estimate of the quantity needed to meet legitimate scientific and medicinal needs. This limited aggregate amount of *hydrocodone* that the DEA allows to be produced in the United States each year is allocated among individual companies, who must submit applications annually to the DEA for individual production and procurement quotas. We and our contract manufacturers must receive an annual quota from the DEA in order to produce or procure any Schedule I or Schedule II substance, including *hydrocodone* for use in manufacturing ZX002. The DEA may adjust aggregate production quotas and individual production and procurement quotas from time to time during the year, although the DEA has substantial discretion in whether or not to make such adjustments. Our, or our contract manufacturers , quota of an active ingredient may not be sufficient to meet commercial demand or complete clinical trials. Any delay or refusal by the DEA in establishing our, or our contract manufacturers , quota for controlled substances could delay or stop our clinical trials or product launches, which could have a material adverse effect on our business, financial position and results of operations.

To meet its responsibilities, the DEA conducts periodic inspections of registered establishments that handle controlled substances. Failure to maintain compliance with applicable requirements, particularly as manifested in loss or diversion, can result in enforcement action that could have a material adverse effect on our business, results of operations and financial condition. The DEA may seek civil penalties, refuse to renew necessary registrations, or initiate proceedings to revoke those registrations. In certain circumstances, violations could eventuate in criminal proceedings.

Individual states also regulate controlled substances, and we and our contract manufacturers will be subject to state regulation on distribution of these products.

International Regulation

In addition to regulations in the United States, we will be subject to a variety of foreign regulations regarding safety and efficacy and governing, among other things, clinical trials and commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we must obtain the necessary approvals by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country and can involve additional product testing and additional review periods, and the time may be longer or shorter than that required to obtain FDA approval and, if applicable, DEA classification. The requirements governing, among other things, the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others.

Under European Union regulatory systems, marketing authorizations may be submitted either under a centralized or decentralized procedure. The centralized procedure provides for the grant of a single marketing authorization that is valid for all European Union member states. The decentralized procedure provides for mutual recognition of national approval decisions. Under this procedure, the holder of a national marketing authorization may submit an application to the remaining member states. Within 90 days of receiving the applications and assessment report, each member state must decide whether to recognize approval.

In addition to regulations in Europe and the United States, we will be subject to a variety of other foreign regulations governing, among other things, the conduct of clinical trials, pricing and reimbursement and commercial distribution of our products. If we fail to comply with applicable foreign regulatory requirements, we may be subject to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Desitin submitted a Marketing Authorization Application for Sumavel DosePro to the Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM)) in Germany, the reference member state, through the Decentralized Procedure in October 2009.

Healthcare Fraud and Abuse Laws

We are subject to various federal, state and local laws targeting fraud and abuse in the healthcare industry. For example, in the United States, there are federal and state anti-kickback laws that prohibit the payment or receipt of kickbacks, bribes or other remuneration intended to induce the purchase or recommendation of healthcare products and services or reward past purchases or recommendations. Violations of these laws can lead to civil and criminal penalties, including fines, imprisonment and exclusion from participation in federal healthcare programs. These laws are potentially applicable to manufacturers of products regulated by the FDA, such as us, and hospitals, physicians and other potential purchasers of such products.

In particular, the federal Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, receiving, offering or providing remuneration, directly or indirectly, to induce either the referral of an individual, or the furnishing, recommending, or arranging for a good or service, for which payment may be made under a federal healthcare program such as the Medicare and Medicaid programs. The term remuneration is not defined in the federal Anti-Kickback Statute and has been broadly interpreted to include anything of value, including for example, gifts, discounts, the furnishing of supplies or equipment, credit arrangements, payments of cash, waivers of payments, ownership interests and providing anything at less than its fair market value. In addition, the recently enacted Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively, the PPACA, among other things, amends the intent requirement of the federal Anti-Kickback Statute and the applicable criminal healthcare fraud statutes contained within 42 U.S.C. § 1320a-7b effective March 23, 2010. Pursuant to the statutory amendment, a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. In addition, the PPACA provides that the government may assert that a claim including items or services resulting from a violation of 42 U.S.C. § 1320a-7b constitutes a false or fraudulent claim for purposes of the civil False Claims Act (discussed below) or the civil monetary penalties statute, which imposes fines against any person who is determined to have presented or caused to be presented claims to a federal health care program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent. Moreover, the lack of uniform court interpretation of the Anti-Kickback Statute makes compliance with the law difficult.

Recognizing that the Anti-Kickback Statute is broad and may technically prohibit many innocuous or beneficial arrangements within the healthcare industry, the U.S. Department of Health and Human Services Office of Inspector General, or OIG, issued regulations in July of 1991, and periodically since that time, which the OIG refers to as safe harbors. These safe harbor regulations set forth certain

provisions which, if met in form and substance, will assure pharmaceutical companies, healthcare providers and other parties that they will not be prosecuted under the federal Anti-Kickback Statute. Additional safe harbor provisions providing similar protections have been published intermittently since 1991. Although full compliance with these provisions ensures against prosecution under the federal Anti-Kickback Statute, the failure of a transaction or arrangement to fit within a specific safe harbor does not necessarily mean that the transaction or arrangement is illegal or that prosecution under the federal Anti-Kickback Statute will be pursued. However, conduct and business arrangements that do not fully satisfy each applicable safe harbor may result in increased scrutiny by government enforcement authorities, such as the OIG or federal prosecutors. Additionally, there are certain statutory exceptions to the federal Anti-Kickback Statute, one or more of which could be used to protect a business arrangement, although we understand that OIG is of the view that an arrangement that does not meet the requirements of a safe harbor cannot satisfy the corresponding statutory exception, if any, under the federal Anti-Kickback Statute.

Additionally, many states have adopted laws similar to the federal Anti-Kickback Statute. Some of these state prohibitions apply to referral of patients for healthcare items or services reimbursed by any third-party payor, not only the Medicare and Medicaid programs in at least some cases, and do not contain safe harbors. Government officials have focused their enforcement efforts on marketing of healthcare services and products, among other activities, and have brought cases against numerous pharmaceutical and medical device companies, and certain sales and marketing personnel for allegedly offering unlawful inducements to potential or existing customers in an attempt to procure their business or reward past purchases or recommendations.

Another development affecting the healthcare industry is the increased use of the federal civil False Claims Act and, in particular, actions brought pursuant to the False Claims Act s whistleblower or qui tam provisions. The civil False Claims Act imposes liability on any person or entity who, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment by a federal healthcare program. The qui tam provisions of the False Claims Act allow a private individual to bring civil actions on behalf of the federal government alleging that the defendant has submitted a false claim to the federal government, and to share in any monetary recovery. In recent years, the number of suits brought by private individuals has increased dramatically. In addition, various states have enacted false claim laws analogous to the False Claims Act. Many of these state laws apply where a claim is submitted to any third-party payor and not merely a federal healthcare program. When an entity is determined to have violated the False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties of $5,500 to $11,000 for each separate false claim. There are many potential bases for liability under the False Claims Act. Liability arises, primarily, when an entity knowingly submits, or causes another to submit, a false claim for reimbursement to the federal government. The False Claims Act has been used to assert liability on the basis of inadequate care, kickbacks and other improper referrals, improperly reported government pricing metrics such as Best Price or Average Manufacturer Price, improper use of Medicare numbers when detailing the provider of services, improper promotion of off-label uses (i.e., uses not expressly approved by FDA in a drug s label), and allegations as to misrepresentations with respect to the services rendered. Our activities relating to the reporting of discount and rebate information and other information affecting federal, state and third party reimbursement of our products, and the sale and marketing of our products and our service arrangements or data purchases, among other activities, may be subject to scrutiny under these laws. We are unable to predict whether we would be subject to actions under the False Claims Act or a similar state law, or the impact of such actions. However, the cost of defending such claims, as well as any sanctions imposed, could adversely affect our financial performance.

Also, the Health Insurance Portability and Accountability Act of 1996, or HIPAA, created several new federal crimes, including health care fraud, and false statements relating to health care matters. The health care fraud statute prohibits knowingly and willfully executing a scheme to defraud any health care benefit program, including private third-party payors. The false statements statute prohibits

knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for health care benefits, items or services.

In addition, under California law, pharmaceutical companies must adopt a comprehensive compliance program that is in accordance with both the April 2003 Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers, or OIG Guidance, and the Pharmaceutical Research and Manufacturers of America Code on Interactions with Healthcare Professionals, or the PhRMA Code. The PhRMA Code seeks to promote transparency in relationships between health care professionals and the pharmaceutical industry and to ensure that pharmaceutical marketing activities comport with the highest ethical standards. The PhRMA Code contains strict limitations on certain interactions between health care professionals and the pharmaceutical industry relating to gifts, meals, entertainment and speaker programs, among others. Also, certain states, such as Massachusetts and Minnesota, have imposed restrictions on the types of interactions that pharmaceutical and medical device companies or their agents (e.g., sales representatives) may have with health care professionals, including bans or strict limitations on the provision of meals, entertainment, hospitality, travel and lodging expenses, and other financial support, including funding for continuing medical education activities.

Healthcare Privacy and Security Laws

We may be subject to, or our marketing activities may be limited by, HIPAA, and its implementing regulations, which established uniform standards for certain covered entities (healthcare providers, health plans and healthcare clearinghouses) governing the conduct of certain electronic healthcare transactions and protecting the security and privacy of protected health information. The American Recovery and Reinvestment Act of 2009, commonly referred to as the economic stimulus package, included sweeping expansion of HIPAA s privacy and security standards called the Health Information Technology for Economic and Clinical Health Act, or HITECH, which became effective on February 17, 2010. Among other things, the new law makes HIPAA s privacy and security standards directly applicable to business associates independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney s fees and costs associated with pursuing federal civil actions.

Third-Party Payor Coverage and Reimbursement

The commercial success of Sumavel DosePro and our product candidates, if and when commercialized, will depend, in part, upon the availability of coverage and reimbursement from third-party payors at the federal, state and private levels. Third-party payors include governmental programs such as Medicare or Medicaid, private insurance plans and managed care plans. These third-party payors may deny coverage or reimbursement for a product or therapy in whole or in part if they determine that the product or therapy was not medically appropriate or necessary. Also, third-party payors have attempted to control costs by limiting coverage through the use of formularies and other cost-containment mechanisms and the amount of reimbursement for particular procedures or drug treatments.

Changes in third-party payor coverage and reimbursement rules can impact our business. For example, the PPACA changes include increased rebates a manufacturer must pay to the Medicaid program and establishes a new Medicare Part D coverage gap discount program, in which manufacturers must provide 50% point-of-sale discounts on products covered under Part D beginning in 2011. Further, also beginning in 2011, the new law imposes a significant annual, nondeductible fee on companies that manufacture or import branded prescription drug products. Substantial new provisions

affecting compliance have also been enacted, which may require us to modify our business practices with health care practitioners. We will not know the full effects of PPACA until applicable federal and state agencies issue regulations or guidance under the new law and these provisions are implemented. Although it is too early to determine the full effect of PPACA, the new law appears likely to continue the pressure on pharmaceutical pricing, and may also increase our regulatory burdens and operating costs. Moreover, in the coming years, additional changes could be made to governmental healthcare programs that could significantly impact the success of our products.

In addition, the cost of pharmaceuticals and devices continues to generate substantial governmental and third party payor interest. We expect that the pharmaceutical industry will experience pricing pressures due to the trend toward managed health care, the increasing influence of managed care organizations and additional legislative proposals. Our results of operations and business could be adversely affected by current and future third-party payor policies as well as health care legislative reforms.

Some third-party payors also require pre-approval of coverage for new or innovative devices or drug therapies before they will reimburse health care providers who use such therapies. While we cannot predict whether any proposed cost-containment measures will be adopted or otherwise implemented in the future, these requirements or any announcement or adoption of such proposals could have a material adverse effect on our ability to obtain adequate prices for Sumavel DosePro and our product candidates and to operate profitably.

In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. There can be no assurance that our products will be considered medically reasonable and necessary for a specific indication, that our products will be considered cost-effective by third-party payors, that an adequate level of reimbursement will be available or that the third-party payors reimbursement policies will not adversely affect our ability to sell our products profitably.

Manufacturing Requirements

We and our third-party manufacturers must comply with applicable FDA regulations relating to FDA s cGMP regulations and, if applicable, QSR requirements. The cGMP regulations include requirements relating to, among other things, organization of personnel, buildings and facilities, equipment, control of components and drug product containers and closures, production and process controls, packaging and labeling controls, holding and distribution, laboratory controls, records and reports, and returned or salvaged products. The manufacturing facilities for our products must meet cGMP requirements to the satisfaction of the FDA pursuant to a pre-approval inspection before we can use them to manufacture our products. We and our third-party manufacturers are also subject to periodic unannounced inspections of facilities by the FDA and other authorities, including procedures and operations used in the testing and manufacture of our products to assess our compliance with applicable regulations. Failure to comply with statutory and regulatory requirements subjects a manufacturer to possible legal or regulatory action, including, among other things, warning letters, the seizure or recall of products, injunctions, consent decrees placing significant restrictions on or suspending manufacturing operations and civil and criminal penalties.

Other Regulatory Requirements

We are also subject to various laws and regulations regarding laboratory practices, the experimental use of animals, and the use and disposal of hazardous or potentially hazardous substances in connection with our research. In each of these areas, as above, the FDA has broad regulatory and enforcement powers, including, among other things, the ability to levy fines and civil penalties, suspend or delay issuance of approvals, seize or recall products, and withdraw approvals, any one or more of which could have a material adverse effect on us.

Legal Proceedings

We are not currently a party to any legal proceeding.

Employees

As of September 30, 2010, we employed 145 full-time employees. Of the full-time employees, 101 were engaged in sales and marketing, 11 were engaged in manufacturing operations, 18 were engaged in product development, quality assurance and clinical and regulatory activities and 15 were engaged in general and administrative activities (including business and corporate development). We do not anticipate significant growth in the number of our full-time employees unless and until we need to prepare for the launch of ZX002. None of our employees are represented by a labor union, and we consider our employee relations to be good. We currently utilize TriNet Employer Group, Inc., an employer services company, to provide human resource services. TriNet Employer Group is the employer of record for payroll, benefits, employee relations and other employment-related administration.

Facilities

Our facilities are located in San Diego and Emeryville, California. Our general and administrative and sales and marketing personnel are located at our San Diego facility. Our manufacturing operations, product development, quality assurance and clinical and regulatory personnel are located in our Emeryville facility.

We occupy 12,128 square feet of office and laboratory space in Emeryville under a lease which expires in 2015. We believe that the space in Emeryville is adequate to meet our needs there, and that, if necessary, additional space can be leased to accommodate any future growth.

We occupy 12,929 square feet of office space in San Diego under a lease which expires in 2011. We can extend the lease on the San Diego office for two additional periods of 36 months no later than six months prior to the end of the term. We believe additional space can be leased to accommodate our potential growth.

The manufacturing equipment used to produce our DosePro technology is currently located at our contract manufacturers and component suppliers facilities in Europe where we occupy an aggregate of more than 20,000 square feet of space that is used to manufacture Sumavel DosePro.

MANAGEMENT

Executive Officers, Key Employees and Directors

The following table sets forth certain information about our executive officers, key employees and directors as of October 31, 2010:

Name	Age	Position
Executive Officers		
Roger L. Hawley	58	Chief Executive Officer and Director
Stephen J. Farr, Ph.D.	51	President, Chief Operating Officer and Director
Ann D. Rhoads	45	Executive Vice President, Chief Financial Officer, Treasurer and Secretary
Cynthia Y. Robinson, Ph.D.	52	Chief Development Officer
Key Employees		
Stephen H. Jenner	42	Senior Director, Marketing
Bret E. Megargel	41	Vice President, Corporate Development
Jonathan M. Rigby	43	Vice President, Business Development
Edward F. Smith III, Ph.D., RAC	57	Vice President, Regulatory Affairs and Safety
Mark R. Thompson	58	Vice President, Sales & Managed Markets
John J. Turanin	53	Vice President & General Manager, Zogenix Technologies
Directors		
Cam L. Garner(1)(2)	62	Chairman of the Board of Directors
James C. Blair, Ph.D.(1)	71	Director
Louis C. Bock(3)	45	Director
Ken Haas(2)	59	Director
Erle T. Mast(2)(3)	48	Director
Arda M. Minocherhomjee, Ph.D.(1)(3)	57	Director
Kurt C. Wheeler(1)	57	Director

(1) Member of the Compensation Committee.

(2) Member of the Nominating/Corporate Governance Committee.

(3) Member of the Audit Committee.

Executive Officers

Roger L. Hawley is one of our co-founders and has served as our Chief Executive Officer and as a member of our board of directors since August 2006. From January 2006 to August 2006, Mr. Hawley served as a consultant to CG Pharma, Inc. From August 2003 to January 2006 he served as Executive Vice President, Commercial and Technical Operations for InterMune, Inc., a biopharmaceutical company focused on therapies in hepatology and pulmonology. From October 2002 to July 2003, Mr. Hawley was the Chief Commercial Officer at Prometheus Laboratories Inc., a specialty pharmaceutical and diagnostics company. From 2001 to 2002, Mr. Hawley served as General Manager & Vice President of Sales and Marketing at Elan Pharmaceuticals, Inc. From 1987 to 2001, Mr. Hawley held a broad range of management positions in commercial operations, alliance/partnership management, and regional sales and corporate finance at GlaxoSmithKline, or GSK. His last position at GSK was Vice President of Sales-CNS/GI Division. From 1976 to 1987, he held various financial management positions with Marathon Oil Company, including serving four years in London, England. While at Marathon, he was a certified treasury manager and a certified public accountant. Mr. Hawley is a member of the board of directors of Cypress Bioscience, Inc., a publicly-traded pharmaceutical company. Mr. Hawley holds a B.Sc. in Accounting from Eastern Illinois University. As one of our co-founders and having served

as our Chief Executive Officer since August 2006, Mr. Hawley s extensive knowledge of our business, history and culture, as well as over 20 years of experience in the pharmaceutical industry, including providing strong executive leadership to numerous biopharmaceutical companies, contributed to our board of directors conclusion that he should serve as a director of our company.

Stephen J. Farr, Ph.D. is one of our co-founders and has served as our President and as a member of our board of directors since our inception in May 2006. From May 2006 to August 2006, Dr. Farr also served as our Chief Executive Officer and since August 2006, Dr. Farr has served as our Chief Operating Officer. From 1995 to August 2006, Dr. Farr held positions of increasing responsibility within pharmaceutical sciences and research and development at Aradigm Corporation, and he served most recently as Senior Vice President and Chief Scientific Officer. In 2003, he played a key role in identifying and acquiring the DosePro technology and became technical director and executive sponsor for the development of *sumatriptan* DosePro at Aradigm Corporation. From 1986 to 1994, Dr. Farr was a tenured professor at the Welsh School of Pharmacy, Cardiff University, United Kingdom, concentrating in the areas of physical pharmacy and biopharmaceutics. He is a fellow of the American Association of Pharmaceutical Scientists and visiting Associate Professor in the Department of Pharmaceutics, School of Pharmacy, Virginia Commonwealth University. Dr. Farr is a registered pharmacist in the United Kingdom and obtained his Ph.D. degree in Pharmaceutics from the University of Wales. As one of our co-founders and having served as our President since May 2006, Dr. Farr s extensive knowledge of our business, history and culture, including his in-depth involvement with the DosePro technology and the development of Sumavel DosePro, as well as his significant experience in research and development and thorough knowledge of the pharmaceutical product development process, contributed to our board of directors conclusion that he should serve as a director of our company.

Ann D. Rhoads has served as our Executive Vice President, Chief Financial Officer, Treasurer and Secretary since March 2010. From 2000 to December 2009, Ms. Rhoads was the Chief Financial Officer and Senior Vice President for Premier, Inc., a healthcare service company, where she had responsibility for all areas of financial management, strategic planning, business development, information technology, and ethics and compliance. From August 1998 to 2000, Ms. Rhoads served as Vice President for strategic initiatives at Premier, where she was responsible for overseeing strategic investments, including a $30 million venture capital fund, as well as assisting Premier operating divisions with long range strategic planning. Prior to joining Premier, Ms. Rhoads held various positions at Sprout Group, a venture capital affiliate of Donaldson, Lufkin & Jenrette (now part of Credit Suisse First Boston), Bain & Company and Merrill Lynch Capital Partners (now known as Stonington Partners). Ms. Rhoads is a member of the board of directors of Novellus Systems, Inc. Ms. Rhoads received an M.B.A. from the Harvard Business School and a B.S. from the University of Arkansas.

Cynthia Y. Robinson, Ph.D. has served as our Chief Development Officer since April 2008, after consulting for us from April 2007 to April 2008. From November 2004 to July 2007, Dr. Robinson served as Senior Vice President, Development Operations at InterMune, Inc. From April 1989 to August 2004, Dr. Robinson held positions of increasing responsibility at Elan Pharmaceuticals, Inc., serving most recently as Vice President, Project Management, where she oversaw a portfolio of 14 global development programs from pre-clinical through commercialization, including multiple products in the therapeutic areas of CNS and pain. These efforts resulted in nine U.S. New Drug Applications, four European Marketing Authorization Applications and four U.S. product launches. Dr. Robinson holds a B.S. in Chemistry and a Ph.D. in Organic Chemistry from the University of Alabama.

Key Employees

Stephen H. Jenner has served as our Senior Director of Marketing since July 2008. From November 2007 to July 2008, Mr. Jenner served as the Senior Vice President of Client Services at MedAccess Communications, an advertising agency specializing in the pharmaceutical industry. From June 2005 to November 2007, Mr. Jenner served as the Senior Director of Marketing for Valeant Pharmaceuticals International, a publicly-held pharmaceutical company, where he led the Neurology Marketing

Department. From July 2003 to June 2005, Mr. Jenner was the Senior Product Manager for Allergan Pharmaceuticals, a publicly-held pharmaceutical company, where he was the lead marketer for all Direct to Consumer activities related to BOTOX Cosmetic. From October 1998 to July 2003, Mr. Jenner held positions of increasing responsibility at Elan Pharmaceuticals, a publicly-held pharmaceutical company, most recently as Product Manager for the CNS/Movement Disorder Franchise. Mr. Jenner holds an M.B.A. from the University of Florida, and a B.S. in Business Administration from California Lutheran University.

Bret E. Megargel is one of our co-founders and has served as our Vice President of Corporate Development since August 2006. From December 2005 to August 2006, Mr. Megargel served as a consultant to CG Pharma, Inc. From January 2005 to August 2007, Mr. Megargel served as Vice President of Planet Technologies, Inc., an allergy products company, where he was responsible for the general management of the company s Allergy Free business. From 2002 to December 2004, Mr. Megargel served as Vice President of Business Development for Avera Pharmaceuticals, Inc., a private, central nervous system-focused development company. From 1999 to 2002, Mr. Megargel served as a Venture Partner for Windamere Venture Partners, LLC. During his tenure at Windamere, Mr. Megargel served as Vice President of Business Development for MD Edge, Inc., and Director of Business Development for Converge Medical, Inc. and was a member of the founding team of Dexcom, Inc. From 1991 to 1996, Mr. Megargel served as a consultant for The Healthcare Group of Marketing Corporation of America (now a Division of The InterPublic Group), where he was a case manager for projects that included major product development, licensing and acquisition, and marketing strategy assignments for pharmaceutical clients. Mr. Megargel received an M.B.A. at the Stanford University Graduate School of Business and is a graduate of Dartmouth College, where he obtained a B.A. in Economics.

Jonathan M. Rigby is one of our co-founders and has served as our Vice President of Business Development since August 2006. From 2002 to August 2006, Mr. Rigby served as Vice President Business Development at Aradigm Corporation, where he was responsible for the strategic acquisition of the DosePro technology and related assets in 2003. In 2006, Mr. Rigby co-led the management buy out of the DosePro assets from Aradigm Corporation and the associated venture financing of the company. From 1995 to 2002, Mr. Rigby served as Head of Business Development, Head of Competitive Intelligence and Head of UK Sales for Profile Therapeutics UK. Earlier in his career, Mr. Rigby served in various sales and marketing capacities for Merck & Co., Inc. and Bristol Myers Squibb. Mr. Rigby is a frequent speaker at industry conferences in the drug delivery sector and serves as Chairman of the Board of the Association of Needle Free Injection Manufacturers. Mr. Rigby earned his undergraduate degree in Biological Sciences with Honors from Sheffield University, UK. He also holds a British Technology Higher National Diploma in Applied Biology from Sheffield University, UK and an M.B.A. from Portsmouth University, UK.

Edward F. Smith III, Ph.D., RAC has served as our Vice President, Regulatory Affairs and Drug Safety since October 2008. From April 2007 to October 2008, he was our Senior Director, Regulatory Affairs. From July 2006 to April 2007, he was the Senior Director, Regulatory Affairs at Connetics, a specialty pharmaceutical company focused on the development and commercialization of innovative therapeutics for the dermatology market. From October 2004 to July 2006, he was the Director, Regulatory Affairs at Nektar Therapeutics, a biopharmaceutical company. Dr. Smith has authored over 90 peer-reviewed scientific articles and has submitted numerous U.S. Food and Drug Administration and European Medicines Agency submissions. He was a Postdoctoral Fellow at the Medical University of South Carolina and the Institute of Pharmacology at the University of Koln in West Germany. Dr. Smith received an M.B.A. at Washington University and a Ph.D. in Physiology at Thomas Jefferson University. He is a graduate of Montana State University where he obtained his B.S. in Biology.

Mark R. Thompson has served as our Vice President, Sales and Managed Markets since April 2008. From January 2006 to July 2007, Mr. Thompson served as Vice President, Sales of Valeant Pharmaceuticals International, a multinational specialty pharmaceutical company, where he led both the hepatology and neuroscience sales teams, as well as management of sales operations, analytics, and

training. From March 2004 to December 2005, Mr. Thompson was the Vice President, Sales at InterMune, Inc., a biopharmaceutical company. From October 2002 to March 2004, Mr. Thompson was the Vice President, Sales at SkinMedica, Inc., a company focused on developing, acquiring and commercializing products that treat dermatologic conditions and improve the appearance of skin, and from August 2001 to October 2002 he served as Senior Director, National Sales for Elan Biopharmaceuticals, Inc., Primary Care Division leading a sales team of approximately 500 people. From July 1980 to August 2001, Mr. Thompson held positions of increasing responsibility at GSK serving most recently as Regional Vice President, where his responsibilities included sales of Imitrex® and other CNS products. Mr. Thompson holds a M.Ed. in Administration and Supervision from the University of North Carolina, Chapel Hill.

John J. Turanin is one of our co-founders and has served as our Vice President and General Manager, Zogenix Technologies since August 2010 and prior to that as our Vice President, Operations since our inception in May 2006. From 1997 to April 2006, Mr. Turanin served as Vice President, Corporate Planning and Program Management and held positions as Senior Director of Program Management, Director of New Product Planning, and Director of Respiratory Products Business Unit at Aradigm Corporation, a specialty pharmaceutical company, where he was responsible for leading numerous product development programs and strategic alliances. Mr. Turanin was also responsible for directing Aradigm s integration of the DosePro technology acquisition and serving as program director for the *sumatriptan* DosePro development program. From 1987 to 1996, Mr. Turanin was General Manager of operations, quality, product development, and marketing for the respiratory therapeutics division at Invacare Corporation, a global manufacturer of home medical products. Mr. Turanin holds an M.B.A. from the University of Pittsburgh and a B.A. in Business from Indiana University of Pennsylvania.

Board of Directors

Cam L. Garner is one of our co-founders and has served as chairman of our board of directors since August 2006. Mr. Garner co-founded specialty pharmaceutical companies Cadence Pharmaceuticals, Inc., Somaxon Pharmaceuticals, Inc., Evoke Pharma, Inc., Elevation Pharmaceuticals, Inc., DJ Pharma, Xcel Pharmaceuticals, Inc. and Meritage Pharma, Inc. He has served as Chairman of Cadence, Evoke, Elevation and Meritage since May 2004, January 2007, December 2007 and February 2008, respectively. Xcel was acquired in March 2005 by Valeant Pharmaceuticals International and DJ Pharma was sold to Biovail in 2000. He was Chief Executive Officer of Dura Pharmaceuticals, Inc. from 1989 to 1995 and its Chairman and Chief Executive Officer from 1995 to 2000 until it was sold to Elan in November 2000. Mr. Garner also serves on the board of directors of Aegis Therapeutics, Inc. Mr. Garner earned an M.B.A. from Baldwin-Wallace College and his B.A. in Biology from Virginia Wesleyan College. As one of our co-founders and having served as our chairman since August 2006, Mr. Garner s extensive knowledge of our business, history and culture, his extensive experience as a board member of multiple publicly-traded and privately-held companies, and expertise in developing, financing and providing strong executive leadership to numerous biopharmaceutical companies, contributed to our board of directors conclusion that he should serve as a director of our company.

James C. Blair, Ph.D. has served as a member of our board of directors since August 2006. Dr. Blair is a Managing Member of Domain Associates, LLC, and he has been a Partner of Domain since its founding in 1985. Dr. Blair s present board memberships include Astute Medical Inc., Cadence Pharmaceuticals, Cell Biosciences, Clovis Oncology, Inc., CoDa Therapeutics, Five Prime Therapeutics, GenVault, IntegenX, Inc., Meritage Pharma and NeuroPace. Dr. Blair has over 40 years experience with venture and emerging growth companies. In the course of this experience, he has been involved in the creation and successful development at the Board level of over 40 life sciences ventures, including Amgen, Aurora Biosciences, Amylin Pharmaceuticals, Applied Biosystems, Dura Pharmaceuticals, GeneOhm Sciences, Molecular Dynamics, Nuvasive, Pharmion and Volcano. A former managing director of Rothschild Inc., Dr. Blair was directly involved at a senior level with Rothschild/New Court venture capital activities from 1978 to 1985. From 1969 to 1978, he was associated with F.S. Smithers and

Co. and White, Weld and Co., two investment banking firms actively involved with new ventures and emerging growth companies. From 1961 to 1969, Dr. Blair was an engineering manager with RCA Corporation, during which time he received a David Sarnoff Fellowship. Dr. Blair currently serves on the Board of Directors of the Prostate Cancer Foundation, and he is on the Advisory Boards of the Department of Molecular Biology at Princeton University, the Department of Biomedical Engineering at the University of Pennsylvania, the USC Stevens Institute for Innovation, and the Division of Chemistry and Chemical Engineering at the California Institute of Technology. Dr. Blair received a B.S.E. from Princeton University and an M.S.E and Ph.D. from the University of Pennsylvania. With more than forty years experience at the board level with venture and emerging growth companies, Dr. Blair s extensive expertise in the evaluation of financing alternatives, strategic planning for life sciences companies, and substantial executive leadership skills, contributed to our board of directors conclusion that he should serve as a director of our company.

Louis C. Bock has served as a member of our board of directors since August 2006. Mr. Bock is a Managing Director of Scale Venture Partners, a venture capital firm. Mr. Bock joined Scale Venture Partners in September 1997 from Gilead Sciences, Inc., a biopharmaceutical company, where he held positions in research, project management, business development and sales from September 1989 to September 1997. Prior to Gilead, he was a research associate at Genentech, Inc. from November 1987 to September 1989. He currently serves as a director of Ascenta Therapeutics, Inc., VaxGen, Inc., Horizon Therapeutics, Inc., Orexigen Therapeutics, Inc. and Sonexa Therapeutics, Inc. and is responsible for Scale Venture Partners prior investments in Seattle Genetics, Prestwick Pharmaceuticals, Inc. and Somaxon Pharmaceuticals, Inc. Mr. Bock received his B.S. in Biology from California State University, Chico and an M.B.A. from California State University, San Francisco. Mr. Bock s extensive clinical and leadership experience in the biotechnology and biopharmaceuticals industries, including experience in research, project management, business development and sales from his time at Gilead, and his membership on other companies boards of directors, including positions on other audit and nominating/corporate governance committees, contributed to our board of directors conclusion that he should serve as a director of our company.

Ken Haas has served as a member of our board of directors since April 2009. Mr. Haas has been a Venture Partner at Abingworth Management Inc. since July 2006 and previously served as a consultant to the firm beginning in January 2005. He has spent 25 years in the management of both private and public high technology and private biotechnology companies. He was part of the founding management team at IntelliGenetics, one of the world s first bioinformatics companies and, from 1992 to 2001, was CEO of IntelliCorp, a publicly-traded enterprise software company. At the beginning of his career he practiced as an attorney in the business and technology group of Heller, Ehrman, White & McAuliffe. Mr. Haas directorships include Broncus Technologies, Inc., Gynesonics, Inc., Intellikine Inc. and Pathwork Diagnostics, Inc. He received a B.A. from Harvard College, an M.A. from the University of Sussex, a J.D. from Harvard Law School and attended the Advanced Management Program at Harvard Business School. Mr. Haas background as a chief executive officer of a publicly-traded company, his management experience across various sectors, and his experience as a venture capitalist focused in the biopharmaceutical industry, bring to our board critical skills related to financial oversight of complex organizations, financing and strategic planning, and contributed to our conclusion that he should serve as a director of our company.

Erle T. Mast has served as a member of our board of directors since May 2008. Mr. Mast has served as Executive Vice President, Chief Financial Officer with Clovis Oncology since May 2009. From July 2002 to May 2008, Mr. Mast served as Executive Vice President and Chief Financial Officer of Pharmion Corporation, until its acquisition by Celgene Corporation. From 2000 to 2002, after Elan Pharma International Ltd. acquired Dura Pharmaceuticals, Inc., Mr. Mast served as Chief Financial Officer for the Global Biopharmaceuticals business unit of Elan. From 1997 to 2000, Mr. Mast served as Vice President of Finance for Dura Pharmaceuticals. From 1984 to 1997, Mr. Mast held positions of increasing responsibility at Deloitte & Touche, LLP, serving most recently as Partner, where he provided

accounting, auditing and business consulting services to companies in various industries, including the healthcare, pharmaceutical, biotech and manufacturing industries. Mr. Mast also serves on the board of directors of Somaxon Pharmaceuticals, Inc. Mr. Mast received a B.Sc. in Business Administration from California State University Bakersfield. Mr. Mast s experience as a former chief financial officer of various companies in the healthcare industry and in providing accounting, auditing and consulting services while at Deloitte & Touche, LLP, as well as his expertise in management, accounting, treasury, and finance functions, contributed to our board of directors conclusion that he should serve as a director of our company.

Arda M. Minocherhomjee, Ph.D. has served as a member of our Board of Directors since December 2009. Dr. Minocherhomjee has been a Partner of Chicago Growth Partners since he co-founded the firm in 2004. Prior to founding Chicago Growth Partners, Dr. Minocherhomjee was a Managing Director at William Blair Capital Partners and, currently, is a Managing Director and member of the Board of Managers of WBCP VI and VII. Prior to that, Dr. Minocherhomjee was a Senior Healthcare Analyst at William Blair & Company. As head of the firm s Healthcare Research Group, Dr. Minocherhomjee covered several sectors, including drugs/drug delivery, medical devices and selected healthcare services. He was a Wall Street Journal All-Star Analyst in both medical device and pharmaceutical sectors. Dr. Minocherhomjee s current and past directorships include: DJ Pharma, EndoGastric Solutions, Genoptix, Lanx, Morton Grove Pharmaceuticals, NovaVision, NuVasive, PharmaResearch Corporation, Proteome, TargeGen, and Xoft. Dr. Minocherhomjee received a MS (Pharmacology) from the University of Toronto, a Ph.D. and a M.B.A. from the University of British Columbia, and was a post-doctoral fellow in Pharmacology at the University of Washington Medical School. Dr. Minocherhomjee s experience as a founder of a private equity firm, significant participation on the boards of directors of various pharmaceutical companies and substantial knowledge of the pharmaceutical industry, contributed to our board of directors conclusion that he should serve as a director of our company.

Kurt C. Wheeler has served as a member of our board of directors since August 2006. Mr. Wheeler is a Managing Director of Clarus Ventures, a venture capital firm, a position he has held since February 2005, and is a General Partner of MPM Capital BioVentures II and III funds, a position he has held since March 2000. From March 1992 to September 1998, Mr. Wheeler was Chairman and Chief Executive Officer of InControl, Inc., a publicly traded medical device company that designed, developed, and marketed implantable medical devices to treat irregular heart rhythms, which was sold to Guidant Corporation. Mr. Wheeler serves on the board of directors of several private medial device and biopharmaceutical companies. Mr. Wheeler holds a B.A. degree from Brigham Young University and a M.B.A. degree from Northwestern University, where he serves on the Kellogg Alumni Advisory Board. Mr. Wheeler s background as a chief executive officer of a large, publicly-traded company, his extensive experience at the board level in various biopharmaceutical companies and his experience as a venture capitalist focused in the biopharmaceutical industry, bring to our board critical skills related to financial oversight of complex organizations, financing and strategic planning, and contributed to our board of directors conclusion that he should serve as a director of our company.

Board Composition and Election of Directors

Our board of directors is currently authorized to have nine members and is currently composed of seven non-employee members, our current Chief Executive Officer, Roger L. Hawley, and our current President and Chief Operating Officer, Stephen J. Farr, Ph.D. Each of our non-employee directors, Cam L. Garner, James C. Blair, Ph.D., Louis C. Bock, Ken Haas, Erle T. Mast, Arda M. Minocherhomjee, Ph.D. and Kurt C. Wheeler, is independent within the meaning of the independent director standards of the Securities and Exchange Commission, or SEC, and the Nasdaq Stock Market, or Nasdaq. Upon completion of this offering, our amended and restated certificate of incorporation will provide for a classified board of directors consisting of three classes of directors, each serving staggered three-year terms. As a result, a portion of our board of directors will be elected each year. Our Class I directors, whose terms will expire at our first annual meeting of stockholders following this offering, will be

Messrs. Bock, Garner and Haas. Our Class II directors, whose terms will expire at our second annual meeting of stockholders following this offering, will be Drs. Blair, Farr and Minocherhomjee. Our Class III directors, whose terms will expire at our third annual meeting of stockholders following this offering, will be Messrs. Hawley, Mast and Wheeler. This classification of our board of directors may have the effect of delaying or preventing changes in our control or management. Our directors may be removed only for cause by the affirmative vote of the holders of at least 66 2/3% of our outstanding voting stock then entitled to vote in the election of directors.

Risk Oversight

Our board of directors has responsibility for the oversight of the company s risk management processes and, either as a whole or through its committees, regularly discusses with management our major risk exposures, their potential impact on our business and the steps we take to manage them. The risk oversight process includes receiving regular reports from board committees and members of senior management to enable our board to understand the company s risk identification, risk management and risk mitigation strategies with respect to areas of potential material risk, including operations, finance, legal, regulatory, strategic and reputational risk.

The audit committee reviews information regarding liquidity and operations, and oversees our management of financial risks. Periodically, the audit committee reviews our policies with respect to risk assessment, risk management, loss prevention and regulatory compliance. Oversight by the audit committee includes direct communication with our external auditors, and discussions with management regarding significant risk exposures and the actions management has taken to limit, monitor or control such exposures. The compensation committee is responsible for assessing whether any of our compensation policies or programs has the potential to encourage excessive risk-taking. The nominating/corporate governance committee manages risks associated with the independence of the board, corporate disclosure practices, and potential conflicts of interest. While each committee is responsible for evaluating certain risks and overseeing the management of such risks, the entire board is regularly informed through committee reports about such risks. Matters of significant strategic risk are considered by our board as a whole.

Board Diversity

Our nominating/corporate governance committee is responsible for reviewing with the board of directors the appropriate characteristics, skills and experience required for the board of directors as a whole and its individual members. In evaluating the suitability of individual candidates (both new candidates and current members), the nominating/corporate governance committee, in recommending candidates for election, and the board of directors, in approving (and, in the case of vacancies, appointing) such candidates, takes into account many factors, including: personal and professional integrity, ethics and values; experience in corporate management, such as serving as an officer or former officer of a publicly held company; commercialization experience in large pharmaceutical companies; strong finance experience; experience relevant to our industry; experience as a board member of another publicly held company; diversity of expertise and experience in substantive matters pertaining to our business relative to other board members; diversity of background and perspective; and practical and mature business judgment. The board of directors evaluates each individual in the context of the board of directors as a whole, with the objective of assembling a group that can best maximize the success of our business and represent stockholder interests through the exercise of sound judgment using its diversity of experience in these various areas.

Board Committees

Our board of directors has established three committees: the audit committee, the compensation committee and the nominating/corporate governance committee. Our board of directors may establish other committees to facilitate the management of our business.

Audit Committee

Our audit committee consists of Messrs. Mast (chairman and audit committee financial expert) and Bock and Dr. Minocherhomjee, each of whom our board of directors has determined is independent within the meaning of the independent director standards of the SEC and Nasdaq.

This committee s main function is to oversee our accounting and financial reporting processes, internal systems of control, independent registered public accounting firm relationships and the audits of our financial statements. This committee s responsibilities include, among other things:

- selecting and engaging our independent registered public accounting firm;
- evaluating the qualifications, independence and performance of our independent registered public accounting firm;
- approving the audit and non-audit services to be performed by our independent registered public accounting firm;
- reviewing the design, implementation, adequacy and effectiveness of our internal controls and our critical accounting policies;
- discussing with management and the independent registered public accounting firm the results of our annual audit and the review of our quarterly unaudited financial statements;
- reviewing, overseeing and monitoring the integrity of our financial statements and our compliance with legal and regulatory requirements as they relate to financial statements or accounting matters;
- reviewing with management and our auditors any earnings announcements and other public announcements regarding our results of operations;
- preparing the report that the SEC requires in our annual proxy statement;
- reviewing and approving any related party transactions and reviewing and monitoring compliance with our code of conduct and ethics; and
- reviewing and evaluating, at least annually, the performance of the audit committee and its members including compliance of the audit committee with its charter.

Compensation Committee

Our compensation committee consists of Drs. Blair and Minocherhomjee and Messrs. Garner (chairman) and Wheeler. Each member of our compensation committee is a non-employee director, as defined in Rule 16b-3 promulgated under the Securities Exchange Act of 1934, as amended, is an outside director, as defined pursuant to Section 162(m) of the Internal Revenue Code of 1986, as amended, or the IRC, and satisfies the Nasdaq independence requirements. This committee s purpose is to assist our board of directors in determining the development plans and compensation for our senior management and directors and recommend these plans to our board. This committee s responsibilities include, among other things:

reviewing our compensation philosophy, including our policies and strategy relative to executive compensation;

reviewing and recommending to the full board for approval the compensation of our chief executive officer;

reviewing and approving the compensation of our other executive officers, including executive employment and severance agreements;

reviewing and recommending to the full board for approval the compensation policies for members of our board of directors and board committees;

reviewing, approving and administering our benefit plans and the issuance of stock options and other awards under our equity incentive plans (other than any such awards that must be approved by the full board);

reviewing and discussing with management our compensation discussion and analysis to be included in our annual proxy report or annual report on Form 10-K and producing the report that the SEC requires in our annual proxy statement; and

reviewing and evaluating, at least annually, the performance of the compensation committee and its members including compliance of the compensation committee with its charter.

Nominating/Corporate Governance Committee

Our nominating/corporate governance committee consists of Messrs. Garner (chairman), Haas and Mast, each of whom our board of directors has determined is independent within the meaning of the independent director standards of Nasdaq. This committee s purpose is to assist our board of directors by identifying individuals qualified to become members of our board of directors, consistent with criteria set by our board, and to develop our corporate governance principles. This committee s responsibilities include among other things:

evaluating the composition, size and governance of our board of directors and its committees and making recommendations regarding future planning and the appointment of directors to our committees;

administering a policy for considering stockholder nominees for election to our board of directors;

evaluating and recommending candidates for election to our board of directors;

developing guidelines for board compensation;

overseeing our board of directors performance and self-evaluation process;

reviewing our corporate governance principles and providing recommendations to the board regarding possible changes; and

reviewing and evaluating, at least annually, the performance of the nominating/corporate governance committee and its members including compliance of the nominating/corporate governance committee with its charter.

Compensation Committee Interlocks and Insider Participation

None of the members of our compensation committee has ever been one of our officers or employees. None of our executive officers currently serves, or has served, as a member of the board of directors or compensation committee, or other committee serving an equivalent function, of any entity that has one or more of its executive officers serving as a member of our board of directors or compensation committee.

Code of Business Conduct and Ethics

Prior to the completion of this offering, we expect to adopt a code of business conduct and ethics that applies to our officers, directors and employees. We expect that our code of business conduct and ethics will be available on our website at www.zogenix.com upon the completion of this offering. We intend to disclose any amendments to the code, or waivers to its requirements, on our website.

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COMPENSATION DISCUSSION AND ANALYSIS

Overview

This compensation discussion and analysis provides information about the material components of our executive compensation program for our named executive officers, consisting of the following persons:

- Roger L. Hawley, our chief executive officer;
- Stephen J. Farr, Ph.D., our president and chief operating officer;
- David W. Nassif, J.D., our former executive vice president, chief financial officer, treasurer and secretary;
- Cynthia Y. Robinson, Ph.D., our chief development officer; and
- J.D. Haldeman, our former chief commercial officer.

Mr. Nassif resigned from his position as executive vice president and chief financial officer in February 2010. In March 2010, we appointed Ann Rhoads as our new executive vice president, chief financial officer, treasurer and secretary. Ms. Rhoads is not currently a named executive officer but will be a named executive officer for our 2010 fiscal year.

Ms. Haldeman resigned from her position as chief commercial officer in July 2010.

Specifically, this compensation discussion and analysis provides an overview of our executive compensation philosophy, the overall objectives of our executive compensation program, and each compensation component that we provide. In addition, we explain how and why the compensation committee and our board of directors arrived at specific compensation policies and decisions involving our executive officers during the year ended December 31, 2009.

Objectives of Our Compensation Program

We recognize that the ability to excel depends on the integrity, knowledge, imagination, skill, diversity and teamwork of our employees. To this end, we strive to create an environment of mutual respect, encouragement and teamwork an environment that rewards commitment and performance and that is responsive to the needs of our employees. The objectives of our compensation and benefits programs for our employees generally, and for our named executive officers specifically, are to:

- attract, engage and retain the workforce that helps ensure our future success;
- motivate and inspire employee behavior that fosters a high-performance culture;
- support a cost-effective and flexible business model;
- reinforce key business objectives; and

align employee interests with stockholder interests.

Most of our compensation elements simultaneously fulfill one or more of these objectives. These elements consist of (1) base salary, (2) performance bonus, (3) long-term equity incentives, (4) retirement savings opportunity, (5) perquisites, health and welfare benefits and other compensation and (6) post-termination benefits. We believe that each component aligns the interests of our named executive officers with the interests of our stockholders in different ways, whether through focusing on short-term and long-term performance goals, promoting an ownership mentality toward one s job, linking individual performance to our performance or by ensuring healthy employees. This mix of compensation is intended to ensure that total compensation reflects our overall success or failure and to motivate executive officers to meet appropriate performance measures. In determining each element of compensation for any given year, our board of directors and our compensation committee consider and

determine each element individually and then review the resulting total compensation and determine whether it is reasonable and competitive. We have no pre-established policy or target for the allocation between either cash and non-cash or short-term and long-term incentive compensation. Each of these compensation elements is described in more detail below.

The compensation programs in which our named executive officers participate are additionally designed to tie annual and long-term cash and equity incentives to the achievement of specified performance objectives and to align executives incentives with the interests of our stockholders.

Compensation Determination Process

The compensation committee of our board of directors develops, reviews and approves each of the elements of the executive compensation program of our company as a whole and for our named executive officers individually, although the full board of directors still makes certain compensation decisions with respect to our named executive officers when the compensation committee deems it to be appropriate. With respect to the compensation of our chief executive officer, our compensation committee has historically reviewed and recommended to the full board of directors corporate goals and objectives relating to the compensation of the chief executive officer, evaluated the performance of the chief executive officer in light of those goals and objectives and reviewed and recommended to the full board of directors the compensation of our chief executive officer based on such evaluation. Following the completion of this offering, we expect that our compensation committee will assume responsibility for the compensation of our chief executive officer. The compensation committee also regularly assesses the effectiveness and competitiveness of our compensation programs.

In the first quarter of each year, the compensation committee reviews the performance of each of our named executive officers during the previous year. At this time the compensation committee also reviews our performance relative to the corporate performance objectives set by the board of directors for that year and makes the final bonus payment determinations based on our performance and the compensation committee s evaluation of each named executive officer s performance for the prior year. In connection with this review, the compensation committee also reviews and adjusts, as appropriate, annual base salaries for our named executive officers and grants, as appropriate, additional stock option awards to our named executive officers and certain other eligible employees for the coming fiscal year. With respect to the compensation for our chief executive officer, the compensation committee historically has presented its recommendations to the full board of directors for approval.

During the first quarter of each year our compensation committee also reviews the corporate performance objectives for purposes of our performance bonus programs for that year, but such objectives historically have been recommended to the full board of directors for approval. Our chief executive officer, with the assistance and support of the human resources department and the other executive officers, aids the compensation committee by providing annual recommendations regarding the compensation of all of our named executive officers, other than himself. The compensation committee also, on occasion, meets with our chief executive officer to obtain recommendations with respect to our compensation programs and practices generally. The compensation committee considers, but is not bound to accept, the chief executive officer s recommendations with respect to named executive officer compensation. In the beginning of each year, our named executive officers work with our chief executive officer to establish their individual performance goals for the year, based on their respective roles within the company.

Our chief executive officer generally attends all of the compensation committee meetings, but the compensation committee also holds executive sessions that are not attended by any members of management or non-independent directors, as needed from time to time. Any decisions regarding our chief executive officer s compensation are made without him present.

Role of Compensation Consultant and Comparable Company Information

Our compensation committee has not historically established compensation levels based on benchmarking. Our compensation committee has instead relied upon the judgment of its members in making compensation decisions, after reviewing our performance and carefully evaluating a named executive officer s performance during the year against established goals, leadership qualities, operational performance, business responsibilities, career with our company, current compensation arrangements and long-term potential to enhance stockholder value. While competitive market compensation paid by other companies has been reviewed by the compensation committee and the board of directors in the past in connection with setting named executive officer compensation, such information was not reviewed by the compensation committee during 2009.

In May 2010, our compensation committee engaged Compensia, Inc., or Compensia, to provide compensation consulting services and to assist the compensation committee in the determination of the key elements of our executive compensation programs. Specifically, for 2010, the compensation committee requested Compensia to advise it on a variety of compensation-related issues, including:

- compiling, analyzing and presenting third-party survey data regarding the compensation of executives at comparable companies;
- evaluating our current executive compensation program relative to this survey data, including base salary, bonus and equity ownership levels; and
- providing general information concerning executive compensation trends and developments.

Compensia has not provided any other services to us in 2010 beyond its engagement as an advisor to the compensation committee on executive compensation matters.

The comparable company information presented to the compensation committee by Compensia in May 2010 consisted of industry survey data for two groups of companies: private companies and public companies. The compensation committee reviewed data from The Radford Global Life Sciences Compensation Survey, which consists of public companies throughout the United States primarily from the life sciences industry with between 50 and 150 employees. The compensation committee also reviewed data from the Advanced HR Option Impact Pre-IPO Compensation Database, which consists of private companies throughout the United States. The data from this survey reviewed by our compensation committee was for companies from the life sciences industry, with between 50 and 150 employees and that had raised more than $100 million in capital. This survey data was presented separately to the compensation committee, so that it could see the relative compensation levels for both private and public companies. With respect to the survey data presented to the compensation committee, the identities of the individual companies included in the survey were not provided to the compensation committee, and the compensation committee did not refer to individual compensation information for such companies. We believe that by utilizing both sets of survey data, our compensation committee is able to review an appropriate set of competitive data for use in making compensation decisions.

While our compensation committee reviewed the foregoing third party survey data in connection with its determinations of the 2010 base salaries, target bonuses and equity awards for our named executive officers, our committee did not attempt to set those compensation levels or awards at a certain target percentile with respect to the third party survey data or otherwise rely entirely on that data to determine named executive officer compensation. Instead, as described above and consistent with past practice, the compensation committee members relied on their judgment and experience in setting those compensation levels and making those awards.

We expect that the compensation committee will continue to review comparable company survey data in connection with setting the compensation we offer our named executive officers to help ensure that our compensation programs are competitive and fair.

The compensation committee is authorized to retain the services of third-party compensation consultants and other outside advisors from time to time, as the committee sees fit, in connection with compensation matters. Compensation consultants and other advisors retained by the compensation committee will report directly to the compensation committee which has the authority to select, retain and terminate any such consultants or advisors.

We strive to achieve an appropriate mix between equity incentive awards and cash payments in order to meet our objectives. Any apportionment goal is not applied rigidly and does not control our compensation decisions, and our compensation committee does not have any policies for allocating compensation between long-term and short-term compensation or cash and non-cash compensation. Our mix of compensation elements is designed to reward recent results and motivate long-term performance through a combination of cash and equity incentive awards. We believe the most important indicator of whether our compensation objectives are being met is our ability to motivate our named executive officers to deliver superior performance and retain them to continue their careers with us on a cost-effective basis.

The compensation levels of the named executive officers reflect to a significant degree the varying roles and responsibilities of such executives. As a result of the compensation committee s and the board of director s assessment of our chief executive officer s and president and chief operating officer s roles and responsibilities within our company, there are significant compensation differentials between these named executive officers and our other named executive officers.

We do not yet have a formal policy to adjust or recover awards or payments if the relevant performance measures upon which they are based are restated or are otherwise adjusted in a manner that would otherwise reduce the size of the initial payment or award.

Executive Compensation Components

The following describes each component of our executive compensation program, the rationale for each, and how compensation amounts are determined.

Base Salaries

In general, base salaries for our named executive officers are initially established through arm s length negotiation at the time the executive is hired, taking into account such executive s qualifications, experience and prior salary. Base salaries of our named executive officers are approved and reviewed annually by our compensation committee and adjustments to base salaries are based on the scope of an executive s responsibilities, individual contribution, prior experience and sustained performance. Decisions regarding salary increases may take into account an executive officer s current salary, equity ownership, and the amounts paid to an executive officer s peers inside our company by conducting an internal analysis, which compares the pay of an executive officer to other members of the management team. Base salaries are also reviewed in the case of promotions or other significant changes in responsibility. Base salaries are not automatically increased if the compensation committee believes that other elements of the named executive officer s compensation are more appropriate in light of our stated objectives. This strategy is consistent with our intent of offering compensation that is both cost-effective, competitive and contingent on the achievement of performance objectives.

Our chief executive officer s base salary is based upon the same policies and criteria used for other named executive officers as described above. Each year the compensation committee reviews the chief executive officer s compensation arrangements and his individual performance for the previous fiscal year, as well as our performance as a whole, and makes recommendations to the full board of directors of adjustments to such compensation, if appropriate.

In early 2009, our board of directors determined to leave 2008 salaries unchanged companywide in order to conserve cash. The base salaries for our named executive officers as of January 1, 2009 were as follows:

Named Executive Officer	Base Salary as of January 1, 2009
Roger L. Hawley	$ 400,000
Stephen J. Farr, Ph.D.	$ 325,000
David W. Nassif, J.D.	$ 260,000
Cynthia Robinson, Ph.D.	$ 260,000
J.D. Haldeman	$ 255,000

Also, as part of a companywide program to conserve cash, in early 2009, our named executive executives agreed to reduce their base salaries by 10%. This reduction was reversed in August 2009. The actual base salaries paid to all of our named executive officers for 2009 are set forth in the Summary Compensation Table below.

In March 2010, Ann Rhoads commenced employment as our executive vice president, chief financial officer, treasurer and secretary, and the compensation committee set her initial base salary at $325,000 per year based on its review and consideration of the factors described in the first paragraph above.

In May 2010, the compensation committee reviewed the base salaries of our named executive officers. The compensation committee, in consultation with our chief executive officer (with respect to the salaries of our other named executive officers) and Compensia, determined to increase base salaries of our named executive officers for 2010, effective April 1, 2010, subject to improvement of our financial condition. In August 2010, in light of our improved financial condition based on our debt restructuring, our compensation committee approved the implementation of the base salary increases of our named executive officers (and the full board of directors approved the increase for Mr. Hawley). The base salaries for our named executive officers as of April 1, 2010 were as follows:

Named Executive Officer	Base Salary as of April 1, 2010
Roger L. Hawley	$ 420,000
Stephen J. Farr, Ph.D.	$ 341,250
Cynthia Robinson, Ph.D.	$ 272,000
J.D. Haldeman	$ 262,700

Performance Bonuses

2009 Performance Bonuses. Historically, each named executive officer has also been eligible for a performance bonus based upon the achievement of certain corporate performance goals and objectives approved by our board of directors and, with respect to our named executive officers other than Mr. Hawley, individual performance.

Bonuses are set based on the executive s base salary as of the end of the bonus year, and are expected to be paid out in the first quarter of the following year. The target levels for executive bonuses currently are as follows: 50% of base salary for the chief executive officer (100% of which is based on corporate objectives), 45% of base salary for our president and chief operating officer and executive vice president and chief financial officer (80% of which is based on corporate objectives and 20% of which is based on individual performance), and 35% of base salary for all other named executive officers (60% of which is based on corporate objectives and 40% of which is based on individual performance).

At the beginning of each year, the board of directors (considering the recommendations of the compensation committee and management) sets corporate goals and milestones for the year. These goals and milestones and the proportional emphasis placed on each are set by the board of directors after considering management input and our overall strategic objectives. These goals generally relate to factors such as financial targets, achievement of product development objectives and establishment of new collaborative arrangements. The board of directors, upon recommendation of the compensation committee, determines the level of achievement of the corporate goals for each year. The individual component of each named executive s bonus award is not necessarily based on the achievement of any predetermined criteria or guidelines but rather on the compensation committee s subjective assessment of the officer s overall performance of his or her duties. In coming to this determination, our compensation committee does not follow any guidelines, nor are there such standing guidelines regarding the exercise of such discretion.

All final bonus payments to our named executive officers are determined by our compensation committee, other than the bonus payments to our chief executive officer, whose compensation is approved by the full board of directors. The actual bonuses awarded in any year, if any, may be more or less than the target, depending on individual performance and the achievement of corporate objectives and may also vary based on other factors at the discretion of the compensation committee (or the full board of directors, with respect to our chief executive officer).

2009 Bonuses. For 2009, in light of our cash position at the beginning of that year, our board of directors determined not to establish a bonus program in line with our historical practice. In lieu of our historical performance bonus program, which is described above, for 2009 our board of directors instituted a companywide bonus program, which paid one to three months of base salary to each full-time employee (depending on title) upon the achievement of two performance objectives: the FDA s approval of Sumavel DosePro and the closing of our Series B preferred stock financing. This bonus program was tailored to incentivize our employees to remain with us through these two critical corporate milestones and to reward them for their efforts towards achieving those goals. This was the only bonus program established by us for 2009.

We achieved these performance objectives during 2009 and the following bonuses were paid to our named executive officers in September 2009 pursuant to this program:

Named Executive Officer	Retention Bonus ($)
Roger L. Hawley	100,000
Stephen J. Farr, Ph.D.	81,250
David W. Nassif, J.D.	65,000
Cynthia Robinson, Ph.D.	65,000
J.D. Haldeman	63,750

Long-Term Equity Incentives

The goals of our long-term, equity-based incentive awards are to align the interests of our named executive officers and other employees, non-employee directors and consultants with the interests of our stockholders. Because vesting is based on continued employment, our equity-based incentives also encourage the retention of our named executive officers through the vesting period of the awards. In determining the size of the long-term equity incentives to be awarded to our named executive officers, we take into account a number of internal factors, such as the relative job scope, the value of existing long-term incentive awards, individual performance history, prior contributions to us and the size of prior grants. Our compensation committee does not refer to competitive market data in determining long-term equity incentive awards. Based upon these factors, the compensation committee determines the size of the long-term equity incentives at levels it considers appropriate to create a meaningful opportunity for reward predicated on the creation of long-term stockholder value. We have not granted any equity awards other than stock options to date.

To reward and retain our named executive officers in a manner that best aligns employees interests with stockholders interests, we use stock options as the primary incentive vehicles for long-term compensation. We believe that stock options are an effective tool for meeting our compensation goal of increasing long-term stockholder value by tying the value of the stock options to our future performance. Because employees are able to profit from stock options only if our stock price increases relative to the stock option s exercise price, we believe stock options provide meaningful incentives to employees to achieve increases in the value of our stock over time.

We use stock options to compensate our named executive officers both in the form of initial grants in connection with the commencement of employment and annual refresher grants. Annual grants of options are typically approved by the compensation committee during the first quarter of each year. While we intend that the majority of stock option awards to our employees be made pursuant to initial grants or our annual grant program, the compensation committee retains discretion to make stock option awards to employees at other times, including in connection with the promotion of an employee, to reward an employee, for retention purposes or for other circumstances recommended by management or the compensation committee.

The exercise price of each stock option grant is the fair market value of our common stock on the grant date, as determined by our board of directors from time to time. Stock option awards to our named executive officers typically vest over a four-year period as follows: 25% of the shares underlying the option vest on the first anniversary of the date of the vesting commencement date and the remainder of the shares underlying the option vest in equal monthly installments over the remaining 36 months thereafter. From time to time, our compensation committee may, however, determine that a different vesting schedule is appropriate. For a description of certain accelerated vesting provisions applicable to such options, see Employee Equity Incentive Plans 2010 Equity Incentive Award Plan and Employee Equity Incentive Plans 2006 Equity Incentive Plan below. We do not have any stock ownership requirements for our named executive officers.

In September 2009, the board of directors awarded the following options to our named executive officers: Mr. Hawley, options to purchase 60,000 shares; Dr. Farr, options to purchase 42,500 shares; Dr. Robinson, options to purchase 10,000 shares and Ms. Haldeman, options to purchase 20,000 shares. Each of these option awards vest in monthly installments over two years and has an exercise price of $2.50 per share, which the board of directors determined was the fair value per share of our common stock on the date of grant. These awards were recommended by the compensation committee. The compensation committee s recommendation regarding each named executive officer s award amount was not based on any quantifiable factors, but instead was based on the compensation committee s subjective analysis of the award levels the committee deemed appropriate for each executive in light of various factors, including: the relative dollar value of the executives base salary reductions during 2009 into account; the fact that the annual bonuses paid to our named executive officers under our revised 2009 bonus program were lower than historical levels, as described above; our clinical and operational successes during 2009 despite our limited cash resources; and the need to continue to incentivize our executives in light of the effect of our cash constraints on our executive compensation program. Each of these factors was taken into consideration by the compensation committee for each executive, as was management s recommendations regarding the appropriate award levels. The final award levels, however, were entirely based on the compensation committee s subjective analysis of these general factors and internal pay equity considerations. The compensation committee also recommended the shorter two year vesting schedule for these awards, which was determined to be appropriate given that the awards were intended, in part, to compensate the executives for their lower than normal compensation during 2008 and 2009.

In March 2010, the compensation committee granted Ms. Rhoads stock options to purchase 150,000 shares of our common stock in connection with her commencement of employment as our executive vice president, chief financial officer, treasurer and secretary. The compensation committee established this award based on its review and consideration of the factors described in the first paragraph above.

In May 2010, the compensation committee, and the board of directors with respect to our chief executive officer, awarded the following options to our named executive officers: Mr. Hawley, options to purchase 150,000 shares; Dr. Farr, options to purchase 100,000 shares; Dr. Robinson, options to purchase 32,000 shares; and Ms. Haldeman, options to purchase 10,000 shares. Each of these option awards vests over a four-year period as follows: 25% of the shares underlying the option vest on the first anniversary of the date of the vesting commencement date and the remainder of the shares underlying the option vest in equal monthly installments over the remaining 36 months thereafter. Each of these options has an exercise price of $4.00 per share. The compensation committee determined that such awards were appropriate in order to incentivize our named executive officers for their strong operational performance.

As a privately-owned company, there has been no active market for our common stock. Accordingly, we have had no program, plan or practice pertaining to the timing of stock option grants to named executive officers coinciding with the release of material non-public information.

Retirement Savings

All of our full-time employees in the U.S., including our named executive officers, are eligible to participate in our 401(k) plan. Pursuant to our 401(k) plan, employees may elect to reduce their current compensation by up to the statutorily prescribed annual limit of $16,500 in 2010 (additional salary deferrals not to exceed $5,500 are available to those employees 50 years of age or older) and to have the amount of this reduction contributed to our 401(k) plan. While we may elect to make matching contributions, no such contributions have been made.

Health and Welfare Benefits, Perquisites and Other Compensation

The establishment of competitive benefit packages for our employees is an important factor in attracting and retaining highly qualified personnel.

Health and Welfare Benefits. Our named executive officers are eligible to participate in all of our employee benefit plans, including our medical, dental, vision, group life and disability insurance plans, in each case on the same basis as other employees. We believe that these health and welfare benefits help ensure that we have a productive and focused workforce through reliable and competitive health and other benefits.

Perquisites. We do not provide significant perquisites or personal benefits to our named executive officers. We do, however, pay the premiums for term life insurance for our named executive officers.

Post Termination Benefits

We have entered into employment agreements which provide for certain severance benefits in the event a named executive officer s employment is involuntarily or constructively terminated. Such severance benefits are intended and designed to alleviate the financial impact of an involuntary termination and maintain a stable work environment through salary continuation and equity award vesting acceleration. We provide severance benefits because they are essential to help us fulfill our objective of attracting and retaining key managerial talent. While these arrangements form an integral part of the total compensation provided to these individuals and are considered by the compensation committee when determining executive officer compensation, the decision to offer these benefits did not influence the compensation committee s determinations concerning other direct compensation or benefit levels. The compensation committee has determined that such arrangements offer protection that is competitive within our industry and for our company size and are designed to attract highly qualified individuals and maintain their employment with us. In determining the severance benefits payable pursuant to the executive employment agreements, the compensation committee considered the input of our executives as to what they expected and what level of severance benefits would be sufficient to retain our current executive team and to recruit talented executives in the future. For a

description of these employment agreements, see Employment and Release Agreements Employment Agreements below.

Tax Deductibility of Executive Compensation

The compensation committee and our board of directors have considered the potential future effects of Section 162(m) of the Internal Revenue Code on the compensation paid to our executive officers. Section 162(m) disallows a tax deduction for any publicly held corporation for individual compensation exceeding $1.0 million in any taxable year for our chief executive officer and each of the other named executive officers (other than our chief financial officer), unless compensation is performance based. As we are not currently publicly-traded, our board of directors has not previously taken the deductibility limit imposed by Section 162(m) into consideration in setting compensation. Our compensation committee, however, has adopted a policy that, where reasonably practicable, we will seek to qualify the variable compensation paid to our executive officers for an exemption from the deductibility limitations of Section 162(m).

In approving the amount and form of compensation for our executive officers, the compensation committee will continue to consider all elements of the cost to our company of providing such compensation, including the potential impact of Section 162(m).

Accounting for Stock-Based Compensation

We follow Financial Accounting Standards Board Accounting Standards Codification Topic 718 (formerly known as SFAS No. 123(R)), or ASC Topic 718, for our stock-based compensation awards. ASC Topic 718 requires companies to calculate the grant date fair value of their stock-based awards using a variety of assumptions. This calculation is performed for accounting purposes and reported in the compensation tables below, even though recipients may never realize any value from their awards. ASC Topic 718 also requires companies to recognize the compensation cost of their stock-based awards in their income statements over the period that an employee is required to render service in exchange for the award.

Risk Assessment of Compensation Program

In September 2010, management assessed our compensation program for the purpose of reviewing and considering any risks presented by our compensation policies and practices that are reasonably likely to have a material adverse effect on us. As part of that assessment, management reviewed the primary elements of our compensation program, including base salary, short-term incentive compensation and long-term incentive compensation. Management s risk assessment included a review of the overall design of each primary element of our compensation program, and an analysis of the various design features, controls and approval rights in place with respect to compensation paid to management and other employees that mitigate potential risks to us that could arise from our compensation program. Following the assessment, management determined that our compensation policies and practices did not create risks that were reasonably likely to have a material adverse effect on us and reported the results of the assessment to our compensation committee.

Summary Compensation Table

The following table shows information regarding the compensation earned by our named executive officers during the fiscal years ended December 31, 2007, 2008 and 2009.

		Annual Compensation		Long Term Compensation		Non-Equity Incentive		
Name and Principal Position	**Year**	**Salary ($)(1)**	**Bonus ($)(2)**	**Stock Awards ($)**	**Option Awards ($)(3)**	**Plan Compensation ($)(4)**	**All Other Compensation ($)(5)**	**Total ($)**
Roger L. Hawley	2009	381,667	100,000		156,223		79	637,969
Chief Executive Officer	2008	400,000			880,290		93	1,280,383
	2007	279,167			31,680	125,000	132	435,979
Stephen J. Farr, Ph.D.	2009	310,104	81,250		110,658		79	502,091
President and Chief Operating Officer	2008	325,000			73,358		93	398,451
	2007	257,500	75,559(6)			93,543	132	426,734
David W. Nassif, J.D.(7)	2009	248,083	65,000				79	313,162
Former Executive Vice President and	2008	260,000					93	260,093
Chief Financial Officer	2007	150,000			44,000	47,504	109,400	350,904
J.D. Haldeman	2009	243,313	63,750		52,074		79	359,216
Former Chief Commercial Officer(8)	2008	251,073					93	251,166
	2007	210,000			28,160	52,085	132	290,377
Cynthia Robinson, Ph.D.(9)	2009	248,083	65,000		26,037		79	339,199
Chief Development Officer	2008	208,333			471,552		89,035	768,920
	2007							

(1) The salaries paid for 2009 are lower than those for 2008, reflecting the 10% voluntary salary reduction taken by the named executive officers for a portion of 2009.

(2) For 2009, represents amounts paid under the retention bonus program.

(3) Represents the grant date fair value of the awards granted in the relevant fiscal year as computed in accordance with ASC Topic 718.

(4) These amounts represent 2007 performance bonuses under our executive bonus program, which is described above under Compensation Discussion and Analysis Performance Bonuses. No bonuses were earned for 2009 or 2008 performance under the executive bonus program due to the need to conserve cash.

(5) Reflects premiums paid by the company for term life insurance for our named executive officers. The amounts shown for Mr. Nassif for 2007 also include consulting fees of $109,400 paid to him by us during the period January 2007 through May 2007, when he commenced employment as our executive vice president and chief financial officer. The amounts shown for Ms. Robinson for 2008 also include consulting fees of $88,975 paid to her by us during the period January 2008 through March 2008, when she commenced employment as our chief development officer.

(6) This amount represents a bonus paid to Dr. Farr pursuant to his employment agreement in consideration of foregone severance otherwise payable by Aradigm, his former employer, following his termination of employment with Aradigm in connection with our acquisition of DosePro needle-free drug delivery system.

(7) For 2007, reflects a pro-rated salary and bonus for Mr. Nassif due to the fact the Mr. Nassif was appointed executive vice president and chief financial officer in May 2007. Effective February 26, 2010, Mr. Nassif resigned his positions with the company. Beginning March 1, 2010, he began providing executive consulting services to the company.

(8) Effective July 26, 2010, Ms. Haldeman resigned her position with us.

(9) For 2008, reflects a pro-rated salary for Ms. Robinson due to the fact the Ms. Robinson was appointed chief development officer in April 2008.

2009 Grants of Plan-Based Awards

All stock options granted to our named executive officers were granted under our 2006 Equity Incentive Plan. The exercise price per share of each stock option is equal to the per share fair market value of our common stock as determined by our board of directors on the date of grant. The following table sets forth summary information regarding grants of plan-based awards made to our named executive officers during the year ended December 31, 2009.

Name	Grant Date(1)	Estimated Possible Payouts Under Non-Equity Incentive Plan Awards Target ($)(2)	All Other Stock Awards: Number of Shares of Stock or Units (#)	All Other Option Awards: Number of Securities Underlying Options (#)	Exercise or Base Price of Option Awards ($/Sh)(3)	Grant Date Fair Value of Stock and Option Awards(4)
Roger L. Hawley	9/1/2009			60,000	2.50	156,223
Stephen J. Farr, Ph.D.	9/1/2009			42,500	2.50	110,658
David W. Nassif, J.D.						
J.D. Haldeman	9/1/2009			20,000	2.50	52,074
Cynthia Robinson, Ph.D.	9/1/2009			10,000	2.50	26,037

(1) All of the stock option awards have a ten year term and vest monthly over two years based on the named executive officer s continued employment by or service to the company on each such vesting date.

(2) Due to the need to conserve cash for most of 2009, the executive bonus program was suspended. There are no minimum thresholds or maximums under the 2009 executive bonus program.

(3) Reflects the fair market value per share of our common stock on the grant date as determined by our board of directors.

(4) Represents the grant date fair value of the awards as computed in accordance with ASC Topic 718. For a discussion of the valuation assumptions, see Note 9 to our consolidated financial statements for the year ended December 31, 2009 included elsewhere in this prospectus.

Discussion of Summary Compensation and Grants of Plan-Based Awards Tables

Our executive compensation policies and practices, pursuant to which the compensation set forth in the Summary Compensation Table and the 2009 Grants of Plan-Based Awards table was paid or awarded, are described above under Compensation Discussion and Analysis. A summary of certain material terms of our employment agreements and compensation plans and arrangements is set forth below.

Employment and Release Agreements

Employment Agreements

In May 2008, our board of directors approved our entering into employment agreements with each of our named executive officers. In March 2010, we entered into an employment agreement with Ms. Rhoads in connection with her commencement of employment as our executive vice president, chief financial officer, treasurer and secretary.

Pursuant to each of the employment agreements, if we terminate such officer s employment without cause (as defined below) or such officer resigns for good reason (as defined below) or such officer s employment is terminated as a result of his or her death or following his or her permanent disability, the executive officer or his or her estate, as applicable, is entitled to the following payments and benefits: (1) his or her

fully earned but unpaid base salary through the date of termination at the rate then in effect, plus all other benefits, if any, under any group retirement plan, nonqualified deferred compensation plan, equity award or agreement, health benefits plan or other group benefit plan to which he or she may be entitled to under the terms of such plans or agreements; (2) a lump sum cash

payment in an amount equal to 12 months of his or her base salary as in effect immediately prior to the date of termination; (3) continuation of health benefits for a period of 12 months following the date of termination; and (4) the automatic acceleration of the vesting and exercisability of outstanding unvested stock awards as to the number of stock awards that would have vested over the 12-month period following termination had such officer remained continuously employed by us during such period.

If a named executive officer is terminated without cause or resigns for good reason during the period commencing 60 days prior to a change in control (as defined below) or 12 months following a change in control, such officer shall be entitled to receive, in addition to the severance benefits described above, the following payments and benefits: (1) a lump sum cash payment in an amount equal to his or her bonus (as defined below) for the year in which the termination of employment occurs; and (2) in the case of Mr. Hawley, an additional lump sum cash payment in an amount equal to six months of his base salary as in effect immediately prior to the date of termination. In addition, in the event of a change in control, the vesting and exercisability of 50% of the executive officer s outstanding unvested stock awards shall be automatically accelerated and, in the event an executive officer is terminated without cause or resigns for good reason within three months prior to or 12 months following a change in control, the vesting and exercisability of 100% of the executive officer s outstanding unvested stock awards shall be automatically accelerated. For a further description of the potential compensation payable to our named executive officers under their employment agreements, please see Potential Payments Upon Termination or Change in Control below.

For purposes of the employment agreements, cause generally means an executive officer s (1) commission of an act of fraud, embezzlement or dishonesty or some other illegal act that has a material adverse impact on us or any successor or affiliate of ours, (2) conviction of, or entry into a plea of guilty or no contest to, a felony, (3) unauthorized use or disclosure of our confidential information or trade secrets or any successor or affiliate of ours that has, or may reasonably be expected to have, a material adverse impact on any such entity, (4) gross negligence, insubordination or material violation of any duty of loyalty to us or any successor or affiliate of ours, or any other material misconduct on the part of the executive officer, (5) ongoing and repeated failure or refusal to perform or neglect of his or her duties as required by his or her employment agreement, which failure, refusal or neglect continues for 15 days following his or receipt of written notice from our board of directors, chief executive officer or supervising officer, as applicable, stating with specificity the nature of such failure, refusal or neglect, or (6) breach of any policy of ours or any material provision of his or her employment agreement.

For purposes of the employment agreements, good reason generally means (1) a material diminution in the executive officer s authority, duties or responsibilities, (2) a material diminution in the executive officer s base compensation, unless such a reduction is imposed across-the-board to senior management of the company, (3) a material change in the geographic location at which the executive officer must perform his or her duties, or (4) any other action or inaction that constitutes a material breach by us or any successor or affiliate of ours of its obligations to the executive officer under his or her employment agreement.

For purposes of the employment agreements, bonus generally means an amount equal to the average of the bonuses awarded to the named executive officer for each of the three fiscal years prior to the date of his or her termination of employment, or such lesser number of years as may be applicable if the executive officer has not been employed for three full years on the date of termination of employment. However, to the extent the executive officer has not received any bonus prior to the date of his or her termination of employment due to the fact that his or her employment commenced during the fiscal year in which the termination occurs, bonus means an amount equal to his or her target bonus for the fiscal year in which such termination occurs (calculated by reference to the target bonus level in effect on the date of termination) multiplied by the corporate performance achievement percentage approved by the board of directors or its designee with respect to the payment of executive bonuses for the preceding fiscal year.

For purposes of the employment agreements, change in control has the same meaning as such term is given under the terms of our 2010 Equity Incentive Award Plan, as described below.

Release Agreements

In February 2010, we entered into a general release of claims with Mr. Nassif, which release superseded his employment agreement. Pursuant to the release, (1) we paid him a cash payment equal to $260,000, representing his annual base salary as in effect immediately prior to his termination of employment, (2) we agreed to continue his health benefits for a period of 12 months following the date of his termination of employment, and (3) the vesting and exercisability of his outstanding unvested stock awards was accelerated as to the number of stock awards that would have vested over the 12-month period following his termination of employment. Following his termination of employment, Mr. Nassif commenced consulting for us in March 2010.

In August 2010, we entered into a general release of claims with Ms. Haldeman, which release superseded her employment agreement. Pursuant to the release (1) we paid her a cash payment equal to $255,000, representing her annual base salary as in effect immediately prior to her termination of employment, (2) we agreed to continue her health benefits for a period of 12 months following the date of her termination of employment, (3) the vesting and exercisability of her outstanding unvested stock awards was accelerated as to the number of stock awards that would have vested over the 12-month period following her termination of employment, and (4) the expiration date of Ms. Haldeman s vested options was extended until July 26, 2011. In addition, in the event of a change in control on or before September 26, 2010, we will pay Ms. Haldeman an additional cash amount of $52,085, representing her bonus as of the date of her termination of employment (as such term was defined in her employment agreement). In the event of a change in control on or before October 26, 2010, the vesting and exercisability of 100% of Ms. Haldeman s outstanding unvested stock awards as of her date of termination shall be automatically accelerated.

Employee Equity Incentive Plans

2010 Equity Incentive Award Plan

We have adopted our 2010 Equity Incentive Award Plan, or the 2010 Plan. The 2010 Plan will become effective immediately prior to the completion of this offering. We plan to initially reserve 2,000,000 shares of our common stock for issuance under the 2010 Plan. In addition, the number of shares initially reserved under the 2010 Plan will be increased by (1) the number of shares of common stock available for issuance and not subject to options granted under our 2006 Equity Incentive Award Plan, or the 2006 Plan, as of the effective date of the 2010 Plan, and (2) the number of shares of common stock related to awards granted under our 2006 Plan that are repurchased, forfeited, expired or are cancelled on or after the effective date of the 2010 Plan. The total number of shares described in clauses (1) and (2) of the preceding sentence shall not exceed 14,034,000 shares of our common stock.

The 2010 Plan contains an evergreen provision that allows for an annual increase in the number of shares available for issuance under the 2010 Plan commencing on the first January 1 after the completion of this offering and on each January 1 thereafter during the ten-year term of the 2010 Plan. The annual increase in the number of shares shall be equal to the least of:

4% of our outstanding common stock on the applicable January 1;

1,000,000 shares; and

a lesser number of shares as determined by our board of directors.

The 2010 Plan will also provide for an aggregate limit of 14,034,000 shares of common stock that may be issued under the 2010 Plan over the course of its ten-year term. The material terms of the 2010 Plan are summarized below.

Administration. The compensation committee of our board of directors will administer the 2010 Plan (except with respect to any award granted to independent directors (as defined in the 2010 Plan), which must be administered by our full board of directors). Following the completion of this offering, to administer the 2010 Plan, our compensation committee must consist solely of at least two members of our board of directors, each of whom is a non-employee director for purposes of Rule 16b-3 under the Securities Exchange Act of 1934, as amended, or the Exchange Act, and, with respect to awards that are intended to constitute performance-based compensation under Section 162(m) of the Internal Revenue Code of 1986, as amended, an outside director for purposes of Section 162(m). Subject to the terms and conditions of the 2010 Plan, our compensation committee has the authority to select the persons to whom awards are to be made, to determine the type or types of awards to be granted to each person, the number of awards to grant, the number of shares to be subject to such awards, and the terms and conditions of such awards, and to make all other determinations and decisions and to take all other actions necessary or advisable for the administration of the 2010 Plan. Our compensation committee is also authorized to establish, adopt, amend or revise rules relating to administration of the 2010 Plan. Our board of directors may at any time revest in itself the authority to administer the 2010 Plan.

Eligibility. Options, stock appreciation rights, or SARs, restricted stock and other awards under the 2010 Plan may be granted to individuals who are then our officers or employees or are the officers or employees of any of our subsidiaries. Such awards may also be granted to our non-employee directors and consultants but only employees may be granted incentive stock options, or ISOs. As of September 30, 2010, there were eight non-employee directors and 145 employees who would have been eligible for awards under the 2010 Plan had it been in effect on such date. At such time after the completion of this offering when we are subject to the requirements of Section 162(m) of the Internal Revenue Code, the maximum number of shares that may be subject to awards granted under the 2010 Plan to any individual in any calendar year cannot exceed 2,000,000 and the maximum amount that may be paid to a participant in cash during any calendar year with respect to one or more cash based awards under the 2010 Plan is $2,000,000.

Awards. The 2010 Plan provides that our compensation committee (or the board of directors, in the case of awards to non-employee directors) may grant or issue stock options, SARs, restricted stock, restricted stock units, dividend equivalents, performance share awards, performance stock units, stock payments, deferred stock, performance bonus awards, performance-based awards, and other stock-based awards, or any combination thereof. Our compensation committee (or the board of directors, in the case of awards to non-employee directors) will consider each award grant subjectively, considering factors such as the individual performance of the recipient and the anticipated contribution of the recipient to the attainment of our long-term goals. Each award will be set forth in a separate agreement with the person receiving the award and will indicate the type, terms and conditions of the award.

Nonqualified stock options, or NQSOs, will provide for the right to purchase shares of our common stock at a specified price which may not be less than the fair market value of a share of common stock on the date of grant, and usually will become exercisable (at the discretion of our compensation committee or our board of directors, in the case of awards to non-employee directors) in one or more installments after the grant date, subject to the participant s continued employment or service with us and/or subject to the satisfaction of performance targets established by our compensation committee (or our board of directors, in the case of awards to non-employee directors). NQSOs may be granted for any term specified by our compensation committee (or our board of directors, in the case of awards to non-employee directors).

Incentive stock options, or ISOs, will be designed to comply with the provisions of the Internal Revenue Code and will be subject to specified restrictions contained in the Internal Revenue

Code. Among such restrictions, ISOs must have an exercise price of not less than the fair market value of a share of common stock on the date of grant, may only be granted to employees, must expire within a specified period of time following the optionee s termination of employment, and must be exercised within the ten years after the date of grant. In the case of an ISO granted to an individual who owns (or is deemed to own) more than 10% of the total combined voting power of all classes of our capital stock, the 2010 Plan provides that the exercise price must be at least 110% of the fair market value of a share of common stock on the date of grant and the ISO must expire upon the fifth anniversary of the date of its grant.

Restricted stock may be granted to participants and made subject to such restrictions as may be determined by our compensation committee (or our board of directors, in the case of awards to non-employee directors). Typically, restricted stock may be forfeited for no consideration if the conditions or restrictions are not met, and it may not be sold or otherwise transferred to third parties until restrictions are removed or expire. Recipients of restricted stock, unlike recipients of options, may have voting rights and may receive dividends, if any, prior to the time when the restrictions lapse.

Restricted stock units may be awarded to participants, typically without payment of consideration or for a nominal purchase price, but subject to vesting conditions including continued employment or on performance criteria established by our compensation committee (or our board of directors, in the case of awards to non-employee directors). Like restricted stock, restricted stock units may not be sold or otherwise transferred or hypothecated until vesting conditions are removed or expire. Unlike restricted stock, stock underlying restricted stock units will not be issued until the restricted stock units have vested, and recipients of restricted stock units generally will have no voting or dividend rights prior to the time when vesting conditions are satisfied.

SARs granted under the 2010 Plan typically will provide for payments to the holder based upon increases in the price of our common stock over the exercise price of the SAR. Except as required by Section 162(m) of the Internal Revenue Code with respect to SARs intended to qualify as performance-based compensation as described in Section 162(m) of the Internal Revenue Code, there are no restrictions specified in the 2010 Plan on the exercise of SARs or the amount of gain realizable therefrom. Our compensation committee (or the board of directors, in the case of awards to non-employee directors) may elect to pay SARs in cash or in common stock or in a combination of both.

Dividend equivalents represent the value of the dividends, if any, per share paid by us, calculated with reference to the number of shares covered by the stock options, SARs or other awards held by the participant.

Performance bonus awards may be granted by our compensation committee on an individual or group basis. Generally, these awards will be based upon the attainment of specific performance goals that are established by our compensation committee and relate to one or more performance criteria on a specified date or dates determined by our compensation committee. Any such cash bonus paid to a covered employee within the meaning of Section 162(m) of the Internal Revenue Code may be, but need not be, qualified performance-based compensation as described below and will be paid in cash.

Stock payments may be authorized by our compensation committee (or our board of directors, in the case of awards to non-employee directors) in the form of common stock or an option or other right to purchase common stock as part of a deferred compensation arrangement, made in lieu of all or any part of compensation, including bonuses, that would otherwise be payable to employees, consultants or members of our board of directors.

Qualified Performance-Based Compensation. The compensation committee may designate employees as covered employees whose compensation for a given fiscal year may be subject to the

limit on deductible compensation imposed by Section 162(m) of the Code. The compensation committee may grant to such covered employees restricted stock, dividend equivalents, stock payments, restricted stock units, cash bonuses and other stock-based awards that are paid, vest or become exercisable upon the attainment of company performance criteria which are related to one or more of the following performance criteria as applicable to our performance or the performance of a division, business unit or an individual, measured either in absolute terms, on a same-property basis, as compared to any incremental increase or as compared to results of a peer group: operating or other costs and expenses, improvements in expense levels, cash flow (including, but not limited to, operating cash flow and free cash flow), return on net assets, shareholders equity, return on shareholders equity, return on sales, gross or net profit or operating margin, working capital, net earnings (either before or after interest, taxes, depreciation and amortization), gross or net sales or revenue, net income (either before or after taxes), adjusted net income, operating earnings, earnings per share of stock, adjusted earnings per share of stock, price per share of stock, capital raised in financing transactions or other financing milestones, market recognition (including but not limited to awards and analyst ratings), financial ratios, implementation of critical projects, comparisons with various stock market indices, and implementation, completion or attainment of objectively-determinable objectives relating to research, development, regulatory, commercial or strategic milestones or development. These performance criteria may be measured in absolute terms or as compared to performance in an earlier period or as compared to any incremental increase or as compared to results of a peer group.

The compensation committee may provide that one or more objectively determinable adjustments will be made to one or more of the performance goals established for any performance period. Such adjustments may include one or more of the following: items related to a change in accounting principle, items relating to financing activities, expenses for restructuring or productivity initiatives, other non-operating items, items related to acquisitions, items attributable to the business operations of any entity acquired by us during the performance period, items related to the disposal of a business of segment of a business, items related to discontinued operations that do not qualify as a segment of a business under applicable accounting standards, items attributable to any stock dividend, stock split, combination or exchange of shares occurring during the performance period, any other items of significant income or expense which are determined to be appropriate adjustments, items relating to unusual or extraordinary corporate transactions, events or developments, items related to amortization of acquired intangible assets, items that are outside the scope of our core, on-going business activities, items relating to changes in tax laws, items relating to gains and losses for litigation, arbitration or contractual settlements, or items relating to any other unusual or nonrecurring events or changes in applicable laws, accounting principles or business conditions.

Adjustments. If there is any stock dividend, stock split, combination or exchange of shares, merger, consolidation or other distribution (other than normal cash dividends) of our assets to stockholders, or any other change affecting the shares of our common stock or the share price of our common stock other than an equity restructuring (as defined in the 2010 Plan), the plan administrator will make such equitable adjustments, if any, as the plan administrator in its discretion may deem appropriate to reflect such change with respect to (1) the aggregate number and type of shares that may be issued under the 2010 Plan (including, but not limited to, adjustments of the number of shares available under the plan and the maximum number of shares which may be subject to one or more awards to a participant pursuant to the plan during any calendar year), (2) the terms and conditions of any outstanding awards (including, without limitation, any applicable performance targets or criteria with respect thereto), and (3) the grant or exercise price per share for any outstanding awards under the plan. If there is any equity restructuring, (1) the number and type of securities subject to each outstanding award and the grant or exercise price per share for each outstanding award, if applicable, will be proportionately adjusted, and (2) the plan administrator will make proportionate adjustments to reflect such equity restructuring with respect to the aggregate number and type of shares that may be issued under the 2010 Plan (including, but not limited to, adjustments of the number of shares available under the plan and the maximum number of shares which may be subject to one or more awards to a

participant pursuant to the plan during any calendar year). Adjustments in the event of an equity restructuring will not be discretionary. Any adjustment affecting an award intended as qualified performance-based compensation will be made consistent with the requirements of Section 162(m) of the Internal Revenue Code. The plan administrator also has the authority under the 2010 Plan to take certain other actions with respect to outstanding awards in the event of a corporate transaction, including provision for the cash-out, termination, assumption or substitution of such awards.

Corporate Transactions. In the event of a change in control where the acquirer does not assume awards granted under the 2010 Plan, awards issued under the 2010 Plan will be subject to accelerated vesting such that 100% of the awards will become vested and exercisable or payable, as applicable. Under the 2010 Plan, a change in control is generally defined as:

a transaction or series of related transactions (other than an offering of our stock to the general public through a registration statement filed with the Securities and Exchange Commission, or SEC) whereby any person or entity or related group of persons or entities (other than us, our subsidiaries, an employee benefit plan maintained by us or any of our subsidiaries or a person or entity that, prior to such transaction, directly or indirectly controls, is controlled by, or is under common control with, us) directly or indirectly acquires beneficial ownership (within the meaning of Rule 13d-3 under the Exchange Act) of more than 50% of the total combined voting power of our securities outstanding immediately after such acquisition;

during any two-year period, individuals who, at the beginning of such period, constitute our board of directors together with any new director(s) whose election by our board of directors or nomination for election by our stockholders was approved by a vote of at least two-thirds of the directors then still in office who either were directors at the beginning of the two-year period or whose election or nomination for election was previously so approved, cease for any reason to constitute a majority of our board of directors; or

our consummation (whether we are directly or indirectly involved through one or more intermediaries) of (x) a merger, consolidation, reorganization, or business combination or (y) the sale, exchange or transfer of all or substantially all of our assets in any single transaction or series of transactions or (z) the acquisition of assets or stock of another entity, in each case other than a transaction:

which results in our voting securities outstanding immediately before the transaction continuing to represent (either by remaining outstanding or by being converted into our voting securities or the voting securities of the person that, as a result of the transaction, controls us, directly or indirectly, or owns, directly or indirectly, all or substantially all of our assets or otherwise succeeds to our business (we or such person being referred to as a successor entity)) directly or indirectly, at least a majority of the combined voting power of the successor entity s outstanding voting securities immediately after the transaction, and

after which no person or group beneficially owns voting securities representing 50% or more of the combined voting power of the successor entity; provided, however, that no person or group is treated as beneficially owning 50% or more of combined voting power of the successor entity solely as a result of the voting power held in us prior to the consummation of the transaction.

Amendment and Termination of the 2010 Plan. Our board of directors may terminate, amend or modify the 2010 Plan. However, stockholder approval of any amendment to the 2010 Plan will be obtained to the extent necessary and desirable to comply with any applicable law, regulation or stock exchange rule, or for any amendment to the 2010 Plan that increases the number of shares available under the 2010 Plan. If not terminated earlier by our board of directors, the 2010 Plan will terminate on the tenth anniversary of the date of its initial approval by our board of directors.

Repricing Permitted. Our compensation committee (or the board of directors, in the case of awards to non-employee directors) shall have the authority, without the approval of our stockholders, to

authorize the amendment of any outstanding award to reduce its price per share and to provide that an award will be canceled and replaced with the grant of an award having a lesser price per share. Our compensation committee (or the board of directors, in the case of awards to non-employee directors) will also have the authority, without the approval of our stockholders, to amend any outstanding award to increase the price per share or to cancel and replace an award with the grant of an award having a price per share that is greater than or equal to the price per share of the original award.

Securities Laws and Federal Income Taxes. The 2010 Plan is designed to comply with various securities and federal tax laws as follows:

Securities Laws. The 2010 Plan is intended to conform to all provisions of the Securities Act of 1933, as amended, or the Securities Act, and the Exchange Act and any and all regulations and rules promulgated by the SEC thereunder, including, without limitation, Rule 16b-3. The 2010 Plan will be administered, and awards will be granted and may be exercised, only in such a manner as to conform to such laws, rules and regulations.

Federal Income Tax Consequences. The federal income tax consequences of the 2010 Plan under current federal income tax law are summarized in the following discussion which deals with the general tax principles applicable to the 2010 Plan and is intended for general information only. The following discussion of federal income tax consequences does not purport to be a complete analysis of all of the potential tax effects of the 2010 Plan. It is based upon laws, regulations, rulings and decisions now in effect, all of which are subject to change. Foreign, state and local tax laws, and employment, estate and gift tax considerations are not discussed, and may vary depending on individual circumstances and from locality to locality.

Stock Options and Stock Appreciation Rights. A 2010 Plan participant generally will not recognize taxable income and we generally will not be entitled to a tax deduction upon the grant of a stock option or stock appreciation right. The tax consequences of exercising a stock option and the subsequent disposition of the shares received upon exercise will depend upon whether the option qualifies as an incentive stock option as defined in Section 422 of the Internal Revenue Code. The 2010 Plan permits the grant of options that are intended to qualify as incentive stock options as well as options that are not intended to so qualify; however, incentive stock options generally may be granted only to our employees and employees of our parent or subsidiary corporations, if any. Upon exercising an option that does not qualify as an incentive stock option when the fair market value of our stock is higher than the exercise price of the option, a 2010 Plan participant generally will recognize taxable income at ordinary income tax rates equal to the excess of the fair market value of the stock on the date of exercise over the purchase price, and we (or our subsidiaries, if any) generally will be entitled to a corresponding tax deduction for compensation expense, in the amount equal to the amount by which the fair market value of the shares purchased exceeds the purchase price for the shares. Upon a subsequent sale or other disposition of the option shares, the participant will recognize a short term or long term capital gain or loss in the amount of the difference between the sales price of the shares and the participant s tax basis in the shares.

Upon exercising an incentive stock option, a 2010 Plan participant generally will not recognize taxable income, and we will not be entitled to a tax deduction for compensation expense. However, upon exercise, the amount by which the fair market value of the shares purchased exceeds the purchase price will be an item of adjustment for alternative minimum tax purposes. The participant will recognize taxable income upon a sale or other taxable disposition of the option shares. For federal income tax purposes, dispositions are divided into two categories: qualifying and disqualifying. A qualifying disposition generally occurs if the sale or other disposition is made more than two years after the date the option was granted and more than one year after the date the shares are transferred upon exercise. If the sale or disposition occurs before these two periods are satisfied, then a disqualifying disposition generally will result.

Upon a qualifying disposition of incentive stock option shares, the participant will recognize long term capital gain in an amount equal to the excess of the amount realized upon the sale or other disposition of the shares over their purchase price. If there is a disqualifying disposition of the shares, then the excess of the fair market value of the shares on the exercise date (or, if less, the price at which the shares are sold) over their purchase price will be taxable as ordinary income to the participant. If there is a disqualifying disposition in the same year of exercise, it eliminates the item of adjustment for alternative minimum tax purposes. Any additional gain or loss recognized upon the disposition will be recognized as a capital gain or loss by the participant.

We will not be entitled to any tax deduction if the participant makes a qualifying disposition of incentive stock option shares. If the participant makes a disqualifying disposition of the shares, we should be entitled to a tax deduction for compensation expense in the amount of the ordinary income recognized by the participant.

Upon exercising or settling a stock appreciation right, a 2010 Plan participant will recognize taxable income at ordinary income tax rates, and we should be entitled to a corresponding tax deduction for compensation expense, in the amount paid or value of the shares issued upon exercise or settlement. Payments in shares will be valued at the fair market value of the shares at the time of the payment, and upon the subsequent disposition of the shares the participant will recognize a short term or long term capital gain or loss in the amount of the difference between the sales price of the shares and the participant s tax basis in the shares.

Restricted Stock and Restricted Stock Units. A 2010 Plan participant generally will not recognize taxable income at ordinary income tax rates and we generally will not be entitled to a tax deduction upon the grant of restricted stock or restricted stock units. Upon the termination of restrictions on restricted stock or the payment of restricted stock units, the participant will recognize taxable income at ordinary income tax rates, and we should be entitled to a corresponding tax deduction for compensation expense, in the amount paid to the participant or the amount by which the then fair market value of the shares received by the participant exceeds the amount, if any, paid for them. Upon the subsequent disposition of any shares, the participant will recognize a short term or long term capital gain or loss in the amount of the difference between the sales price of the shares and the participant s tax basis in the shares. However, a 2010 Plan participant granted restricted stock that is subject to forfeiture or repurchase through a vesting schedule such that it is subject to a risk of forfeiture (as defined in Section 83 of the Internal Revenue Code) may make an election under Section 83(b) of the Internal Revenue Code to recognize taxable income at ordinary income tax rates, at the time of the grant, in an amount equal to the fair market value of the shares of common stock on the date of grant, less the amount paid, if any, for such shares. We will be entitled to a corresponding tax deduction for compensation, in the amount recognized as taxable income by the participant. If a timely Section 83(b) election is made, the participant will not recognize any additional ordinary income on the termination of restrictions on restricted stock, and we will not be entitled to any additional tax deduction.

Dividend Equivalents, Stock Payment Awards and Cash-Based Awards. A 2010 Plan participant will not recognize taxable income and we will not be entitled to a tax deduction upon the grant of dividend equivalents, stock payment awards or cash-based awards until cash or shares are paid or distributed to the participant. At that time, any cash payments or the fair market value of shares that the participant receives will be taxable to the participant at ordinary income tax rates and we should be entitled to a corresponding tax deduction for compensation expense. Payments in shares will be valued at the fair market value of the shares at the time of the payment, and upon the subsequent disposition of the shares, the participant will recognize a short term or long term capital gain or loss in the amount of the difference between the sales price of the shares and the participant s tax basis in the shares.

Section 409A of the Internal Revenue Code. Certain types of awards under the 2010 Plan may constitute, or provide for, a deferral of compensation under Section 409A. Unless certain requirements set forth in Section 409A are complied with, holders of such awards may be taxed earlier than would otherwise be the case (e.g., at the time of vesting instead of the time of payment) and may be subject to an additional 20% federal income tax (and, potentially, certain interest penalties). To the extent applicable, the 2010 Plan and awards granted under the 2010 Plan will be structured and interpreted to comply with Section 409A and the Department of Treasury regulations and other interpretive guidance that may be issued pursuant to Section 409A.

Section 162(m) Limitation. In general, under Section 162(m) of the Internal Revenue Code, income tax deductions of publicly-held corporations may be limited to the extent total compensation (including base salary, annual bonus, stock option exercises and non-qualified benefits paid) for certain executive officers exceeds $1 million (less the amount of any excess parachute payments as defined in Section 280G of the Internal Revenue Code) in any one year. However, under Section 162(m), the deduction limit does not apply to certain performance-based compensation if an independent compensation committee determines performance goals and if the material terms of the performance-based compensation are disclosed to and approved by our stockholders. In particular, stock options and SARs will satisfy the performance-based compensation exception if the awards are made by a qualifying compensation committee, the plan sets the maximum number of shares that can be granted to any person within a specified period and the compensation is based solely on an increase in the stock price after the grant date. Specifically, the option exercise price must be equal to or greater than the fair market value of the stock subject to the award on the grant date. Under a Section 162(m) transition rule for compensation plans of corporations which are privately-held and which become publicly-held in an initial public offering, the 2010 Plan will not be subject to Section 162(m) until a specified transition date, which is the earlier of (1) the material modification of the 2010 Plan, (2) the issuance of all employer stock and other compensation that has been allocated under the 2010 Plan, or (3) the first annual meeting of stockholders at which directors are to be elected that occurs after the close of the third calendar year following the calendar year in which the initial public offering occurs. After the transition date, rights or awards granted under the 2010 Plan, other than options and SARs, will not qualify as performance-based compensation for purposes of Section 162(m) unless such rights or awards are granted or vest upon pre-established objective performance goals, the material terms of which are disclosed to and approved by our stockholders.

We have attempted to structure the 2010 Plan in such a manner that, after the transition date, the compensation attributable to stock options and SARs which meet the other requirements of Section 162(m) will not be subject to the $1 million limitation. We have not, however, requested a ruling from the Internal Revenue Service, or IRS, or an opinion of counsel regarding this issue.

2006 Equity Incentive Plan

On October 4, 2006, our board of directors approved the Zogenix, Inc. 2006 Equity Incentive Plan, or the 2006 Plan. The 2006 Plan was approved by our stockholders in February 2007.

A total of 2,034,000 shares of our common stock are reserved for issuance under the 2006 Plan. As of September 30, 2010, 1,482,780 shares of our common stock were subject to outstanding option awards and 233,689 shares of our common stock remained available for future issuance. After the effective date of the 2010 Plan, no additional awards will be granted under the 2006 Plan.

Administration. The compensation committee of our board of directors administers the 2006 Plan, except with respect to any award granted to non-employee directors (as defined in the 2006 Plan), which must be administered by our full board of directors. Subject to the terms and conditions of the 2006 Plan, the administrator has the authority to select the persons to whom awards are to be made, to

determine the type or types of awards to be granted to each person, determine the number of awards to grant, determine the number of shares to be subject to such awards, and the terms and conditions of such awards, and make all other determinations and decisions and to take all other actions necessary or advisable for the administration of the 2006 Plan. The plan administrator is also authorized to establish, adopt, amend or revise rules relating to administration of the 2006 Plan, subject to certain restrictions.

Eligibility. Options, stock appreciation rights, or SARs, restricted stock and other awards under the 2006 Plan may be granted to individuals who are then our employees, consultants and members of our board of directors and our subsidiaries. Only employees may be granted incentive stock options, or ISOs.

Awards. The 2006 Plan provides that our administrator may grant or issue stock options, restricted stock, restricted stock units, SARs, dividend equivalents, stock payments, or any combination thereof. The administrator considers each award grant subjectively, considering factors such as the individual performance of the recipient and the anticipated contribution of the recipient to the attainment of our long-term goals. Each award is set forth in a separate agreement with the person receiving the award and indicates the type, terms and conditions of the award.

NQSOs provide for the right to purchase shares of our common stock at a specified price which may not be less than the fair market value of a share of stock on the date of grant, and usually will become exercisable (at the discretion of our compensation committee or the board of directors, in the case of awards to non-employee directors) in one or more installments after the grant date, subject to the participant s continued employment or service with us and/or subject to the satisfaction of performance targets established by our compensation committee (or the board of directors, in the case of awards to non-employee directors). NQSOs may be granted for any term specified by our compensation committee (or the board of directors, in the case of awards to non-employee directors), but the term may not exceed ten years.

ISOs are designed to comply with the provisions of the Internal Revenue Code and are subject to specified restrictions contained in the Internal Revenue Code applicable to ISOs. Among such restrictions, ISOs must have an exercise price of not less than the fair market value of a share of common stock on the date of grant, may only be granted to employees, must expire within a specified period of time following the optionee s termination of employment, and must be exercised within the ten years after the date of grant. In the case of an ISO granted to an individual who owns (or is deemed to own) more than 10% of the total combined voting power of all classes of our capital stock on the date of grant, the 2006 Plan provides that the exercise price must be at least 110% of the fair market value of a share of common stock on the date of grant and the ISO must expire on the fifth anniversary of the date of its grant.

Restricted stock may be granted to participants and made subject to such restrictions as may be determined by the administrator. Typically, restricted stock may be repurchased by us at the original purchase price or, if no cash consideration was paid for such stock, forfeited for no consideration if the conditions or restrictions are not met, and the restricted stock may not be sold or otherwise transferred to third parties until restrictions are removed or expire. Recipients of restricted stock, unlike recipients of options, may have voting rights and may receive dividends, if any, prior to when the restrictions lapse.

Restricted stock units may be awarded to participants, typically without payment of consideration or for a nominal purchase price, but subject to vesting conditions including continued employment or on performance criteria established by the administrator. Like restricted stock, restricted stock units may not be sold or otherwise transferred or hypothecated until vesting conditions are removed or expire. Unlike restricted stock, stock underlying restricted stock units will not be issued until some time after the restricted stock units have vested, and recipients of restricted stock units generally will have no voting or dividend rights prior to the time when vesting conditions are satisfied and the shares have been issued.

SARs typically will provide for payments to the holder based upon increases in the price of our common stock over the exercise price of the SAR. There are no restrictions specified in the 2006 Plan on the exercise of SARs or the amount of gain realizable therefrom. The administrator may elect to pay SARs in cash or in common stock or in a combination of both.

Dividend equivalents may be awarded to participants and represent the value of the dividends, if any, per share paid by us, calculated with reference to the number of shares covered by the stock options, SARs or other awards held by the participant.

Stock payments may be authorized by the administrator in the form of common stock or an option or other right to purchase common stock as part of a deferred compensation arrangement, made in lieu of all or any part of compensation, including bonuses, that would otherwise be payable to employees, consultants or members of our board of directors.

Corporate Transactions. In the event of a change of control where the acquiror does not assume awards granted under the 2006 Plan, awards issued under the 2006 Plan will be subject to accelerated vesting such that 100% of the awards will become vested and exercisable or payable, as applicable, immediately prior to the change in control. Under the 2006 Plan, a change of control is generally defined as:

a transaction or series of related transactions whereby any person or entity or related group of persons or entities (other than us, our subsidiaries, an employee benefit plan maintained by us or any of our subsidiaries or a person or entity that, prior to such transaction, directly or indirectly controls, is controlled by, or is under common control with, us) directly or indirectly acquires beneficial ownership (within the meaning of Rule 13d-3 under the Exchange Act) of more than 50% of the total combined voting power of our securities outstanding immediately after such acquisition;

during any two-year period, individuals who, at the beginning of such period, constitute our board of directors together with any new director(s) whose election by our board of directors or nomination for election by our stockholders was approved by a vote of at least two-thirds of the directors then still in office who either were directors at the beginning of the two-year period or whose election or nomination for election was previously so approved, cease for any reason to constitute a majority of our board of directors;

our consummation (whether we are directly or indirectly involved through one or more intermediaries) of (1) a merger, consolidation, reorganization, or business combination, (2) the sale or other disposition of all or substantially all of our assets or (3) the acquisition of assets or stock of another entity, in each case other than a transaction that results in our voting securities outstanding immediately before the transaction continuing to represent, directly or indirectly, at least a majority of the combined voting power of the successor entity s outstanding voting securities immediately after the transaction, and after which no person or entity beneficially owns voting securities representing 50% or more of the combined voting power of the acquiring company that is not attributable to voting power held in the company prior to such transaction; or

the approval by our stockholders of a liquidation or dissolution of our company.

Amendment and Termination of the 2006 Plan. Our board of directors may terminate, amend or modify the 2006 Plan. However, stockholder approval of any amendment to the 2006 Plan must be obtained to the extent necessary and desirable to comply with any applicable law, regulation or stock exchange rule, or for any amendment to the 2006 Plan that increases the number of shares available under the 2006 Plan. The administrator may, with the consent of the affected option holders, cancel any or all outstanding awards under the 2006 Plan and grant new awards in substitution. If not terminated earlier by the compensation committee or the board of directors, the 2006 Plan will terminate in October 2016.

Securities Laws and Federal Income Taxes. The 2006 Plan is designed to comply with applicable securities laws in the same manner as described above in the description of the 2010 Plan under the heading 2010 Equity Incentive Award Plan Securities Laws and Federal Income Taxes Securities Laws. The general federal tax consequences of awards under the 2006 Plan are the same as those described above in the description of the 2010 Plan under the heading 2010 Equity Incentive Award Plan Securities Laws and Federal Income Taxes Federal Income Tax Consequences.

2010 Employee Stock Purchase Plan

We have adopted our 2010 Employee Stock Purchase Plan, or the Purchase Plan. The compensation committee of the board of directors will administer the Purchase Plan, the implementation of which will be in the discretion of our compensation committee. The Purchase Plan will be designed to allow our eligible employees and the eligible employees of our participating subsidiaries to purchase shares of common stock with accumulated payroll deductions. The Purchase Plan will become effective after the completion of this offering. We intend to initially reserve a total of 500,000 shares of our common stock for issuance under the Purchase Plan.

The Purchase Plan will contain an evergreen provision that allows for an annual increase in the number of shares available for issuance under the Purchase Plan commencing on the first January 1 after the completion of this offering and on each January 1 thereafter during the ten-year term of the Purchase Plan. The annual increase in the number of shares shall be equal to the least of:

1% of our outstanding common stock on the applicable January 1;

250,000 shares; and

a lesser number of shares as determined by our board of directors.

The Purchase Plan will also provide for an aggregate limit of 3,000,000 shares of common stock that may be issued under the Purchase Plan over the course of its ten-year term. The material terms of the Purchase Plan are summarized below. The Purchase Plan is filed as an exhibit to the registration statement of which this prospectus is a part.

Stock will be offered under the Purchase Plan during offering periods. The length of the offering periods under the Purchase Plan will be determined by our compensation committee and may be up to twenty-seven months long. Employee payroll deductions will be used to purchase shares on each purchase date during an offering period. The purchase dates will be determined by the compensation committee for each offering but will generally be the last day in each offering period. Offering periods under the Purchase Plan will commence when determined by our compensation committee. Our compensation committee may change the frequency and duration of offering periods under the Purchase Plan.

Individuals scheduled to work more than 20 hours per week for more than 5 calendar months per year may join an offering period on the first day of the offering period to the extent such individual does not, immediately after any rights under the Purchase Plan are granted, own (directly or through attribution) stock possessing 5% or more of the total combined voting power or value of all classes of our common or other stock. As of September 30, 2010, 145 of our employees would have been eligible to participate in the Purchase Plan if it were in effect.

Participants may contribute up to 20% of their cash earnings through payroll deductions, and the accumulated deductions will be applied to the purchase of shares on each purchase date. The purchase price per share will be established by our compensation committee but will not be less than 85% of the fair market value per share on the first day of the offering period or, if lower, 85% of the fair market value per share on the purchase date. In each calendar year, no employee is permitted to purchase shares under the Purchase Plan at a rate in excess of $25,000 worth of shares, based on the fair market value per share determined as of the first day of the offering period, for each year such a purchase right is outstanding. In addition, no employee is permitted to purchase more than 20,000 shares during any offering period.

In the event there is a specified type of change in our capital structure, such as a stock dividend or stock split, the committee may make appropriate adjustments to (1) the number and type of shares that may be issued under the Purchase Plan, including the maximum number of shares by which the share reserve may increase automatically each year, (2) the class(es) and number of shares and price per share of stock subject to outstanding rights and (3) the purchase price with respect to any outstanding rights.

In the event of certain significant corporate transactions or a change in control (as defined in the Purchase Plan), the committee may provide for (1) either the replacement or termination of outstanding rights in exchange for cash, (2) the assumption or substitution of outstanding rights by the successor or survivor corporation or parent or subsidiary thereof, if any, (3) the adjustment in the number and type of shares of stock subject to outstanding rights, (4) the use of participants accumulated payroll deductions to purchase stock on a new purchase date prior to the next purchase date and termination of any rights under ongoing offering periods or (5) the termination of all outstanding rights. Under the Purchase Plan, a change in control has the same definition as given to such term in the 2010 Plan.

The compensation committee may amend, suspend or terminate the Purchase Plan. However, stockholder approval of any amendment to the Purchase Plan will be obtained for any amendment which changes the aggregate number of shares that may be sold pursuant to rights under the Purchase Plan, changes the corporations or classes of corporations whose employees are eligible to participate in the Purchase Plan or changes the Purchase Plan in any manner that would cause the Purchase Plan to no longer be an employee stock purchase plan within the meaning of Section 423(b) of the Internal Revenue Code. The Purchase Plan will terminate no later than the tenth anniversary of the Purchase Plan s initial adoption by our board of directors.

Securities Laws. The Purchase Plan has been designed to comply with various securities laws in the same manner as described above in the description of the Purchase Plan under the heading 2010 Equity Incentive Award Plan Securities Laws and Federal Income Taxes Securities Laws.

Federal Income Taxes. The federal income tax consequences of the Purchase Plan under current federal income tax law are summarized in the following discussion which deals with the general tax principles applicable to the Purchase Plan and is intended for general information only. The following discussion of federal income tax consequences does not purport to be a complete analysis of all of the potential tax effects of the Purchase Plan. It is based upon laws, regulations, rulings and decisions now in effect, all of which are subject to change. Foreign, state and local tax laws, and employment, estate and gift tax considerations are not discussed, and may vary depending on individual circumstances and from locality to locality.

The Purchase Plan, and the right of participants to make purchases thereunder, is intended to qualify under the provisions of Section 423 of the Internal Revenue Code. Under the applicable Internal Revenue Code provisions, no income will be taxable to a participant until the sale or other disposition of the shares purchased under the Purchase Plan. This means that an eligible employee will not recognize taxable income on the date the employee is granted an option under the Purchase Plan (i.e., the first day of the offering period). In addition, the employee will not recognize taxable income upon the purchase of shares. Upon such sale or disposition, the participant will generally be subject to tax in an amount that depends upon the length of time such shares are held by the participant prior to disposing of them. If the shares are sold or disposed of more than two years from the first day of the offering period during which the shares were purchased and one year from the date of purchase, or if the participant dies while holding the shares, the participant (or his or her estate) will recognize ordinary income measured as the lesser of (1) the excess of the fair market value of the shares at the time of such sale or disposition over the purchase price or (2) an amount equal to 15% of the fair market value of the shares as of the first day of the offering period. Any additional gain will be treated as long-term capital gain. If the shares are held for the holding periods described above but are sold for a price that is less than the purchase price, there is no ordinary income and the participating employee has a long-term capital loss for the difference between the sale price and the purchase price.

If the shares are sold or otherwise disposed of before the expiration of the holding periods described above, the participant will recognize ordinary income generally measured as the excess of the fair market value of the shares on the date the shares are purchased over the purchase price and we will be entitled to a tax deduction for compensation expense in the amount of ordinary income recognized by the employee. Any additional gain or loss on such sale or disposition will be long-term or short-term capital gain or loss, depending on how long the shares were held following the date they were purchased by the participant prior to disposing of them. If the shares are sold or otherwise disposed of before the expiration of the holding periods described above but are sold for a price that is less than the purchase price, the participant will recognize ordinary income equal to the excess of the fair market value of the shares on the date of purchase over the purchase price (and we will be entitled to a corresponding deduction), but the participant generally will be able to report a capital loss equal to the difference between the sales price of the shares and the fair market value of the shares on the date of purchase.

401(k) Plan

We provide a basic savings plan, or 401(k) plan, which is intended to qualify under Section 401(k) of the Internal Revenue Code so that contributions to our 401(k) plan by employees or by us, and the investment earnings thereon, are not taxable to employees until withdrawn from our 401(k) plan. If our 401(k) plan qualifies under Section 401(k) of the Internal Revenue Code, contributions by us, if any, will be deductible by us when made.

All of our full-time employees in the U.S. are eligible to participate in our 401(k) plan. Pursuant to our 401(k) plan, employees may elect to reduce their current compensation by up to the statutorily prescribed annual limit of $16,500 in 2010 and to have the amount of this reduction contributed to our 401(k) plan. Participants that are 50 years or older can also make catch-up contributions, which in calendar year 2010 may be up to an additional $5,500 above the statutory limit. Under the 401(k) plan, each participant is fully vested in his or her deferred salary contributions when contributed. Participant contributions are held and invested, pursuant to the participant s instructions, by the plan s trustee. Our 401(k) plan permits, but does not require, additional matching contributions to our 401(k) plan by us on behalf of all participants in our 401(k) plan. While we may elect to make matching contributions, no contributions have been made. The 401(k) Plan currently does not offer the ability to invest in our securities.

Outstanding Equity Awards at Fiscal Year-End

The following table sets forth specified information concerning unexercised stock options and unvested stock awards for each of the named executive officers outstanding as of December 31, 2009.

	Option Awards(1)					Stock Awards	
Name	Number of Securities Underlying Unexercised Options Exercisable (#)	Number of Securities Underlying Unexercised Options Unexercisable (#)	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	Option Exercise Price ($)	Option Expiration Date(2)	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested ($)
Roger L. Hawley	60,000			2.50	8/30/2019		
	90,000			3.50	10/20/2018		
						26,260	$ 94,536
Stephen J. Farr, Ph.D.	42,500			2.50	8/30/2019		
	7,500			3.50	10/20/2018		
David W. Nassif, J.D.							
J.D. Haldeman	20,000			2.50	8/30/2019		
	15,000			.50	5/29/2017		
	32,500			.50	2/12/2017		
Cynthia Robinson, Ph.D.	10,000			2.50	8/30/2019		
	48,000			3.50	10/20/2018		

(1) Unless otherwise indicated, 25% of the shares underlying options vest on the first anniversary of the vesting commencement date and the remaining options vest on a monthly basis over the subsequent three-year period of continuous service and all options have a 10-year term from the date of grant. All options are immediately exercisable. Unvested options are subject to a right of repurchase within 60 days of termination of employment.

(2) The options granted with an expiration date of 8/30/2019 vest on a monthly basis over a two-year period of continuous service and have a 10-term from the date of grant.

Option Exercises and Stock Vested

The following table summarizes information regarding each exercise of stock options during 2009 for each of the named executive officers. None of the named executive officers vested in any stock awards during 2009.

	Option Awards		Stock Awards	
Name	Number of Shares Acquired On Exercise (#)	Value Realized on Exercise ($)(1)	Number of Shares Acquired On Vesting (#)	Value Realized On Vesting ($)
Roger L. Hawley				
Stephen J. Farr, Ph.D.				
David W. Nassif, J.D.	75,000	$ 270,000		
J.D. Haldeman				
Cynthia Robinson, Ph.D.				

(1) The value realized upon exercise of an option is calculated based on the number of shares issued upon exercise of such option multiplied by the difference between the fair market value per share on the date of exercise less the exercise price per share of such option.

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Potential Payments Upon Termination or Change in Control

The following table summarizes the potential payments to our named executive officers in four scenarios: (1) upon termination by us without cause or the executive s resignation for good reason apart from a change in control; (2) upon termination by us following the executive s permanent disability or as a result of the executive s death; (3) upon termination by us without cause or the executive s resignation for good reason within 60 days prior to or 12 months following a change in control; or (4) in the event of a change in control without a termination of employment. The table assumes that the termination of employment or change in control, as applicable, occurred on December 31, 2009. The definitions of cause , good reason and bonus are contained in the applicable employment agreement for each of our named executive officers, which are described above under the heading Employment and Release Agreements Employment Agreements.

Name and Position	Benefit Type	Payment in the Event of a Termination by the Company Without Cause or by Executive for Good Reason Apart from a Change in Control(1)(2)	Payment in the Event of a Termination by the Company following Executive s Permanent Disability or as a Result of Executive s Death(1)(2)	Payment in the Event of a Termination by the Company Without Cause or by Executive for Good Reason Within 60 Days Prior to or 12 Months Following a Change in Control(3)(4)	Payment in the Event of a Change in Control Without Termination(5)
Roger L. Hawley	Severance	$ 400,000	$ 400,000	$ 725,000	
Chief Executive Officer	Benefits(6)	9,197	9,197	9,197	
	Equity Awards	199,245	199,245	257,182	$ 128,591
Stephen J. Farr, Ph.D.	Severance	325,000	325,000	418,543	
President and Chief Operating Officer	Benefits(6)	13,315	13,315	13,315	
	Equity Awards	23,563	23,563	41,438	20,719
David W. Nassif, J.D.	Severance	260,000	260,000	307,504	
Former *Executive Vice Pres. and*	Benefits(6)	12,390	12,390	12,390	
Chief Financial Officer	Equity Awards	96,875	96,875	137,239	68,619
Cynthia Y. Robinson, Ph.D.	Severance	260,000	260,000	260,000	
Chief Development Officer	Benefits(6)	4,842	4,842	4,842	
	Equity Awards	6,700	6,700	13,025	6,513
J. D. Haldeman.	Severance	255,000	255,000	307,085	
Former *Chief Commercial Officer*	Benefits(6)	9,212	9,212	9,212	
	Equity Awards	73,000	73,000	77,697	38,849

(1) Cash severance represents 12 months of base salary for each named executive officer, payable in cash in a lump sum.

(2) Value of equity award acceleration represents the value of those options and restricted stock that would immediately vest and/or be released from the company s repurchase option, respectively, as a result of the named executive officer s termination or as a result of the named executive officer s death or disability. The value attributable to stock options not previously exercised that would vest in such event is the difference between the fair market value per share of our common stock on December 31, 2009 ($3.60) less the exercise price per share of such stock option multiplied by the number of shares that would vest. The value attributable to shares of restricted stock issued upon the early exercise of stock options that would be released from our repurchase option in such event equals the fair market value per share of our

common stock on December 31, 2009 ($3.60) multiplied by the number of shares that would be released.

(3) Cash severance represents the sum of the following, payable in a lump sum cash payment: (1) 12 months of base salary for each executive officer (18 months in the case of Mr. Hawley) payable in a lump sum cash payment, plus (2) the average of the bonuses awarded to the executive officer for the fiscal years 2007, 2008 and 2009 (in this case, this amount is equal to the 2007 bonus paid to the named executive officer, as there were no bonuses paid for 2008 and 2009 under the company s executive bonus program). Please see the definition of bonus under the heading Employment and Release Agreements Employment Agreements above.

(4) Value of equity award acceleration in the event named executive officer s employment is terminated without cause or he or she resigns for good reason within three months prior to or 12 months following a change in control. Value of equity award acceleration represents the value of those options and restricted stock that would immediately vest and/or be released from the company s repurchase option, respectively, as a result of the named executive officer s termination. The value attributable to stock options not previously exercised that would vest in such event is the difference between the fair market value per share of our common stock on December 31, 2009 ($3.60) less the exercise price per share of such stock option multiplied by the number of shares that would vest. The value attributable to shares of restricted stock issued upon the early exercise of stock options that would be released from our repurchase option in such event equals the fair market value per share of our common stock on December 31, 2009 ($3.60) multiplied by the number of shares that would be released.

(5) Value of equity award acceleration represents the value of those options and restricted stock that would immediately vest and/or be released from the company s repurchase option, respectively, upon a change in control without a termination of employment. The value attributable to stock options not previously exercised that would vest in such event is the difference between the fair market value per share of our common stock on December 31, 2009 ($3.60) less the exercise price per share of such stock option multiplied by the number of shares that would vest. The value attributable to shares of restricted stock issued to the named executive officer pursuant to a founder s stock agreement or upon the early exercise of stock options that would be released from our repurchase option in such event equals the fair market value per share of our common stock on December 31, 2009 ($3.60) multiplied by the number of shares that would be released.

(6) Represents the value of the continuation of health benefits for a period of 12 months following the date of the named executive officer s termination.

Director Compensation

We compensate non-employee members of the board of directors. Directors who are also employees do not receive cash or equity compensation for service on the board of directors in addition to compensation payable for their service as our employees.

The non-employee members of our board of directors are reimbursed for travel, lodging and other reasonable expenses incurred in attending board of directors or committee meetings. We provide an annual cash retainer of $50,000 to Cam L. Garner, the chairman of our board of directors, payable monthly. We do not currently provide any cash compensation to our other non-employee directors.

In addition, under a board of director-approved compensation program, our non-employee directors are eligible for automatic awards of stock options to purchase shares of our common stock in the form of initial option grants and annual option grants. Prior to the completion of this offering, any non-employee director who is first elected to the board of directors will be granted an option to purchase 7,500 shares of our common stock on the date of his or her initial election to the board of directors. Such options will have an exercise price per share equal to the fair market value of our common stock on the date of grant and will be fully vested on the date of grant. In addition, prior to the completion of this offering, each year on May 30 (and December 9 with respect to Arda M. Minocherhomjee, Ph.D.), each non-employee director will be eligible to receive an option to purchase 1,750 shares of common stock. The annual option grants will have an exercise price per share equal to the fair market value of our common stock on the date of grant and will vest monthly over 12 months following the date of grant. The term of each option granted to a non-employee director is ten years. These options have historically been granted under our 2006 Plan. The terms of these options are described in more detail under Equity Compensation Plans and Other Benefit Plans Employee Equity Incentive Plans 2006 Equity Incentive Plan.

Following the completion of this offering, we will provide cash compensation in the form of an annual retainer of $37,000 for each non-employee director. We will also pay an additional annual retainer of $60,000 to the chairman of our board of directors (however the total cash compensation paid to the chairman of the board in all capacities cannot exceed $100,000 in any calendar year), $20,000 to the chair of our audit committee, $10,000 to the chair of our compensation committee, and $7,500 to the chair of our nominating/ corporate governance committee. We will also pay an additional $7,000 per year to members of the audit committee, an additional $5,000 per year to members of our compensation committee and an additional $4,000 per year to members of our nominating/corporate governance

committee. We have reimbursed and will continue to reimburse our non-employee directors for their reasonable expenses incurred in attending meetings of our board of directors and committees of the board of directors.

Following the completion of this offering, any non-employee director who is first elected to the board of directors will be granted an option to purchase 25,000 shares of our common stock on the date of his or her initial election to the board of directors. In addition, on the date of each annual meeting of our stockholders following this offering, each non-employee director will be eligible to receive an option to purchase 12,500 shares of common stock. Such options will have an exercise price per share equal to the fair market value of our common stock on the date of grant.

The initial options granted to non-employee directors described above will vest over 3 years in 36 equal monthly installments, subject to the director s continuing service on our board of directors on those dates. The annual options granted to non-employee directors described above will vest over one year in 12 equal monthly installments, subject to the director s continuing service on our board of directors (and, with respect to grants to a chairman of the board of directors or board committee, service as chairman of the board of directors or a committee) on those dates. The term of each option granted to a non-employee director will be ten years. The terms of these options are described in more detail under Equity Compensation Plans and Other Benefit Plans Employee Equity Incentive Plans 2010 Equity Incentive Award Plan.

The following table summarizes cash and stock compensation received by our non-employee directors during the year ended December 31, 2009.

Name	Fees Earned or Paid in Cash	Stock Awards	Option Awards (1)	All Other Compensation	Total
Alex Zisson	$	$	$ 4,598		$ 4,598
Arda M. Minocherhomjee, Ph.D.			23,049		23,049
Cam L. Garner	58,326(2)		4,598		62,924
Erle T. Mast			4,598		4,598
James C. Blair, Ph.D.			4,598		4,598
Ken Haas			19,431		19,431
Kurt C. Wheeler			4,598		4,598
Louis C. Bock			4,598		4,598

(1) Represents the grant date fair value of the awards granted in 2009 as computed in accordance with ASC Topic 718. For a discussion of the valuation assumptions, see Note 9 to our consolidated financial statements for the year ended December 31, 2009 included elsewhere in this prospectus.

(2) Mr. Garner receives $49,993 per year in equal monthly installments for services as the chairman of the board of directors. In 2009, he was also paid $8,333, which represented the part of his 2008 retainer which we were not able to pay on time due to our need to conserve cash.

The aggregate number of shares subject to stock options outstanding at the end of fiscal 2009 for each non-employee director is as follows:

Name	Number of Shares Underlying Options Outstanding At December 31, 2009
Alex Zisson	11,000
Arda M. Minocherhomjee, Ph.D.	7,500
Cam L. Garner	1,750
Erle T. Mast	11,750
James C. Blair, Ph.D.	
Ken Haas	7,500
Kurt C. Wheeler	11,000
Louis C. Bock	11,000

Limitations of Liability and Indemnification Matters

Our amended and restated certificate of incorporation and our amended and restated bylaws, each of which will become effective upon the completion of this offering, will provide that we will indemnify our directors and officers to the fullest extent permitted by the Delaware General Corporation Law, which prohibits our amended and restated certificate of incorporation from limiting the liability of our directors for the following:

- any breach of the director s duty of loyalty to us or our stockholders;
- acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law;
- unlawful payment of dividends or unlawful stock repurchases or redemptions; or
- any transaction from which the director derived an improper personal benefit.

Our amended and restated certificate of incorporation and our amended and restated bylaws will also provide that if Delaware law is amended to authorize corporate action further eliminating or limiting the personal liability of a director, then the liability of our directors will be eliminated or limited to the fullest extent permitted by Delaware law, as so amended. This limitation of liability does not apply to liabilities arising under the federal securities laws and does not affect the availability of equitable remedies such as injunctive relief or rescission.

Our amended and restated certificate of incorporation and our amended and restated bylaws also will provide that we shall have the power to indemnify our employees and agents to the fullest extent permitted by law. Our amended and restated bylaws also permit us to secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions in this capacity, regardless of whether our amended and restated bylaws would permit indemnification. We have obtained directors and officers liability insurance.

We have entered into separate indemnification agreements with our directors and executive officers, in addition to indemnification provided for in our amended and restated certificate of incorporation and amended and restated bylaws. These agreements, among other things, provide for indemnification of our directors and executive officers for expenses, judgments, fines and settlement amounts incurred by this person in any action or proceeding arising out of this person s services as a director or executive officer or at our request. We believe that these provisions in our amended and restated certificate of incorporation and amended and restated bylaws and indemnification agreements are necessary to attract and retain qualified persons as directors and executive officers.

The above description of the indemnification provisions of our amended and restated certificate of incorporation, our amended and restated bylaws and our indemnification agreements is not complete and is qualified in its entirety by reference to these documents, each of which is attached as an exhibit to this registration statement.

The limitation of liability and indemnification provisions in our amended and restated certificate of incorporation and amended and restated bylaws may discourage stockholders from bringing a lawsuit against directors for breach of their fiduciary duties. They may also reduce the likelihood of derivative litigation against directors and officers, even though an action, if successful, might benefit us and our stockholders. A stockholder s investment may be harmed to the extent we pay the costs of settlement and damage awards against directors and officers pursuant to these indemnification provisions. Insofar as indemnification for liabilities under the Securities Act may be permitted to directors, officers or persons controlling us, we have been informed that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable. There is no pending litigation or proceeding naming any of our directors or officers as to which indemnification is being sought, nor are we aware of any pending or threatened litigation that may result in claims for indemnification by any director or officer.

PRINCIPAL STOCKHOLDERS

The following table sets forth information about the beneficial ownership of our common stock at September 30, 2010, and as adjusted to reflect the sale of the shares of common stock in this offering, for:

- each person known to us, or group of affiliated persons, to be the beneficial owner of more than 5% of our common stock;
- each of our named executive officers;
- each of our directors; and
- all of our executive officers and directors as a group.

Unless otherwise noted below, the address of each beneficial owner listed on the table is c/o Zogenix, Inc., 12671 High Bluff Drive, Suite 200, San Diego, CA 92130. We have determined beneficial ownership in accordance with the rules of the Securities and Exchange Commission. Except as indicated by the footnotes below, we believe, based on the information furnished to us, that the persons and entities named in the tables below have sole voting and investment power with respect to all shares of common stock that they beneficially own, subject to applicable community property laws.

In computing the number of shares of common stock beneficially owned by a person and the percentage ownership of that person, we deemed outstanding shares of common stock subject to options or warrants held by that person that are currently exercisable or exercisable within 60 days of September 30, 2010. We did not deem these shares outstanding, however, for the purpose of computing the percentage ownership of any other person.

Abingworth Bioventures, Chicago Growth Partners II, L.P., Clarus Lifesciences I, L.P., Domain Associates, L.L.C., Scale Venture Partners II, LP, Thomas, McNerney & Partners, L.P. and Cam L. Garner, or funds affiliated with them, each of which is a current stockholder and which we refer to collectively as the Current Stockholders, have indicated an interest in purchasing an aggregate of 7,138,895 shares of our common stock in this offering at the initial public offering price. Although we anticipate that the Current Stockholders will purchase, and that the underwriters will sell to the Current Stockholders, all of these shares, indications of interest are not binding agreements or commitments to purchase and the Current Stockholders may determine to purchase less or no shares in this offering and the underwriters may determine to sell less or no shares in this offering to the Current Stockholders. The information on beneficial ownership after this offering set forth in the table and footnotes below assumes the purchase of all of these shares in this offering by the Current Stockholders, with each Current Stockholder purchasing the number of shares set forth in the respective footnote to the table below for such Current Stockholder.

We have based our calculation of beneficial ownership prior to the offering on 15,690,046 shares of common stock outstanding on September 30, 2010, which assumes the conversion of all outstanding shares of our convertible preferred stock into 14,239,797 shares of common stock and the conversion of all outstanding warrants to purchase shares of our convertible stock into warrants to purchase shares of our common stock. We have based our calculation of beneficial ownership after the offering on 33,563,802 shares of our common stock outstanding immediately after the completion of this offering, which gives effect to (1) the issuance of 3,873,756 shares of our common stock upon completion of this offering as a result of the automatic conversion of the $15.0 million in aggregate principal amount of convertible promissory notes we issued in July 2010, or the 2010 Notes (including accrued interest thereon), based on the initial public offering price of $4.00 per share and assuming the conversion occurs on November 29, 2010 (the expected closing date of the offering), (2) the termination of outstanding warrants exercisable for an aggregate of 1,290,887 shares of our common stock, or the Series B Warrants, without having been exercised (the Series B Warrants will terminate automatically upon completion of this offering and we have assumed that these warrants will terminate without having been exercised because the exercise price exceeds the initial public offering price of our common

stock in this offering), and (3) the issuance of 14,000,000 shares of common stock in this offering, including the purchase of 7,138,895 shares of our common stock in this offering by the Current Stockholders as described in the preceding paragraph. Ownership information assumes no exercise of the underwriters over-allotment option.

	Number of Shares Beneficially Owned		Percentage of Common Stock Beneficially Owned	
Beneficial Owner	**Prior to Offering**	**After Offering**	**Prior to Offering**	**After Offering**
5% or Greater Stockholders:				
Funds affiliated with Domain Associates, L.L.C.(1) One Palmer Square Princeton, NJ 08542	3,548,185	6,615,336	22.4%	19.7%
Clarus Lifesciences I, LP(2) One Memorial Drive, Suite 1230 Cambridge, MA 92142	3,531,439	5,995,189	22.2%	17.9%
Scale Venture Partners II, LP(3) 950 Tower Lane, Suite 700 Foster City, CA 94404	2,358,479	4,084,296	14.9%	12.2%
Chicago Growth Partners II, L.P.(4) 3030 W. Madison Avenue, Suite 250 Chicago, IL 60606	2,371,135	2,969,827	14.6%	8.8%
Funds affiliated with Thomas, McNerney & Partners, L.P.(5) 60 South 6th Street, Suite 3620 Minneapolis, MN 55402	2,127,379	3,165,630	13.4%	9.4%
Funds affiliated with Abingworth Bioventures(6) 3000 Sand Hill Road Bldg. 4, Suite 135 Menlo Park, CA 94025	1,546,365	2,344,468	9.8%	7.0%
Directors and Executive Officers:				
Roger L. Hawley(7)	610,000	610,000	3.8%	1.8%
Stephen J. Farr, Ph.D.(8)	450,000	450,000	2.8%	1.3%
David Nassif(9)	125,000	125,000	*	*
J.D. Haldeman(10)	101,248	101,248	*	*
Cynthia Y. Robinson, Ph.D.(11)	90,000	90,000	*	*
James C. Blair, Ph.D.(1)	3,548,185	6,615,336	22.4%	19.7%
Kurt C. Wheeler(2)	3,531,439	5,995,189	22.2%	17.9%
Louis C. Bock(3)	2,358,479	4,084,296	14.9%	12.2%
Arda M. Minocherhomjee(4)	2,371,135	2,969,827	14.6%	8.8%
Ken Haas(6)	1,546,365	2,344,468	9.8%	7.0%
Cam L. Garner(12)	200,250	230,250	1.3%	*
Erle T. Mast(13)	13,500	13,500	*	*
Executive officers and directors as a group (13 persons)(14)	15,115,601	23,799,114	84.0%	69.2%

* Represents beneficial ownership of less than one percent of our outstanding common stock.

(1) Includes (a) 11,000 shares of common stock held by Domain Associates, L.L.C., (b) 9,894 shares of common stock held by Domain Partners VI, L.P., (c) 106 shares of common stock held by DP VI Associates, L.P., (d) 3,297,642 shares of common stock and 168,677

shares of common stock issuable upon the exercise of warrants held by Domain Partners VII, L.P. and (e) 56,242 shares of common stock and 2,874 shares of

common stock issuable upon the exercise of warrants held by DP VII Associates, L.P. Also includes 1,750 shares of common stock Mr. Blair has the right to acquire pursuant to outstanding options which are immediately exercisable, 1,020 of which would be subject to our right of repurchase within 60 days of September 30, 2010. In addition, the number of shares beneficially owned after the offering includes (a) 873,800 and 14,903 shares of common stock issuable upon the conversion of 2010 Notes held by Domain Partners VII, L.P. and DP VII Associates, L.P., respectively, based on the initial public offering price of $4.00 per share and assuming the conversion occurs on November 29, 2010, and (b) the purchase of 2,310,589 and 39,410 shares of common stock in this offering by Domain Partners VII, L.P. and DP VII Associates, L.P., respectively, and excludes shares of common stock issuable upon the exercise of Series B Warrants which we expect to terminate upon completion of this offering. The voting and disposition of the shares held by Domain Partners VI, L.P. and DP VI Associates, L.P. is determined by the managing members of One Palmer Square Associates VI, L.L.C., the general partner of Domain Partners VI, L.P. and DP VI Associates, L.P. The voting and disposition of the shares held by Domain Partners VII, L.P. and DP VII Associates, L.P. is determined by the managing members of One Palmer Square Associates VII, L.L.C., the general partner of Domain Partners VII, L.P. and DP VII Associates, L.P. Dr. Blair is a managing member of Domain Associates, L.L.C., One Palmer Square Associates VI, L.L.C. and One Palmer Square Associates VII, L.L.C. and disclaims beneficial ownership of these shares except to the extent of his pecuniary interest therein.

(2) Includes 3,347,947 shares of common stock and 170,742 shares of common stock issuable upon the exercise of warrants. In addition, the number of shares beneficially owned after the offering includes (a) 884,492 shares of common stock issuable upon the conversion of a 2010 Note, based on the initial public offering price of $4.00 per share and assuming the conversion occurs on November 29, 2010, and (b) the purchase of 1,750,000 shares of common stock in this offering, and excludes shares of common stock issuable upon the exercise of Series B Warrants which we expect to terminate upon completion of this offering. Mr. Wheeler is a managing director of Clarus Ventures I, LLC, the General Partner to Clarus Ventures I Management, L.P., the General Partner to Clarus Lifesciences I, L.P. and has shared voting and disposition power related to all shares. All shares are held for the benefit of Clarus Lifesciences I, L.P. Mr. Wheeler disclaims beneficial ownership of these shares except to the extent of his pecuniary interest therein. Also includes 12,750 shares of common stock Mr. Wheeler has the right to acquire pursuant to outstanding options which are immediately exercisable, 1,020 of which would be subject to our right of repurchase within 60 days of September 30, 2010.

(3) Includes 2,231,901 shares of common stock and 113,828 shares of common stock issuable upon the exercise of warrants. In addition, the number of shares beneficially owned after the offering includes (a) 589,645 shares of common stock issuable upon the conversion of a 2010 Note, based on the initial public offering price of $4.00 per share and assuming the conversion occurs on November 29, 2010, and (b) the purchase of 1,250,000 shares of common stock in this offering, and excludes shares of common stock issuable upon the exercise of Series B Warrants which we expect to terminate upon completion of this offering. The voting and disposition of the shares held by Scale Venture Partners II, LP is determined by a majority in interest of the five managers of Scale Venture Management II, LLC, the ultimate general partner of Scale Venture Partners II, LP. Mr. Bock is one of the managers of Scale Venture Management II, LLC and as such has a proportionate pecuniary interest in such shares, but does not have sole voting or investment power with respect to such shares. Mr. Bock disclaims beneficial ownership of these shares except to the extent of his pecuniary interest therein. Also includes 12,750 shares of common stock Mr. Bock has the right to acquire pursuant to outstanding options which are immediately exercisable, 1,020 of which would be subject to our right to repurchase within 60 days of September 30, 2010.

(4) Includes 1,818,181 shares of common stock and 545,454 shares of common stock issuable upon the exercise of warrants. The number of shares beneficially owned after the offering includes (a) 594,146 shares of common stock issuable upon the conversion of a 2010 Note, based on the initial public offering price of $4.00 per share and assuming the conversion occurs on November 29, 2010, and (b) the purchase of 550,000 shares of common stock in this offering, and excludes shares of common stock issuable upon the exercise of Series B Warrants which we expect to terminate upon completion of this offering. Chicago Growth Management II, LLC is the general partner of Chicago Growth Management II, LP, the general partner of Chicago Growth Partners II, L.P. Chicago Growth Management II, LLC and Chicago Growth Management II, LP have shared voting and dispositive power over the shares. Dr. Minocherhomjee is a Managing Director of Chicago Growth Management II, LLC and Chicago Growth Management II, LP and as such has a proportionate pecuniary interest in such shares, but does not have sole voting or investment power with respect to such shares. Dr. Minocherhomjee disclaims beneficial ownership of these shares except to the extent of his pecuniary

interest therein. Also includes 7,500 shares of common stock Mr. Minocherhomjee has the right to acquire pursuant to outstanding options which are immediately exercisable.

(5) Includes (a) 1,359,939 shares of common stock and 50,230 shares of common stock issuable upon the exercise of warrants held by Thomas McNerney & Partners, L.P., (b) 50,537 shares of common stock and 1,866 shares of common stock issuable upon the exercise of warrants held by TMP Nominee LLC, (c) 51,669 shares of common stock and 1,906 shares of common stock issuable upon the exercise of warrants held by TMP Associates L.P., (d) 490,502 shares of common stock and 147,150 shares of common stock issuable upon the exercise of warrants held by Thomas McNerney & Partners II, L.P., (e) 5,123 shares of common stock and 1,537 shares of common stock issuable upon the exercise of warrants held by TMP Nominee II, LLC and (f) 1,840 shares of common stock and 552 shares of common stock issuable upon the exercise of warrants held by TMP Associates II, L.P. In addition, the number of shares beneficially owned after the offering includes (a) 129,855, 2,379, 484, 392,585, 4,101 and 1,473 shares of common stock issuable upon the conversion of 2010 Notes held by Thomas McNerney & Partners, L.P., TMP Nominee LLC, TMP Associates L.P., Thomas McNerney & Partners II, L.P., TMP Nominee II, LLC and TMP Associates II, L.P., respectively, based on the initial public offering price of $4.00 per share and assuming the conversion occurs on November 29, 2010, and (b) the purchase of 173,399, 647, 3,178, 524,229, 1,967 and 5,476 shares of common stock in this offering by Thomas, McNerney & Partners, L.P., TMP Associates, L.P., TMP Nominee, LLC, Thomas, McNerney & Partners II, L.P., TMP Associates II, L.P. and TMP Nominee II, LLC, respectively, and excludes shares of common stock issuable upon the exercise of Series B Warrants which we expect to terminate upon completion of this offering. Also includes 12,750 shares of common stock that Alex Zisson, a former director who is affiliated with these stockholders, has the right to acquire pursuant to outstanding options which are immediately exercisable, 1,020 of which would be subject to our right of repurchase within 60 days of September 30, 2010.

(6) Includes (a) 1,437,066 shares of common stock and 87,046 shares of common stock issuable upon the exercise of warrants held by Abingworth Bioventures IV LP and (b) 12,319 shares of common stock and 744 shares of common stock issuable upon the exercise of warrants held by Abingworth Bioventures IV Executives LP. In addition, the number of shares beneficially owned after the offering includes (a) 382,613 and 3,280 shares of common stock issuable upon the conversion of 2010 Notes held by Abingworth Bioventures IV LP and Abingworth Bioventures IV Executives LP, respectively, based on the initial public offering price of $4.00 per share and assuming the conversion occurs on November 29, 2010, and (b) the purchase of 495,750 and 4,250 shares of common stock in this offering by Abingworth Bioventures IV L.P. and Abingworth Bioventures IV Executives L.P., respectively, and excludes shares of common stock issuable upon the exercise of Series B Warrants which we expect to terminate upon completion of this offering. Abingworth Management Ltd. serves as investment manager of Abingworth Bioventures IV L.P. and Abingworth Bioventures IV Executives L.P. Dr. Joe Anderson, Mr. Michael Bigham, Dr. Stephen Bunting and Dr. Jonathan MacQuitty comprise the investment committee of Abingworth Management Ltd. and may be deemed to have voting and investment control over the shares held by these stockholders. Abingworth Management Ltd. and the individuals noted above disclaim beneficial ownership of the securities except to the extent of their pecuniary interest therein. Mr. Haas disclaims beneficial ownership of these shares except to the extent of his pecuniary interest therein. Also includes 9,250 shares of common stock Mr. Haas has the right to acquire pursuant to outstanding options which are immediately exercisable, 1,020 of which would be subject to our right of repurchase within 60 days of September 30, 2010.

(7) Includes 90,000 shares Mr. Hawley acquired upon the early exercise of options, 13,125 of which are subject to our right of repurchase within 60 days of September 30, 2010. Includes 300,000 shares Mr. Hawley has the right to acquire pursuant to outstanding options which are immediately exercisable, 218,125 of which would be subject to our right of repurchase within 60 days of September 30, 2010.

(8) Includes 150,000 shares Dr. Farr has the right to acquire pursuant to outstanding options which are immediately exercisable, 121,301 of which would be subject to our right of repurchase within 60 days of September 30, 2010.

(9) Effective February 26, 2010, Mr. Nassif resigned as our executive vice president, chief financial officer, treasurer and secretary.

(10) Includes 62,967 shares Ms. Haldeman has the right to acquire pursuant to outstanding options which are immediately exercisable. Effective July 26, 2010, Ms. Haldeman resigned as our chief commercial officer.

(11) Includes 90,000 shares Dr. Robinson has the right to acquire pursuant to outstanding options which are immediately exercisable, 59,166 of which would be subject to our right of repurchase within 60 days of September 30, 2010.

(12) Includes 196,750 shares held by Garner Investments, LLC, of which Mr. Garner is the managing member, and 3,500 shares Mr. Garner has the right to acquire pursuant to outstanding options which are immediately exercisable, 1,020 of which would be subject to our right of repurchase within 60 days of September 30, 2010. In addition, the number of shares beneficially owned after the offering includes the purchase of 30,000 shares of common stock in this offering by Garner Investments, LLC.

(13) Includes 13,500 shares Mr. Mast has the right to acquire pursuant to outstanding options which are immediately exercisable, 1,020 of which would be subject to our right of repurchase within 60 days of September 30, 2010.

(14) Includes (a) 833,967 shares of common stock subject to outstanding options which are immediately exercisable, 549,712 of which would be subject to our right of repurchase within 60 days of September 30, 2010, (b) 127,458 shares acquired upon the early exercise of options, 13,125 of which are subject to our right of repurchase within 60 days of September 30, 2010, and (c) 1,089,365 shares of common stock issuable upon the exercise of warrants. In addition, the number of shares beneficially owned after the offering includes (a) 3,342,879 shares of common stock issuable upon the conversion of 2010 Notes, based on the initial public offering price of $4.00 per share and assuming the conversion occurs on November 29, 2010, and (b) the purchase of 6,429,999 shares of common stock in this offering by certain of the Current Stockholders, and excludes shares of common stock issuable upon the exercise of Series B Warrants which we expect to terminate upon completion of this offering.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

The following is a summary of transactions and series of similar transactions, since our inception, to which we were a party or will be a party, in which:

- the amount involved exceeded or will exceed $120,000; and
- a director, executive officer, holder of more than 5% of our capital stock or any member of their immediate family had or will have a direct or indirect material interest.

We also describe below certain other transactions with our directors, executive officers and stockholders. Although we have had no formal written policy in the past, as of the date of completion of this offering, our written policy will require that any transaction with a related party required to be reported under applicable Securities and Exchange Commission rules, other than compensation-related matters, be reviewed and approved by our audit committee. We will not adopt written procedures for review of, or standards for approval of, these transactions, but instead we intend to review such transactions on a case by case basis. In addition, our compensation committee will approve all compensation-related policies.

The following directors are affiliated with our principal stockholders as indicated in the following table and further described in Principal Stockholders above:

Director	Principal Stockholder
James C. Blair, Ph.D.	Funds affiliated with Domain Associates, L.L.C.
Louis C. Bock	Scale Venture Partners II, LP
Ken Haas	Funds affiliated with Abingworth Bioventures
Arda M. Minocherhomjee, Ph.D.	Chicago Growth Partners II, L.P.
Kurt C. Wheeler	Clarus Lifesciences I, L.P.

Preferred Stock Issuances and 2009 Convertible Notes Financing

In August 2006, September 2007 and December 2007, we issued in private placements an aggregate of 68,800,000 shares of Series A-1 convertible preferred stock at a per share price of $1.00, for aggregate consideration of $68.8 million. In December 2007, we issued in a private placement an aggregate of 9,090,909 shares of Series A-2 convertible preferred stock at a per share price of $1.10, for aggregate consideration of approximately $10.0 million.

In February 2009, we entered into a note and warrant purchase agreement with certain existing investors pursuant to which we sold, in a private placement in four tranches between February 2009 and July 2009, an aggregate of $14.8 million of convertible promissory notes, or the 2009 notes, and issued warrants, or the bridge warrants. The 2009 notes accrued interest at a rate of 8% per annum and were due one year from the date of issuance, subject to their earlier conversion in the event we completed a qualified equity financing or upon the occurrence of a deemed liquidation event (as defined in our current amended and restated certificate of incorporation). The bridge warrants were exercisable for the same class of shares of capital stock issued in the next qualified equity financing, or if no such financing occurred, shares of Series A-2 convertible preferred stock. In connection with the Series B financing, the principal amount of the 2009 notes and accrued interest thereon were automatically converted into an aggregate of 13,870,881 shares of Series B convertible preferred stock in September 2009 and the bridge warrants became exercisable for an aggregate of 3,363,619 shares of Series B convertible preferred stock at an exercise price of $1.10 per share. These warrants will become exercisable for shares of common stock at an exercise price of $11.00 per share upon completion of this offering, and will terminate if not exercised prior to the completion of this offering. Because the exercise price of these warrants of $11.00 per share of common stock exceeds the initial public offering price per share in this offering, we expect that these warrants will terminate upon the completion of this offering without having been exercised.

In September 2009 and December 2009, we issued in private placements an aggregate of 64,507,233 shares of Series B convertible preferred stock in the Series B financing at a per share price of $1.10, for aggregate consideration of approximately $71.0 million, including the conversion of approximately $15.3 million of the 2009 notes. In the December 2009 second closing of the Series B financing, we issued warrants to investors to purchase an aggregate of 9,545,447 shares of our Series B convertible preferred stock at an exercise price of $1.10 per share, which warrants were amended in October 2010 to allow for their current exercisability. These warrants will become exercisable for shares of common stock at an exercise price of $11.00 per share upon completion of this offering, and will terminate if not exercised prior to the completion of this offering. Because the exercise price of these warrants of $11.00 per share of common stock exceeds the initial public offering price per share in this offering, we expect that these warrants will terminate upon the completion of this offering without having been exercised.

The following table sets forth the aggregate number of these securities acquired by the listed directors, executive officers or holders of more than 5% of our capital stock, or their affiliates. Each share of, or warrants exercisable for shares of, convertible preferred stock identified in the following table will convert into one-tenth of a share of, or warrants exercisable for, common stock upon completion of this offering.

Investor(1)	Series A-1 Preferred Stock	Series A-2 Preferred Stock	Series B Preferred Stock	Series B Warrants
Funds affiliated with Domain Associates, L.L.C.(2)	21,100,000		12,538,899	1,715,565
Clarus Lifesciences I, L.P. (3)	21,000,000		12,479,474	1,707,437
Scale Venture Partners II, LP(4)	14,000,000		8,319,024	1,138,291
Funds affiliated with Thomas, McNerney & Partners, L.P.(5)	12,000,000		7,131,106	2,015,297
Chicago Growth Partners II, L.P.(6)			18,181,818	5,454,545
Funds affiliated with Abingworth Bioventures(7)		9,090,909	5,402,367	877,931
Roger L. Hawley	100,000			
Cam L. Garner	100,000			

(1) Additional details regarding these stockholders and their equity holdings is provided in Principal Stockholders above.

(2) Includes (a) 98,940 shares of Series A-1 convertible preferred stock held by Domain Partners VI, L.P., (b) 1,060 shares of Series A-1 convertible preferred stock held by DP VI Associates, L.P., (c) 20,647,825 shares of Series A-1 convertible preferred stock, 12,328,620 shares of Series B convertible preferred stock, 904,023 shares of Series B convertible preferred stock issuable upon the exercise of bridge warrants and 782,774 shares of Series B convertible preferred stock issuable upon the exercise of Series B warrants held by Domain Partners VII, L.P. and (d) 352,175 shares of Series A-1 convertible preferred stock, 210,279 shares of Series B convertible preferred stock, 15,417 shares of Series B convertible preferred stock issuable upon the exercise of bridge warrants and 13,351 shares of Series B convertible preferred stock issuable upon the exercise of Series B warrants held by DP VII Associates, L.P

(3) Includes 21,000,000 shares of Series A-1 convertible preferred stock, 12,479,474 shares of Series B convertible preferred stock, 915,084 shares of Series B convertible preferred stock issuable upon the exercise of bridge warrants and 792,353 shares of Series B convertible preferred stock issuable upon the exercise of Series B warrants.

(4) Includes 14,000,000 shares of Series A-1 convertible preferred stock, 8,319,024 shares of Series B convertible preferred stock, 610,056 shares of Series B convertible preferred stock issuable upon the exercise of bridge warrants and 528,235 shares of Series B convertible preferred stock issuable upon the exercise of Series B warrants.

(5) Includes (a) 11,527,800 shares of Series A-1 convertible preferred stock, 2,071,593 shares of Series B convertible preferred stock and 502,327 shares of Series B convertible preferred stock issuable upon the exercise of bridge warrants held by Thomas McNerney & Partners, L.P., (b) 428,400 shares of Series A-1 convertible preferred stock, 76,975 shares of Series B convertible preferred stock and 18,667 shares of Series B convertible preferred stock issuable upon the exercise of bridge warrants held by TMP Nominee LLC,

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(c) 43,800 shares of Series A-1 convertible preferred stock, 7,869 shares of Series B convertible preferred stock and 1,906 shares of Series B convertible preferred stock issuable upon the exercise of bridge warrants held by TMP Associates L.P., (d) 4,905,024 shares of Series B convertible preferred stock and 1,471,505 shares of Series B convertible preferred stock issuable upon the exercise of Series B warrants held by Thomas McNerney & Partners II, L.P., (e) 51,239 shares of Series B convertible preferred stock and 15,371 shares of Series B convertible preferred stock issuable upon the exercise of Series B warrants held by TMP Nominee II, LLC and (f) 18,406 shares of Series B convertible preferred stock and 5,521 shares of Series B convertible preferred stock issuable upon the exercise of Series B warrants held by TMP Associates II, L.P.

(6) Includes 18,181,818 shares of Series B convertible preferred stock and 5,454,545 shares of Series B convertible preferred stock issuable upon the exercise of Series B warrants.

(7) Includes (a) 9,013,631 shares of Series A-2 convertible preferred stock, 5,356,437 shares of Series B convertible preferred stock, 392,773 shares of Series B convertible preferred stock issuable upon the exercise of bridge warrants and 477,696 shares of Series B convertible preferred stock issuable upon the exercise of Series B warrants held by Abingworth Bioventures IV LP and (b) 77,278 shares of Series A-2 convertible preferred stock, 45,930 shares of Series B convertible preferred stock, 3,366 shares of Series B convertible preferred stock issuable upon the exercise of bridge warrants and 4,096 shares of Series B convertible preferred stock issuable upon the exercise of Series B warrants held by Abingworth Bioventures IV Executives LP.

Common Stock Issuances

In May and August 2006, we issued an aggregate of 710,000 shares of common stock for aggregate consideration of $5,000 to certain directors and executive officers. The following table sets forth these issuances:

Executive Officer/Director	Shares of Common Stock
Roger L. Hawley	210,000
Stephen J. Farr, Ph.D.(1)	300,000
Cam L. Garner(2)	200,000

(1) Includes 216,000 shares that were issued to Dr. Farr on August 16, 2006 as the result of a 1 for 3.571429 forward stock split.

(2) Of these 200,000 shares, 185,000 shares are held by a limited liability company for which Mr. Garner is the sole member and 15,000 shares are held by siblings of Mr. Garner.

2010 Convertible Note Financing

In July 2010, we entered into a note purchase agreement with certain existing investors pursuant to which we sold in a private placement an aggregate of $15.0 million of convertible promissory notes, or the 2010 Notes. The 2010 Notes accrue interest at a rate of 8% per annum and become due and payable one year from the date of issuance. The principal amount of the 2010 Notes and accrued interest thereon will automatically convert into shares of our common stock upon completion of this offering at a conversion price equal to our initial public offering price. If a deemed liquidation event (as defined in our current amended and restated certificate of incorporation) occurs prior to the completion of this offering, the holders of the 2010 Notes may elect to (1) receive the repayment of the notes or (2) convert the notes into shares of Series B convertible preferred stock at a conversion price of $1.10 per share.

The participants in the 2010 convertible note financing included the following holders of more than 5% of our capital stock, or entities affiliated with them. The following table sets forth the principal amount of 2010 Notes issued to each such party:

Investor(1)	Principal Amount
Funds affiliated with Domain Associates L.L.C.(2)	$ 3,440,206
Clarus Lifesciences I, L.P.	$ 3,423,902
Chicago Growth Partners II, L.P.	$ 2,299,963
Scale Venture Partners II, LP	$ 2,282,541
Funds affiliated with Thomas, McNerney & Partners, L.P.(3)	$ 2,057,675
Funds affiliated with Abingworth Bioventures(4)	$ 1,495,713

(1) Additional details regarding these stockholders and their equity holdings is provided in Principal Stockholders above.

(2) Includes $3,382,513 issued to Domain Partners VII, L.P. and $57,693 issued to DP VII Associates, L.P.

(3) Includes $503,318 issued to Thomas, McNerney & Partners, L.P., $9,224 issued to TMP Nominee, LLC, $1,878 issued to TMP Associates, L.P., $1,521,650 issued to Thomas McNerney & Partners II, L.P., $15,896 issued to TMP Nominee II, LLC and $5,710 issued to TMP Associates II, L.P.

(4) Includes $12,714 issued to Abingworth Bioventures IV Executives LP and $1,482,999 issued to Abingworth Bioventures IV LP.

Investors Rights Agreement

We have entered into an amended and restated investors rights agreement, or the investors rights agreement, with holders of our convertible preferred stock, holders of our warrants exercisable for shares of our convertible preferred stock and holders of the 2010 Notes. This agreement provides for certain rights relating to the registration of their shares of common stock issuable upon conversion of their convertible preferred stock and 2010 Notes (which will occur upon the closing of this offering) and exercise of the warrants (which will become exercisable for shares of common stock upon completion of this offering), a right of first refusal to purchase future securities sold by us and certain additional covenants made by us. Except for the registration rights (including the related provisions pursuant to which we have agreed to indemnify the parties to the investors rights agreement), all rights under this agreement will terminate upon completion of this offering. The registration rights will continue following this offering and will terminate five years following the completion of this offering, or for any particular holder with registration rights, at such time following this offering when all securities held by that stockholder subject to registration rights may be sold pursuant to Rule 144 under the Securities Act. All holders of our convertible preferred stock are parties to this agreement. See Description of Capital Stock Registration Rights for additional information.

Voting Agreement

Pursuant to a voting agreement originally entered into in August 2006 and most recently amended in December 2009 by and among us and certain of our stockholders, the following directors were each elected to serve as members on our board of directors and, as of the date of this prospectus, continue to so serve: Drs. Blair, Farr and Minocherhomjee and Messrs. Bock, Garner, Haas, Hawley, Mast and Wheeler. Pursuant to the voting agreement, Mr. Hawley, as our chief executive officer, was initially selected to serve on our board of directors as a representative of our common stock, as designated by a majority of our common stockholders. Drs. Blair and Minocherhomjee and Messrs. Bock, Haas and Wheeler were initially selected to serve on our board of directors as representatives of our convertible

preferred stock, as designated by Domain Partners VII, L.P., Chicago Growth Partners, Scale Venture Partners II, LP, Abingworth Management Limited, Clarus Lifesciences I, L.P. and Thomas, McNerney & Partners, L.P., respectively. Dr. Farr was initially selected to serve on our board of directors as chosen unanimously by the remaining directors.

The voting agreement will terminate upon completion of this offering, and members previously elected to our board of directors pursuant to this agreement will continue to serve as directors until they resign, are removed or their successors are duly elected by holders of our common stock. The composition of our board of directors after this offering is described in more detail under Management Board Composition and Election of Directors.

Participation in this Offering

Abingworth Bioventures, Chicago Growth Partners II, L.P., Clarus Lifesciences I, L.P., Domain Associates, L.L.C., Scale Venture Partners II, LP, Thomas, McNerney & Partners, L.P. and Cam L. Garner, or funds affiliated with them, each of which is a current stockholder and which we refer to collectively as the Current Stockholders, have indicated an interest in purchasing an aggregate of 7,138,895 shares of our common stock in this offering at the initial public offering price. Although we anticipate that the Current Stockholders will purchase, and that the underwriters will sell to the Current Stockholders, all of these shares, indications of interest are not binding agreements or commitments to purchase and the Current Stockholders may determine to purchase less or no shares in this offering and the underwriters may determine to sell less or no shares in this offering to the Current Stockholders. The underwriters will receive underwriting discounts and commissions of $0.0981 per share on any shares sold to the Current Stockholders.

Employment and Release Agreements

We have entered into employment agreements with the following executive officers: Roger L. Hawley, our Chief Executive Officer; Stephen J. Farr, Ph.D., our President and Chief Operating Officer; Ann Rhoads, our Executive Vice President, Chief Financial Officer, Treasurer and Secretary; Cynthia Y. Robinson, Ph.D., our Chief Development Officer. For further information, see Compensation Discussion and Analysis Employment and Release Agreements Employment Agreements.

We have also entered into release agreements with David W. Nassif, J.D., our former executive vice president and chief financial officer; and J.D. Haldeman, our former chief commercial officer. See Compensation Discussion and Analysis Employment and Release Agreements Release Agreements.

Indemnification of Officers and Directors

Our amended and restated certificate of incorporation and amended and restated bylaws, which will become effective upon the completion of this offering, will provide that we will indemnify each of our directors and officers to the fullest extent permitted by the Delaware General Corporation Law. Further, we have entered into indemnification agreements with each of our directors and officers, and we have purchased a policy of directors and officers liability insurance that insures our directors and officers against the cost of defense, settlement or payment of a judgment under certain circumstances. For further information, see Compensation Discussion and Analysis Limitations of Liability and Indemnification Matters.

Consulting Agreement

In March 2010, we entered into a consulting agreement with David W. Nassif, J.D. pursuant to which Mr. Nassif provides executive consulting services to us. As of September 30, 2010, we had paid him a total of $59,775 as compensation for such services.

Stock Option Grants to Executive Officers and Directors

We have granted stock options to our executive officers and certain of our directors. For further information, see Compensation Discussion and Analysis.

DESCRIPTION OF CAPITAL STOCK

Upon completion of this offering and the filing of our amended and restated certificate of incorporation, our authorized capital stock will consist of 100,000,000 shares of common stock, $0.001 par value per share, and 10,000,000 shares of preferred stock, $0.001 par value per share. The following description summarizes some of the terms of our amended and restated certificate of incorporation and amended and restated bylaws, which will become effective prior to the completion of this offering, our outstanding warrants, the investors rights agreement and of the Delaware General Corporation Law. Because it is only a summary, it does not contain all the information that may be important to you. For a complete description you should refer to our amended and restated certificate of incorporation, amended and restated bylaws, warrants and investors rights agreement, copies of which have been filed as exhibits to the registration statement of which the prospectus is a part, as well as the relevant provisions of the Delaware General Corporation Law.

Common Stock

On September 30, 2010, there were 1,450,249 shares of common stock outstanding, held of record by 28 stockholders. The holders of our common stock are entitled to one vote for each share held of record on all matters submitted to a vote of the stockholders, including the election of directors, and do not have cumulative voting rights. Accordingly, the holders of a majority of the outstanding shares of common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they so choose, other than any directors that holders of our preferred stock may be entitled to elect. Subject to preferences that may be applicable to any then outstanding preferred stock, holders of common stock are entitled to receive ratably those dividends, if any, as may be declared by the board of directors out of legally available funds. In the event of our liquidation, dissolution or winding up, the holders of common stock will be entitled to share ratably in the assets legally available for distribution to stockholders after the payment of or provision for all of our debts and other liabilities, subject to the prior rights of any preferred stock then outstanding. Holders of common stock have no preemptive or conversion rights or other subscription rights and there are no redemption or sinking funds provisions applicable to the common stock. All outstanding shares of common stock are, and the common stock to be outstanding upon completion of this offering will be, duly authorized, validly issued, fully paid and nonassessable.

Preferred Stock

On September 30, 2010, there were 142,398,142 shares of convertible preferred stock outstanding, held of record by 30 stockholders. Our stockholders have agreed to convert their shares of convertible preferred stock to common stock immediately prior to the completion of this offering. Accordingly, upon the completion of this offering, all outstanding shares of convertible preferred stock as of September 30, 2010 will automatically convert into 14,239,797 shares of our common stock.

Following the completion of this offering, under the terms of our amended and restated certificate of incorporation, our board of directors will have the authority, without further action by our stockholders, to issue up to 10,000,000 shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each such series, to fix the dividend, voting and other rights, preferences and privileges of the shares of each wholly unissued series and any qualifications, limitations or restrictions thereon, and to increase or decrease the number of shares of any such series, but not below the number of shares of such series then outstanding.

Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of the common stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in our control and may adversely affect the market price of the common stock and the voting and other rights of the holders of common stock. We have no current plans to issue any shares of preferred stock.

Warrants

General Electric Capital Corporation. In March 2007, in connection with the closing of a debt facility, we issued a warrant exercisable for an aggregate of 200,000 shares of our Series A-1 convertible preferred stock to General Electric Capital Corporation. This warrant is immediately exercisable at an exercise price of $1.00 per share and, excluding certain mergers or acquisitions and similar transactions, expires seven years from the date of grant, which is March 5, 2014. This warrant will become exercisable for an aggregate of 20,000 shares of our common stock, at an exercise price of $10.00 per share, upon completion of this offering.

Oxford Finance Corporation, CIT Healthcare LLC and Silicon Valley Bank. In June 2008, in connection with the closing of a debt facility, or the original Oxford debt facility, we issued warrants exercisable for an aggregate of 777,273 shares of our Series A-2 convertible preferred stock to Oxford Finance Corporation, or Oxford, and CIT Healthcare LLC. These warrants are immediately exercisable at an exercise price of $1.10 per share and, excluding certain mergers, acquisitions and similar transactions, expire 10 years from the date of grant, which is June 29, 2018. These warrants will become exercisable for an aggregate of 77,726 shares of our common stock, at an exercise price of $11.00 per share, upon completion of this offering.

In July 2010, in connection with the closing of a debt facility, which replaced the original Oxford debt facility, we issued warrants exercisable for an aggregate of 1,590,910 shares of our Series B convertible preferred stock to Oxford and Silicon Valley Bank. These warrants are immediately exercisable at an exercise price of $1.10 per share and, excluding certain mergers, acquisitions and similar transactions, expire on the earlier to occur of 10 years from the date of grant or five years following the effective date of the registration statement of which this prospectus is a part. These warrants will become exercisable for an aggregate of 159,090 shares of our common stock, at an exercise price of $11.00 per share, upon completion of this offering.

2009 Bridge Warrants. Between February and July 2009, in connection with the sale of convertible promissory notes to certain of our existing investors, we issued warrants which, upon the first closing of our Series B preferred stock financing in September 2009, became exercisable for an aggregate of 3,363,619 shares of our Series B convertible preferred stock. These warrants will become exercisable for shares of common stock at an exercise price of $11.00 per share upon completion of this offering, and will terminate if not exercised prior to the completion of this offering. Because the exercise price of these warrants of $11.00 per share of common stock exceeds the initial public offering price per share in this offering, we expect that these warrants will terminate upon the completion of this offering without having been exercised.

Series B Warrants. In December 2009, in connection with the second closing of our Series B preferred stock financing, we issued warrants to investors exercisable for an aggregate of 9,545,447 shares of our Series B convertible preferred stock at an exercise price of $1.10 per share, which warrants were amended in October 2010 to allow for their current exercisability. These warrants will become exercisable for shares of common stock at an exercise price of $11.00 per share upon completion of this offering, and will terminate if not exercised prior to the completion of this offering. Because the exercise price of these warrants of $11.00 per share of common stock exceeds the initial public offering price per share in this offering, we expect that these warrants will terminate upon the completion of this offering without having been exercised.

Each of the above warrants has a net exercise provision under which their holders may, in lieu of payment of the exercise price in cash, surrender the warrant and receive, after this offering, a net amount of shares of our common stock based on the fair market value of our common stock at the time of the net exercise of the warrant after deduction of the aggregate exercise price. These warrants also contain provisions for the adjustment of the exercise price and the aggregate number of shares issuable upon the exercise of the warrants in the event of stock dividends, stock splits, reorganizations and reclassifications and consolidations.

Registration Rights

After this offering and assuming that the Series B Warrants terminate upon completion of this offering without having been exercised, the holders of approximately 18,370,369 shares of common stock (including 3,873,756 shares of our common stock issuable upon completion of this offering as a result of the automatic conversion of the $15.0 million in aggregate principal amount of convertible promissory notes, or the 2010 Notes, issued in July 2010 (including accrued interest thereon), based on the initial public offering price of $4.00 per share and assuming the conversion occurs on November 29, 2010 (the expected closing date of this offering)) and the holders of warrants to purchase 256,816 shares of common stock that we expect will remain outstanding upon completion of this offering will be entitled to rights with respect to the registration of these shares under the Securities Act. These shares are referred to as registrable securities. Under the terms of the agreement between us and the holders of the registrable securities, if we propose to register any of our securities under the Securities Act, these holders are entitled to notice of such registration and are entitled to include their shares of registrable securities in our registration. Certain of these holders are also entitled to demand registration, pursuant to which they may require us to use our best efforts to register their registrable securities under the Securities Act at our expense, up to a maximum of three such registrations. Holders of registrable securities may also require us to file an unlimited number of additional registration statements on Form S-3 at our expense so long as the holders propose to sell registrable securities of at least $5.0 million and we have not already filed two such registration statements on Form S-3 in the previous 12 months.

All of these registration rights are subject to certain conditions and limitations, among them the right of the underwriters of an offering to limit the number of shares included in such registration and our right not to effect a requested registration 60 days prior to or 180 days after an offering of our securities, including this offering. These registration rights, which will remain in effect following this offering, will terminate five years following the completion of this offering, or for any particular holder with registration rights, at such time following this offering when all securities held by that stockholder entitled to registration rights may be immediately sold pursuant to Rule 144 under the Securities Act during any 90 day period. These registration rights have been waived with respect to this offering and for the period beginning 180 days after the date of this prospectus.

Anti-Takeover Effects of Provisions of Our Amended and Restated Certificate of Incorporation,

Our Bylaws and Delaware Law

Some provisions of Delaware law, our amended and restated certificate of incorporation and our amended and restated bylaws contain provisions that could make the following transactions more difficult: an acquisition of us by means of a tender offer; an acquisition of us by means of a proxy contest or otherwise; or the removal of our incumbent officers and directors. It is possible that these provisions could make it more difficult to accomplish or could deter transactions that stockholders may otherwise consider to be in their best interest or in our best interests, including transactions which provide for payment of a premium over the market price for our shares.

These provisions, summarized below, are intended to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our board of directors. We believe that the benefits of the increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure us outweigh the disadvantages of discouraging these proposals because negotiation of these proposals could result in an improvement of their terms.

Undesignated Preferred Stock

The ability of our board of directors, without action by the stockholders, to issue up to 10,000,000 shares of undesignated preferred stock with voting or other rights or preferences as designated by our

board of directors could impede the success of any attempt to change control of us. These and other provisions may have the effect of deferring hostile takeovers or delaying changes in control or management of our company.

Stockholder Meetings

Our amended and restated bylaws provide that a special meeting of stockholders may be called only by our chairman of the board, chief executive officer or president, or by a resolution adopted by a majority of our board of directors.

Requirements for Advance Notification of Stockholder Nominations and Proposals

Our amended and restated bylaws establish advance notice procedures with respect to stockholder proposals to be brought before a stockholder meeting and the nomination of candidates for election as directors, other than nominations made by or at the direction of the board of directors or a committee of the board of directors.

Elimination of Stockholder Action by Written Consent

Our amended and restated certificate of incorporation and amended and restated bylaws eliminate the right of stockholders to act by written consent without a meeting.

Staggered Board

Our board of directors is divided into three classes. The directors in each class will serve for a three-year term, one class being elected each year by our stockholders. For more information on the classified board, see Management Board Composition and Election of Directors. This system of electing and removing directors may tend to discourage a third-party from making a tender offer or otherwise attempting to obtain control of us, because it generally makes it more difficult for stockholders to replace a majority of the directors.

Removal of Directors

Our amended and restated certificate of incorporation provides that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than 66 $^{2}/_{3}$% of the total voting power of all of our outstanding voting stock then entitled to vote in the election of directors.

Stockholders Not Entitled to Cumulative Voting

Our amended and restated certificate of incorporation does not permit stockholders to cumulate their votes in the election of directors. Accordingly, the holders of a majority of the outstanding shares of our common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they choose, other than any directors that holders of our preferred stock may be entitled to elect.

Delaware Anti-Takeover Statute

We are subject to Section 203 of the Delaware General Corporation Law, which prohibits persons deemed to be interested stockholders from engaging in a business combination with a publicly held Delaware corporation for three years following the date these persons become interested stockholders unless the business combination is, or the transaction in which the person became an interested stockholder was, approved in a prescribed manner or another prescribed exception applies. Generally, an interested stockholder is a person who, together with affiliates and associates, owns, or within three years prior to the determination of interested stockholder status did own, 15% or more of a corporation s voting stock. Generally, a business combination includes a merger, asset or stock sale,

or other transaction resulting in a financial benefit to the interested stockholder. The existence of this provision may have an anti-takeover effect with respect to transactions not approved in advance by the board of directors.

Amendment of Charter Provisions

The amendment of any of the above provisions, except for the provision making it possible for our board of directors to issue preferred stock, would require approval by holders of at least $66^{2}/_{3}\%$ of the total voting power of all of our outstanding voting stock.

The provisions of Delaware law, our amended and restated certificate of incorporation and our amended and restated bylaws could have the effect of discouraging others from attempting hostile takeovers and, as a consequence, they may also inhibit temporary fluctuations in the market price of our common stock that often result from actual or rumored hostile takeover attempts. These provisions may also have the effect of preventing changes in the composition of our board and management. It is possible that these provisions could make it more difficult to accomplish transactions that stockholders may otherwise deem to be in their best interests.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is American Stock Transfer & Trust Company, LLC, located at 6201 15th Avenue, Brooklyn, NY 11219.

Nasdaq Global Market Listing

Our common stock has been approved for listing on the Nasdaq Global Market under the symbol ZGNX.

SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no public market for our common stock. Future sales of our common stock, including shares issued upon the exercise of outstanding options or warrants, in the public market after this offering, or the perception that those sales may occur, could cause the prevailing market price for our common stock to fall or impair our ability to raise equity capital in the future. As described below, only a limited number of shares of our common stock will be available for sale in the public market for a period of several months after completion of this offering due to contractual and legal restrictions on resale described below. Future sales of our common stock in the public market either before (to the extent permitted) or after restrictions lapse, or the perception that those sales may occur, could adversely affect the prevailing market price of our common stock at such time and our ability to raise equity capital at a time and price we deem appropriate.

Sales of Restricted Shares

Based on the number of shares of our common stock outstanding as of September 30, 2010, upon the closing of this offering and assuming (1) the conversion of our outstanding convertible preferred stock into common stock, (2) the conversion of the 2010 Notes and accrued interest thereon into common stock as described elsewhere in this prospectus, based on the initial public offering price of $4.00 per share and assuming that the conversion occurs on November 29, 2010, (3) no exercise of the underwriters option to purchase additional shares of common stock to cover over-allotments, (4) no exercise of outstanding options or warrants and (5) that certain of our current stockholders, referred to herein as the Current Stockholders, purchase all of the 7,138,895 shares of common stock that they have indicated an interest in purchasing as described elsewhere in this prospectus, we will have outstanding an aggregate of approximately 33,563,802 shares of common stock. Of these shares, 6,861,105 of the 14,000,000 shares of common stock to be sold in this offering to new investors, and any shares sold upon exercise of the underwriters option to purchase additional shares to cover over-allotments, will be freely tradable in the public market without restriction or further registration under the Securities Act of 1933, as amended, or the Securities Act, unless the shares are held by any of our affiliates as such term is defined in Rule 144 of the Securities Act. All remaining shares of common stock held by existing stockholders immediately prior to the completion of this offering, all shares issued on conversion of the 2010 Notes and all shares purchased by the Current Stockholders in this offering, will be restricted securities as such term is defined in Rule 144. These restricted securities were issued and sold by us in private transactions and are eligible for public sale only if registered under the Securities Act or if they qualify for an exemption from registration under the Securities Act, including the exemptions provided by Rule 144 or Rule 701, which rules are summarized below.

As a result of the lock-up agreements referred to below and the provisions of Rule 144 and Rule 701 under the Securities Act, the shares of our common stock (excluding the 6,861,105 shares sold in this offering to new investors) that will be available for sale in the public market are as follows:

Approximate Number of Shares	First Date Available for Sale into Public Market
26,702,697 shares	180 days after the date of this prospectus, or longer if the lock-up period is extended, upon expiration of the lock-up agreements referred to below, subject in some cases to applicable volume limitations under Rule 144

Lock-up Agreements

As described under Underwriting Lock-Up Agreements below, we, each of our directors and officers, the holders of substantially all of the other shares of our common stock outstanding prior to this offering and the holders of substantially all of our warrants and options outstanding prior to this offering, have agreed, subject to specified exceptions, not to, directly or indirectly, issue (in the case of us), offer, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend or otherwise transfer or dispose of any shares of our common stock or any securities convertible into or exercisable or exchangeable for shares of our common stock, without the prior written consent of Wells Fargo Securities, LLC and Leerink Swann LLC, for a period of 180 days from the date of the final prospectus for the offering, or longer if the lock-up period is extended.

Wells Fargo Securities, LLC and Leerink Swann LLC, in their sole discretion, at any time or from time to time and without notice, release for sale in the public market all or any portion of the shares restricted by the terms of the lock-up agreements.

Rule 144

In general, under Rule 144, as currently in effect, once we have been subject to the public company reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, for at least 90 days, a person (or persons whose shares are required to be aggregated) who is not deemed to have been one of our affiliates for purposes of Rule 144 at any time during the three months preceding a sale, and who has beneficially owned restricted securities within the meaning of Rule 144 for at least six months, including the holding period of any prior owner other than one of our affiliates, is entitled to sell those shares in the public market (subject to the lock-up agreement referred to above, if applicable) without complying with the manner of sale, volume limitations or notice provisions of Rule 144, but subject to compliance with the public information requirements of Rule 144. If such a person has beneficially owned the sales proposed to be sold for at least one year, including the holding period of any prior owner other than affiliates, then such person is entitled to sell such shares in the public market without complying with any of the requirements of Rule 144 (subject to the lock-up agreement referred to above, if applicable).

In general, under Rule 144, as currently in effect, once we have been subject to the public company reporting requirements of the Exchange Act for at least 90 days, our affiliates, as defined in Rule 144, who have beneficially owned the shares proposed to be sold for at least six months are entitled to sell in the public market, upon expiration of any applicable lock-up agreements and within any three-month period, a number of those shares of our common stock that does not exceed the greater of:

- 1% of the number of common shares then outstanding, which will equal approximately 335,638 shares of common stock immediately after this offering (calculated on the basis of the assumptions described above and assuming no exercise of the underwriter s option to purchase additional shares and no exercise of outstanding options or warrants); or

- the average weekly trading volume of our common stock on the Nasdaq Global Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale.

Such sales under Rule 144 by our affiliates or persons selling shares on behalf of our affiliates are also subject to certain manner of sale provisions, notice requirements and to the availability of current public information about us. Notwithstanding the availability of Rule 144, the holders of substantially all of our restricted securities have entered into lock-up agreements as referenced above and their restricted securities will become eligible for sale (subject to the above limitations under Rule 144) upon the expiration of the restrictions set forth in those agreements.

Rule 701

In general, under Rule 701 as currently in effect, any of our employees, directors, officers, consultants or advisors who acquired common stock from us in connection with a written compensatory stock or option plan or other written agreement in compliance with Rule 701 under the Securities Act before the effective date of the registration statement of which this prospectus is a part (to the extent such common stock is not subject to a lock-up agreement) is entitled to rely on Rule 701 to resell such shares beginning 90 days after we become subject to the public company reporting requirements of the Exchange Act in reliance on Rule 144, but without compliance with the holding period requirements contained in Rule 144. Accordingly, subject to any applicable lock-up agreements, beginning 90 days after we become subject to the public company reporting requirements of the Exchange Act, under Rule 701 persons who are not our affiliates, as defined in Rule 144, may resell those shares without complying with the minimum holding period or public information requirements of Rule 144, and persons who are our affiliates may resell those shares without compliance with Rule 144 s minimum holding period requirements (subject to the terms of the lock-up agreement referred to above, if applicable).

Stock Options and Stock Plans

As of September 30, 2010, options to purchase an aggregate of 1,482,780 shares of our common stock were outstanding, of which 1,249,586 were exercisable and 467,573 were vested. Substantially all of the shares issuable upon the exercise of options are subject to the terms of the lock-up agreements with the underwriters. Upon completion of this offering, 2,000,000 additional shares of common stock will be reserved for future issuance under our 2010 Plan, which will become effective immediately prior to the completion of this offering, plus 233,689 shares of common stock reserved for future grant or issuance under our 2006 Plan, as of September 30, 2010, which shares will be added to the shares to be reserved under our 2010 Plan upon the effectiveness of the 2010 Plan, plus any annual increases in the number of shares of common stock reserved for future issuance under the 2010 Plan pursuant to an evergreen provision and any other shares that may become issuable under the 2010 Plan pursuant to it terms, as more fully described in Compensation Discussion and Analysis Employee Equity Incentive Plans 2010 Equity Incentive Award Plan.

We intend to file one or more registration statements on Form S-8 under the Securities Act to register shares of our common stock subject to outstanding options and reserved for issuance under our equity incentive and employee stock purchase plans. See Compensation Discussion and Analysis Employee Equity Incentive Plans for additional information regarding these plans. The first such registration statement is expected to be filed soon after the date of this prospectus and will automatically become effective upon filing with the SEC. Accordingly, shares registered under such registration statement will be available for sale in the open market following the effective date, unless such shares are subject to vesting restrictions with us, Rule 144 restrictions applicable to our affiliates or the lock-up restrictions described above.

Warrants

As of September 30, 2010, warrants to purchase an aggregate of 15,477,249 shares of our convertible preferred stock were outstanding. Of this amount, warrants exercisable for an aggregate of 12,909,066 shares of our convertible preferred stock are expected to terminate upon the completion of this offering without having been exercised because the exercise price of these warrants exceeds the initial public offering price per share in this offering. The warrants which are expected to remain outstanding upon completion of this offering will become exercisable for an aggregate of 256,816 shares of our common stock at a weighted average exercise price of $10.92 per share. Any shares acquired upon the net exercise of these warrants may be sold in the public market pursuant to Rule 144, subject to the lock-up restrictions described above. See Description of Capital Stock Warrants. Substantially all of these shares are subject to the terms of the lock-up agreements with the underwriters. In addition, these shares are entitled to registration rights as described under Description of Capital Stock Registration Rights.

MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES TO

NON-U.S. HOLDERS OF OUR COMMON STOCK

The following discussion is a summary of the material U.S. federal income tax consequences to non-U.S. holders (as defined below) of the acquisition, ownership and disposition of shares of our common stock issued pursuant to this offering. This discussion is not a complete analysis of all the potential U.S. federal income tax consequences relating thereto, nor does it address any tax consequences arising under any state, local or non-U.S. tax laws, the U.S. federal estate tax or gift tax rules or any other U.S. federal tax laws. This discussion is based on the Internal Revenue Code of 1986, as amended, or the Code, Treasury Regulations promulgated thereunder, judicial decisions, and published rulings and administrative pronouncements of the Internal Revenue Service, or the IRS, all as in effect as of the date of this offering. These authorities may change, possibly retroactively, resulting in U.S. federal income tax consequences different from those discussed below. No ruling has been or will be sought from the IRS with respect to the matters discussed below, and there can be no assurance that the IRS will not take a contrary position regarding the tax consequences of the acquisition, ownership or disposition of shares of our common stock, or that any such contrary position would not be sustained by a court.

This discussion is limited to non-U.S. holders who purchase shares of our common stock issued pursuant to this offering and who hold shares of our common stock as a capital asset within the meaning of Section 1221 of the Code (generally, property held for investment). This discussion does not address all U.S. federal income tax considerations that may be relevant to a particular holder in light of that holder s particular circumstances. This discussion also does not consider any specific facts or circumstances that may be relevant to holders subject to special rules under the U.S. federal income tax laws, including, without limitation:

banks, thrifts and other financial institutions;

insurance companies;

partnerships, S corporations and other pass-through entities;

real estate investment trusts;

regulated investment companies;

controlled foreign corporations ;

passive foreign investment companies ;

corporations that accumulate earnings to avoid U.S. federal income tax;

brokers, dealers or traders in securities, commodities or currencies;

tax-exempt organizations;

tax-qualified retirement plans;

certain former citizens or permanent residents of the United States;

U.S. expatriates;

persons subject to the alternative minimum tax;

persons that hold or receive shares of our common stock pursuant to the exercise of any employee stock option or otherwise as compensation;

persons that own, or are deemed to own, more than 5% of our outstanding common stock (except to the extent specifically set forth below);

persons holding shares of our common stock as part of a hedge, straddle or other risk reduction strategy or as part of a conversion transaction or other integrated investment; or

persons deemed to sell shares of our common stock under the constructive sale provisions of the Code.

If a partnership (or other entity taxed as a partnership for U.S. federal income tax purposes) holds shares of our common stock, the tax treatment of a partner in the partnership generally will depend on the status of the partner and upon the activities of the partnership. Accordingly, partnerships that hold shares of our common stock and partners in such partnerships are urged to consult their tax advisors regarding the specific U.S. federal income tax consequences to them of acquiring, owning or disposing of shares of our common stock.

PROSPECTIVE INVESTORS ARE URGED TO CONSULT THEIR TAX ADVISORS REGARDING THE PARTICULAR U.S. FEDERAL INCOME TAX CONSEQUENCES TO THEM OF ACQUIRING, OWNING AND DISPOSING OF SHARES OF OUR COMMON STOCK, AS WELL AS ANY TAX CONSEQUENCES ARISING UNDER ANY STATE, LOCAL OR NON-U.S. TAX LAWS, THE U.S. FEDERAL ESTATE OR GIFT TAX RULES, ANY OTHER U.S. FEDERAL TAX LAWS AND ANY APPLICABLE TAX TREATY.

Definition of Non-U.S. Holder

For purposes of this discussion, a non-U.S. holder is any beneficial owner of shares of our common stock that is not a U.S. person or a partnership for U.S. federal income tax purposes. A U.S. person is any of the following:

- an individual citizen or resident of the United States;
- a corporation (or other entity treated as a corporation for U.S. federal income tax purposes) created or organized under the laws of the United States, any state thereof or the District of Columbia;
- an estate the income of which is subject to U.S. federal income taxation regardless of its source; or
- a trust (i) if a court within the United States is able to exercise primary supervision over the administration of such trust and one or more U.S. persons have the authority to control all substantial decisions of such trust or (ii) that has a valid election in effect to be treated as a U.S. person for U.S. federal income tax purposes.

Distributions on Our Common Stock

As described above in the section titled Dividend Policy, we do not anticipate paying cash dividends on shares of our common stock. If, however, we do make distributions of cash or property on shares of our common stock, such distributions will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Amounts not treated as dividends for U.S. federal income tax purposes will constitute a return of capital and first be applied against and reduce a non-U.S. holder s adjusted tax basis in its shares of our common stock, but not below zero. Any excess will be treated as capital gain and will be treated as described below under Gain on Sale or Disposition of Shares of Our Common Stock.

Dividends paid to a non-U.S. holder of shares of our common stock that are not effectively connected with a U.S. trade or business conducted by such non-U.S. holder generally will be subject to U.S. federal withholding tax at a rate of 30% of the gross amount of the dividends, or such lower rate as is specified by an applicable tax treaty. To receive the benefit of a reduced treaty rate, a non-U.S. holder must furnish to us or our paying agent a valid IRS Form W-8BEN (or applicable successor form) certifying such non-U.S. holder s qualification for the reduced rate. This certification must be provided to us or our paying agent prior to the payment of dividends and must be updated periodically. If the non-U.S. holder holds the stock through a financial institution or other agent acting on the non-U.S. holder s behalf, the non-U.S. holder will be required to provide appropriate documentation to the agent, who then will be required to provide certification to us or our paying agent, either directly or through other intermediaries. Non-U.S. holders that do not timely provide us or our paying agent with the

required certification, but which qualify for a reduced treaty rate, may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS. Non-U.S. holders should consult their tax advisors regarding possible entitlement to benefits under a tax treaty.

If a non-U.S. holder holds shares of our common stock in connection with the conduct of a trade or business in the United States, and dividends paid on the shares of our common stock are effectively connected with such non-U.S. holder s U.S. trade or business (and, if required by an applicable tax treaty, attributable to a permanent establishment maintained by the non-U.S. holder in the United States), the non-U.S. holder will be exempt from U.S. federal withholding tax. To claim the exemption, the non-U.S. holder must furnish to us or our paying agent a valid IRS Form W-8ECI (or applicable successor form), certifying that the dividends are effectively connected with the non-U.S. holder s conduct of a trade or business within the United States.

Any dividends paid on shares of our common stock that are effectively connected with a non-U.S. holder s U.S. trade or business (and, if required by an applicable tax treaty, attributable to a permanent establishment maintained by the non-U.S. holder in the United States) generally will be subject to U.S. federal income tax on a net income basis in the same manner as if such non-U.S. holder were a U.S. person and, for a non-U.S. holder that is a corporation, also may be subject to a branch profits tax at a rate of 30% (or such lower rate as is specified by an applicable tax treaty). Non-U.S. holders should consult their tax advisors regarding any applicable tax treaties that may provide for different rules.

Gain on Sale or Disposition of Shares of Our Common Stock

Subject to the discussion below regarding backup withholding, a non-U.S. holder generally will not be subject to U.S. federal income tax on any gain realized upon the sale or disposition of shares of our common stock unless:

- the gain is effectively connected with the non-U.S. holder s conduct of a trade or business in the United States and, if required by an applicable tax treaty, attributable to a permanent establishment maintained by the non-U.S. holder in the United States;

- the non-U.S. holder is a nonresident alien individual present in the United States for 183 days or more during the taxable year of the sale or disposition and certain other requirements are met; or

- shares of our common stock constitutes a U.S. real property interest by reason of our status as a U.S. real property holding corporation, or a USRPHC, for U.S. federal income tax purposes at any time within the shorter of (i) the five-year period ending on the date of the sale or disposition of shares of our common stock or (ii) the non-U.S. holder s holding period for shares of our common stock.

Unless an applicable tax treaty provides otherwise, the gain described in the first bullet point above generally will be subject to U.S. federal income tax on a net income basis in the same manner as if such non-U.S. holder were a U.S. person. A non-U.S. holder that is a corporation also may be subject to a branch profits tax at a rate of 30% (or such lower rate as is specified by an applicable tax treaty). Non-U.S. holders should consult their tax advisors regarding any applicable tax treaties that may provide for different rules.

Gain described in the second bullet point above generally will be subject to U.S. federal income tax at a flat 30% rate (or such lower rate as is specified by an applicable income tax treaty), but may be offset by U.S. source capital losses of the non-U.S. holder (even though the individual is not considered a resident of the United States), provided that the non-U.S. holder has timely filed U.S. federal income tax returns with respect to such losses.

With respect to the third bullet point above, we believe that we currently are not, and we do not anticipate becoming, a USRPHC. Because the determination of whether we are a USRPHC depends on the fair market value of our U.S. real property interests relative to the fair market value of our other business assets, however, there can be no assurance that we will not become a USRPHC in the future. In

the event we do become a USRPHC, as long as shares of our common stock are regularly traded on an established securities market, shares of our common stock will be treated as a U.S. real property interest only with respect to a non-U.S. holder that actually or constructively held more than 5% of shares of our common stock at any time during the shorter of (i) the five-year period ending on the date of the sale or disposition of shares of our common stock or (ii) the non-U.S. holder s holding period for shares of our common stock.

Information Reporting and Backup Withholding

Generally, we must report annually to the IRS and to each non-U.S. holder the amount of dividends paid to such non-U.S. holder and the amount, if any, of tax withheld with respect to those dividends. This information also may be made available under a specific treaty or agreement with the tax authorities of the country in which the non-U.S. holder resides or is established. Under certain circumstances, the Code imposes backup withholding on certain reportable payments. Backup withholding generally will not, however, apply to payments of dividends to a non-U.S. holder of shares of our common stock, provided that the non-U.S. holder furnishes to us or our paying agent the required certification as to its non-U.S. status, such as by providing a valid IRS Form W-8BEN or W-8ECI, or otherwise establishes an exemption.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules may be allowed as a refund or a credit against a non-U.S. holder s U.S. federal income tax liability, provided that the required information is timely furnished to the IRS.

New Legislation Relating to Foreign Accounts

Newly enacted legislation may impose withholding taxes on certain types of payments made to foreign financial institutions (as specially defined under those rules) and certain other non-U.S. entities. Under this legislation, the failure to comply with additional certification, information reporting and other specified requirements could result in a withholding tax being imposed on payments of dividends and sales proceeds to foreign intermediaries and certain non-U.S. holders. The legislation imposes a 30% withholding tax on dividends on, or gross proceeds from the sale or other disposition of, shares of our common stock paid to a foreign financial institution or to a foreign non-financial entity, unless (i) the foreign financial institution undertakes certain diligence and reporting obligations or (ii) the foreign non-financial entity either certifies it does not have any substantial U.S. owners or furnishes identifying information regarding each substantial U.S. owner. If the payee is a foreign financial institution, it must enter into an agreement with the U.S. Treasury requiring, among other things, that it undertake to identify accounts held by certain U.S. persons or U.S.-owned foreign entities, annually report certain information about such accounts, and withhold 30% on payments to account holders whose actions prevent it from complying with these reporting and other requirements. The legislation would apply to payments made after December 31, 2012. Prospective investors should consult their tax advisors regarding this legislation.

UNDERWRITING

Subject to the terms and conditions set forth in an underwriting agreement, we have agreed to sell to the underwriters named below, and the underwriters, for whom Wells Fargo Securities, LLC and Leerink Swann LLC are acting as joint-book running managers and representatives, have severally agreed to purchase, the respective numbers of shares of common stock appearing opposite their names below:

Underwriter	Number of Shares
Wells Fargo Securities, LLC	4,900,000
Leerink Swann LLC	4,900,000
Oppenheimer & Co. Inc.	2,100,000
Stifel, Nicolaus & Company, Incorporated	2,100,000
Total	14,000,000

All of the shares to be purchased by the underwriters will be purchased from us.

The underwriting agreement provides that the obligations of the several underwriters are subject to various conditions, including approval of legal matters by counsel. The shares of common stock are offered by the underwriters, subject to prior sale, when, as and if issued to and accepted by them. The underwriters reserve the right to withdraw, cancel or modify the offer and to reject orders in whole or in part.

The underwriting agreement provides that the underwriters are obligated to purchase all the shares of common stock offered by this prospectus if any are purchased, other than those shares covered by the over-allotment option described below. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the non-defaulting underwriters may be increased or the underwriting agreement may be terminated.

Over-Allotment Option

We have granted a 30-day option to the underwriters to purchase up to a total of 2,100,000 additional shares of our common stock from us at the initial public offering price per share less the underwriting discounts and commissions per share, as set forth on the cover page of this prospectus, and less any dividends or distributions declared, paid or payable on the shares that the underwriters have agreed to purchase from us but that are not payable on such additional shares, to cover over-allotment, if any. If the underwriters exercise this option in whole or in part, then the underwriters will be severally committed, subject to the conditions described in the underwriting agreement, to purchase the additional shares of our common stock in proportion to their respective commitments set forth in the prior table.

Discounts and Commissions

Shares sold by the underwriters to the public will initially be offered at the initial public offering price set forth on the cover of this prospectus and to certain dealers at that price less a concession of not more than $0.168 per share. After the initial offering, the public offering price and concession to dealers may be changed.

The following table summarizes the underwriting discounts and commissions and the proceeds, before expenses, payable to us, both on a per share basis and in total, assuming either no exercise or full exercise by the underwriters of their overallotment option:

		Total	
	Per Share	Without Option	With Option
Initial public offering price	$ 4.00	$ 56,000,000	$ 64,400,000
Underwriting discounts and commissions from shares offered to certain of our current stockholders(1)	$ 0.0981	$ 700,326	$ 700,326
Proceeds, before expenses, to us from shares offered to certain of our current stockholders(1)	$ 3.9019	$ 27,855,254	$ 27,855,254
Underwriting discounts and commissions from shares offered to the public(1)	$ 0.28	$ 1,921,109	$ 2,509,109
Proceeds, before expenses, to us from shares offered to the public(1)	$ 3.72	$ 25,523,311	$ 33,335,311

(1) Assumes that certain of our current stockholders purchase an aggregate of 7,138,895 shares of our common stock in this offering as described below.

We estimate that the expenses of this offering payable by us, not including underwriting discounts and commissions, will be approximately $2,770,000.

Abingworth Bioventures, Chicago Growth Partners II, L.P., Clarus Lifesciences I, L.P., Domain Associates, L.L.C., Scale Venture Partners II, LP, Thomas, McNerney & Partners, L.P. and Cam L. Garner, or funds affiliated with them, each of which is a current stockholder and which we refer to collectively as the Current Stockholders, have indicated an interest in purchasing an aggregate of 7,138,895 shares of our common stock in this offering at the initial public offering price. Although we anticipate that the Current Stockholders will purchase, and that the underwriters will sell to the Current Stockholders, all of these shares, indications of interest are not binding agreements or commitments to purchase and the Current Stockholders may determine to purchase less or no shares in this offering and the underwriters may determine to sell less or no shares in this offering to the Current Stockholders. The underwriters will receive underwriting discounts and commissions of $0.0981 per share on any shares sold to the Current Stockholders.

Indemnification of Underwriters

The underwriting agreement provides that we will indemnify the underwriters against specified liabilities, including liabilities under the Securities Act, or contribute to payments that the underwriters may be required to make in respect of those liabilities.

Lock-Up Agreements

We, each of our directors and officers, the holders of substantially all of the other shares of our common stock outstanding prior to this offering, and the holders of substantially all of our warrants and options outstanding prior to this offering, have agreed, subject to certain exceptions described below, that, without the prior written consent of Wells Fargo Securities, LLC and Leerink Swann LLC, we and they will not, during the period beginning on and including the date of this prospectus through and including the date that is the 180th day after the date of this prospectus, directly or indirectly:

- issue (in the case of us), offer, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend or

otherwise transfer or dispose of any shares of our common stock or other capital stock or any securities convertible into or exercisable or exchangeable for our common stock or other capital stock;

in the case of us, file or cause the filing of any registration statement under the Securities Act with respect to any shares of our common stock or other capital stock or any securities convertible into or exercisable or exchangeable for our common stock or other capital stock other than registration statements filed to register shares of common stock to be sold to the underwriters and other than registration statements on Form S-8 filed with the Securities and Exchange Commission after the date of this prospectus; or

enter into any swap or other agreement, arrangement, hedge or transaction that transfers to another, in whole or in part, directly or indirectly, any of the economic consequences of ownership of our common stock or other capital stock or any securities convertible into or exercisable or exchangeable for our common stock or other capital stock,

whether any transaction described in any of the foregoing bullet points is to be settled by delivery of our common stock or other capital stock, other securities, in cash or otherwise, or publicly announce an intention to do any of the foregoing. Moreover, if:

during the last 17 days of the lock-up period, we issue an earnings release or material news or a material event relating to us occurs; or

prior to the expiration of the lock-up period, we announce that we will release earnings results or become aware that material news or a material event relating to us will occur during the 16-day period beginning on the last day of the lock-up period,

the restrictions described in the immediately preceding sentence will continue to apply until the expiration of the 18-day period beginning on the issuance of the earnings release or the occurrence of the material news or material event, as the case may be, unless Wells Fargo Securities, LLC and Leerink Swann LLC waive, in writing, that extension.

Notwithstanding the provisions set forth in the immediately preceding paragraph, we may, without the prior written consent of Wells Fargo Securities, LLC and Leerink Swann LLC:

(1) issue securities to the underwriters pursuant to the underwriting agreement;

(2) issue shares, and options to purchase shares, of common stock pursuant to equity incentive plans, employee stock option plans and employee stock purchase plans described in this prospectus, as those plans are in effect on the date of this prospectus;

(3) issue shares of common stock (A) upon the exercise of stock options issued under equity incentive plans referred to in clause (2) above, as those plans are in effect on the date of this prospectus, (B) upon the exercise of warrants outstanding on the date of the underwriting agreement and described in this prospectus, as those warrants are in effect on the date of this prospectus or (C) upon the conversion of convertible debt securities outstanding on the date of this prospectus and described in this prospectus, as those debt securities are in effect on the date of this prospectus; and

(4) issue shares of common stock to one or more counterparties in connection with the consummation of a bona fide strategic partnership, joint venture, collaboration, merger, co-promotion or distribution arrangement, or the acquisition or in-licensing of any business products or technologies; provided that the aggregate number of shares of Common Stock issued under this clause (4) shall not exceed 20% of the number of securities sold in this offering, excluding any shares sold to cover over-allotments, if any;

provided, however, that in the case of any issuance described in clauses (2), (3) and (4) above, it shall be a condition to the issuance that each recipient executes and delivers to Wells Fargo Securities, LLC

and Leerink Swann LLC, acting on behalf of the underwriters, not later than one business day prior to the date of such issuance, a lock-up agreement satisfactory in form and substance to Wells Fargo Securities, LLC and Leerink Swann LLC.

The restrictions of the lock-up agreements to which our directors, officers, holders of substantially all of the other shares of our common stock outstanding prior to the offering and the holders of substantially all of our warrants and options outstanding prior to this offering are party to do not apply to the following:

- transfers of our securities by individuals as a bona fide gift, by will, intestate succession or pursuant to certain trusts, to certain family members pursuant to domestic relations or similar orders, or to us when we are entitled to repurchase securities from a terminated employee;

- transfers of our securities by entities to their equity owners or affiliated entities, provided such transfer is not for value; and

- transfers to a nominee or custodian of a person or entity to whom transfer would be permissible in the above circumstances;

provided that (1) the recipient enters into a lock-up agreement in a form satisfactory to Wells Fargo Securities, LLC and Leerink Swann LLC no later than one business day before the transfer, (2) for transfers by will, intestate succession or pursuant to certain trusts, any report required under specified sections of the Exchange Act will state the reason for the transfer and that the transfer was not for value, and (3) for all other transfers, no report under specified sections of the Securities Act or Exchange Act is required to be filed during the lock-up period, and no other public announcement is made in connection with the transfer.

Wells Fargo Securities, LLC and Leerink Swann LLC may, in their sole discretion and at any time or from time to time, without notice, release all or any portion of the shares or other securities subject to the lock-up agreements. Any determination to release any shares or other securities subject to the lock-up agreements would be based on a number of factors at the time of determination, which may include the market price of the common stock, the liquidity of the trading market for the common stock, general market conditions, the number of shares or other securities proposed to be sold or otherwise transferred and the timing, purpose and terms of the proposed sale or other transfer.

Nasdaq Global Market Listing

Our common stock has been approved for listing on the Nasdaq Global Market under the symbol ZGNX.

Stabilization

In order to facilitate this offering of our common stock, the underwriters may engage in transactions that stabilize, maintain or otherwise affect the market price of our common stock. Specifically, the underwriters may sell more shares of common stock than they are obligated to purchase under the underwriting agreement, creating a short position. A short sale is covered if the short position is no greater than the number of shares of common stock available for purchase by the underwriters under the over-allotment option. The underwriters may close out a covered short sale by exercising the over-allotment option or purchasing common stock in the open market. In determining the source of common stock to close out a covered short sale, the underwriters may consider, among other things, the market price of common stock compared to the price payable under the over-allotment option. The underwriters may also sell shares of common stock in excess of the over-allotment option, creating a naked short position. The underwriters must close out any naked short position by purchasing shares of common stock in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common stock in

the open market after the date of pricing of this offering that could adversely affect investors who purchase in this offering.

As an additional means of facilitating this offering, the underwriters may bid for, and purchase, common stock in the open market to stabilize the price of our common stock, so long as stabilizing bids do not exceed a specified maximum. The underwriting syndicate may also reclaim selling concessions allowed to an underwriter or a dealer for distributing common stock in this offering if the underwriting syndicate repurchases previously distributed common stock to cover syndicate short positions or to stabilize the price of the common stock.

The foregoing transactions, if commenced, may raise or maintain the market price of our common stock above independent market levels or prevent or retard a decline in the market price of the common stock.

The foregoing transactions, if commenced, may be effected on the Nasdaq Global Market or otherwise. Neither we nor any of the underwriters makes any representation that the underwriters will engage in any of these transactions and these transactions, if commenced, may be discontinued at any time without notice. Neither we nor any of the underwriters makes any representation or prediction as to the direction or magnitude of the effect that the transactions described above, if commenced, may have on the market price of our common stock.

Discretionary Accounts

The underwriters have informed us that they do not intend to confirm sales to accounts over which they exercise discretionary authority in excess of 5% of the total number of shares of common stock offered by them.

Pricing of this Offering

Prior to this offering, there has been no public market for our common stock. Consequently, the initial public offering price for our common stock was determined between us and the representative of the underwriters. The factors considered in determining the initial public offering price included:

- prevailing market conditions;
- our results of operations and financial condition;
- financial and operating information and market valuations with respect to other companies that we and the representative of the underwriters believe to be comparable or similar to us;
- the present state of our development; and
- our future prospects.

An active trading market for our common stock may not develop. It is possible that the market price of our common stock after this offering will be less than the initial public offering price.

Relationships

The underwriters and/or their respective affiliates may in the future provide various financial advisory, investment banking, commercial banking and other financial services to us, for which they may receive compensation.

Sales Outside the United States

No action has been or will be taken in any jurisdiction (except in the United States) that would permit a public offering of the common stock, or the possession, circulation or distribution of this prospectus or any other material relating to us or the common stock in any jurisdiction where action for that purpose is required. Accordingly, the common stock may not be offered or sold, directly or indirectly, and neither of this prospectus nor any other offering material or advertisements in connection with the common stock may be distributed or published, in or from any country or jurisdiction except in compliance with any applicable rules and regulations of any such country or jurisdiction.

Each of the underwriters may arrange to sell common stock offered by this prospectus in certain jurisdictions outside the United States, either directly or through affiliates, where they are permitted to do so. In that regard, Wells Fargo Securities, LLC may arrange to sell shares in certain jurisdictions through an affiliate, Wells Fargo Securities International Limited, or WFSIL. WFSIL is a wholly-owned indirect subsidiary of Wells Fargo & Company and an affiliate of Wells Fargo Securities, LLC. WFSIL is a U.K. incorporated investment firm regulated by the Financial Services Authority. Wells Fargo Securities is the trade name for certain corporate and investment banking services of Wells Fargo & Company and its affiliates, including Wells Fargo Securities, LLC and WFSIL.

European Economic Area

In relation to each Member State of the European Economic Area which has implemented the Prospectus Directive (each, a Relevant Member State) an offer to the public of any shares of common stock which are the subject of the offering contemplated by this prospectus (the Shares) may not be made in that Relevant Member State except that an offer to the public in that Relevant Member State of any Shares may be made at any time under the following exemptions under the Prospectus Directive, if they have been implemented in that Relevant Member State:

(a) to legal entities which are authorized or regulated to operate in the financial markets or, if not so authorized or regulated, whose corporate purpose is solely to invest in securities;

(b) to any legal entity which has two or more of (1) an average of at least 250 employees during the last financial year; (2) a total balance sheet of more than 43,000,000; and (3) an annual net turnover of more than 50,000,000, as shown in its last annual or consolidated accounts;

(c) to fewer than 100 natural or legal persons (other than qualified investors as defined in the Prospectus Directive) subject to obtaining the prior consent of the representatives of the underwriters; or

(d) in any other circumstances falling within Article 3(2) of the Prospectus Directive,

provided that no such offer of Shares shall result in a requirement for the publication by us or any underwriter of a prospectus pursuant to Article 3 of the Prospectus Directive.

For the purposes of this provision, the expression an offer to the public in relation to any Shares in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and any Shares to be offered so as to enable an investor to decide to purchase any Shares, as the same may be varied in that Member State by any measure implementing the Prospectus Directive in that Member State and the expression Prospectus Directive means Directive 2003/71/EC and includes any relevant implementing measure in each Relevant Member State.

United Kingdom

This prospectus and any other material in relation to the shares described herein is only being distributed to, and is only directed at, persons in the United Kingdom that are qualified investors within the meaning of Article 2(1)(e) of the Prospective Directive (qualified investors) that also (i) have professional experience in matters relating to investments falling within Article 19(5) of the Financial

Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended, or the Order, (ii) who fall within Article 49(2)(a) to (d) of the Order or (iii) to whom it may otherwise lawfully be communicated (all such persons together being referred to as relevant persons). The shares are only available to, and any invitation, offer or agreement to purchase or otherwise acquire such shares will be engaged in only with, relevant persons. This offering memorandum and its contents are confidential and should not be distributed, published or reproduced (in whole or in part) or disclosed by recipients to any other person in the United Kingdom. Any person in the United Kingdom that is not a relevant person should not act or rely on this prospectus or any of its contents.

The distribution of this prospectus in the United Kingdom to anyone not falling within the above categories is not permitted and may contravene the Financial Services and Markets Act of 2000. No person falling outside those categories should treat this prospectus as constituting a promotion to him, or act on it for any purposes whatever. Recipients of this prospectus are advised that we, the underwriters and any other person that communicates this prospectus are not, as a result solely of communicating this prospectus, acting for or advising them and are not responsible for providing recipients of this prospectus with the protections which would be given to those who are clients of any aforementioned entities that is subject to the Financial Services Authority Rules.

France

The prospectus supplement and the accompanying prospectus (including any amendment, supplement or replacement thereto) have not been approved either by the *Autorité des marchés financiers* or by the competent authority of another State that is a contracting party to the Agreement on the European Economic Area and notified to the *Autorité des marchés financiers*; no security has been offered or sold and will be offered or sold, directly or indirectly, to the public in France within the meaning of Article L. 411-1 of the French *Code Monétaire et Financier* except to permitted investors, or Permitted Investors, consisting of persons licensed to provide the investment service of portfolio management for the account of third parties, qualified investors (*investisseurs qualifiés*) acting for their own account and/or a limited circle of investors (*cercle restreint d investisseurs*) acting for their own account, with qualified investors and limited circle of investors having the meaning ascribed to them in Articles L. 411-2, D. 411-1, D. 411-2, D. 411-4, D. 744-1, D. 754-1 and D. 764-1 of the French *Code Monétaire et Financier*; none of this prospectus supplement and the accompanying Prospectus or any other materials related to the offer or information contained therein relating to our securities has been released, issued or distributed to the public in France except to Permitted Investors; and the direct or indirect resale to the public in France of any securities acquired by any Permitted Investors may be made only as provided by Articles L. 411-1, L. 411-2, L. 412-1 and L. 621-8 to L. 621-8-3 of the French *Code Monétaire et Financier* and applicable regulations thereunder.

Notice to the Residents of Germany

This document has not been prepared in accordance with the requirements for a securities or sales prospectus under the German Securities Prospectus Act (*Wertpapierprospektgesetz*), the German Sales Prospectus Act (*Verkaufsprospektgesetz*), or the German Investment Act (*Investmentgesetz*). Neither the German Federal Financial Services Supervisory Authority (*Bundesanstalt fur Finanzdienstleistungsaufsicht BaFin*) nor any other German authority has been notified of the intention to distribute the securities in Germany. Consequently, the securities may not be distributed in Germany by way of public offering, public advertisement or in any similar manner AND THIS DOCUMENT AND ANY OTHER DOCUMENT RELATING TO THE OFFERING, AS WELL AS INFORMATION OR STATEMENTS CONTAINED THEREIN, MAY NOT BE SUPPLIED TO THE PUBLIC IN GERMANY OR USED IN CONNECTION WITH ANY OFFER FOR SUBSCRIPTION OF THE SECURITIES TO THE PUBLIC IN GERMANY OR ANY OTHER MEANS OF PUBLIC MARKETING. The securities are being offered and sold in Germany only to qualified investors which are referred to in Section 3, paragraph 2 no. 1, in connection with Section 2, no. 6, of the German Securities Prospectus Act. This document is strictly for use of the person who has received it. It may not be forwarded to other persons or published in Germany.

Switzerland

This document does not constitute a prospectus within the meaning of Art. 652a of the Swiss Code of Obligations. The shares of common stock may not be sold directly or indirectly in or into Switzerland except in a manner which will not result in a public offering within the meaning of the Swiss Code of Obligations. Neither this document nor any other offering materials relating to the shares of common stock may be distributed, published or otherwise made available in Switzerland except in a manner which will not constitute a public offer of the shares of common stock in Switzerland.

LEGAL MATTERS

The validity of our common stock offered by this prospectus will be passed upon for us by Latham & Watkins LLP, San Diego, California. Latham & Watkins LLP and certain attorneys and investment funds affiliated with the firm collectively own an aggregate of 25,000 shares of our convertible preferred stock, which will convert into an aggregate of 2,500 shares of our common stock upon the completion of this offering. Sidley Austin LLP, San Francisco, California, will act as counsel for the underwriters.

EXPERTS

Ernst & Young LLP, independent registered public accounting firm, has audited our consolidated financial statements at December 31, 2008 and 2009, and for each of the three years in the period ended December 31, 2009, as set forth in their report (which contains an explanatory paragraph describing conditions that raise substantial doubt about our ability to continue as a going concern as described in Note 1 to our consolidated financial statements). We have included our financial statements in the prospectus and elsewhere in the registration statement in reliance upon Ernst & Young LLP s report, given on their authority as experts in accounting and auditing.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed with the SEC a registration statement on Form S-1 (including the exhibits, schedules and amendments thereto) under the Securities Act of 1933, as amended, with respect to the shares of our common stock offered hereby. This prospectus does not contain all of the information set forth in the registration statement and the exhibits and schedules thereto. Some items are omitted in accordance with the rules and regulations of the SEC. For further information with respect to us and the common stock offered hereby, we refer you to the registration statement and the exhibits and schedules filed therewith. Statements contained in this prospectus as to the contents of any contract, agreement or any other document are summaries of the material terms of this contract, agreement or other document and are not complete. With respect to each of these contracts, agreements or other documents filed as an exhibit to the registration statement, reference is made to the exhibits for a more complete description of the matter involved. Each of these statements is qualified in all respects by this reference. A copy of the registration statement, and the exhibits and schedules thereto, may be inspected without charge at the public reference facilities maintained by the SEC at 100 F Street NE, Washington, D.C. 20549. Copies of these materials may be obtained, upon payment of a duplicating fee, from the Public Reference Section of the SEC at 100 F Street NE, Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the operation of the public reference facility. The SEC maintains a web site that contains reports, proxy and information statements and other information regarding registrants that file electronically with the SEC. The address of the SEC s website is http://www.sec.gov.

Upon completion of this offering, we will become subject to the information reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act. Under the Exchange Act, we will file periodic reports, proxy statements and other information with the SEC. This registration statement and future filings will be available for inspection and copying at the SEC s Public Reference Room and the website of the SEC referred to above.

Zogenix, Inc.

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Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of Zogenix, Inc.

We have audited the accompanying balance sheets of Zogenix, Inc. as of December 31, 2009 and 2008, and the related statements of operations, convertible preferred stock and stockholders equity (deficit), and cash flows for each of the three years in the period ended December 31, 2009. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company s internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company s internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Zogenix, Inc. at December 31, 2009 and 2008, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2009, in conformity with U.S. generally accepted accounting principles.

As discussed in Note 1 to the financial statements, the Company s recurring losses from operations and lack of sufficient working capital raise substantial doubt about its ability to continue as a going concern. Management s plans as to these matters also are described in Note 1. The December 31, 2009 financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Ernst & Young LLP

San Diego, California

September 3, 2010

Except for the second paragraph of Note 12, as to which the date is

November 3, 2010

Zogenix, Inc.

Consolidated Balance Sheets

(In Thousands, except Par Value)

	December 31,			Pro Forma Stockholders Equity at September 30, 2010
	2008	2009	September 30, 2010 (Unaudited)	
Assets				
Current assets:				
Cash and cash equivalents	$ 14,225	$ 44,911	$ 11,673	
Trade accounts receivable			2,165	
Inventory		13,160	17,599	
Prepaid expenses and other current assets	1,019	2,788	2,913	
Total current assets	15,244	60,859	34,350	
Property and equipment, net	11,750	12,991	14,522	
Other assets	631	718	6,162	
Total assets	$ 27,625	$ 74,568	$ 55,034	
Liabilities, convertible preferred stock and stockholders equity (deficit)				
Current liabilities:				
Accounts payable	$ 6,051	$ 4,670	$ 2,461	
Accrued expenses	1,438	2,491	7,572	
Accrued compensation	515	915	2,643	
Revolving credit facility			2,546	
Bridge loan from related parties			9,805	
Long-term debt, current portion	4,208	6,558	1,189	
Deferred revenue, current portion		4,123	9,054	
Total current liabilities	12,212	18,757	35,270	
Long-term debt, less current portion	15,336	8,778	22,390	
Deferred rent	189	103	382	
Deferred revenue, less current portion		14,877	10,939	
Convertible preferred stock warrant liability	467	5,041	20,301	
Other long-term liabilities			220	
Commitments and contingencies				
Series A and B convertible preferred stock, $0.001 par value; 83,000 shares of Series A-1, A-2 and A-3 authorized; 77,891 shares of series A-1 and A-2 issued and outstanding at December 31, 2008; 156,416 and 172,750 shares of Series A-1, A-2 and B authorized at December 31, 2009 and September 30, 2010 (unaudited), respectively; 142,398 shares of Series A-1, A-2 and B issued and outstanding at December 31, 2009 and September 30, 2010 (unaudited); aggregate liquidation preference of $78,800, $149,758 and $149,758 at December 31, 2008 and 2009 and September 30, 2010 (unaudited), respectively; no shares authorized, issued and outstanding, pro forma (unaudited)	76,955	149,312	149,312	
Stockholders equity (deficit):				
Common stock, $0.001 par value; 111,000, 183,983 and 205,000 shares authorized at December 31, 2008 and 2009 and September 30, 2010 (unaudited), respectively; 1,346, 1,444 and 1,450 shares issued and outstanding at December 31, 2008 and 2009 and September 30, 2010 (unaudited), respectively; 19,564 issued and outstanding, pro forma (unaudited)	1	1	1	20
Additional paid-in capital	1,114	2,237	12,186	191,585
Accumulated deficit	(78,649)	(124,538)	(195,967)	(195,967)

Total stockholders equity (deficit)	(77,534)	(122,300)	(183,780)	$	(4,362)
Total liabilities, convertible preferred stock and stockholders equity (deficit)	$ 27,625	$ 74,568	$ 55,034		

See accompanying notes.

Zogenix, Inc.

Consolidated Statements of Operations

(In Thousands, except Per Share Amounts)

	Year Ended December 31,			Nine Months Ended September 30,	
	2007	2008	2009	2009	2010
				(Unaudited)	
Revenue:					
Net product revenue	$	$	$	$	$ 11,828
Contract revenue					2,810
Total revenue					14,638
Operating expenses:					
Cost of sales					9,403
Royalty expense					598
Research and development	24,329	33,910	21,438	22,305	19,394
Selling, general and administrative	4,725	11,820	14,102	8,027	36,792
Total operating expenses	29,054	45,730	35,540	30,332	66,187
Loss from operations	(29,054)	(45,730)	(35,540)	(30,332)	(51,549)
Other income (expense):					
Interest income	927	696	10	7	4
Interest expense	(377)	(1,718)	(9,188)	(8,563)	(6,938)
Change in fair value of warrant liability	(107)	1,119	(755)	(505)	(12,833)
Other financing income	906				
Other income (expense)	25	63	(416)	(350)	(113)
Total other income (expense)	1,374	160	(10,349)	(9,411)	(19,880)
Net loss	(27,680)	(45,570)	(45,889)	(39,743)	(71,429)
Deemed dividend for the beneficial conversion on Series A-1 and Series A-2 convertible preferred stock	(18,360)				
Net loss applicable to common stockholders	$ (46,040)	$ (45,570)	$ (45,889)	$ (39,743)	$ (71,429)
Net loss per share, basic and diluted	$ (80.77)	$ (52.68)	$ (40.97)	$ (36.43)	$ (53.31)
Weighted average shares outstanding, basic and diluted	570	865	1,120	1,091	1,340
Pro forma net loss per share, basic and diluted (unaudited)			$ (4.49)		$ (3.47)
Weighted average pro forma shares outstanding, basic and diluted (unaudited)			10,057		16,810

See accompanying notes.

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Zogenix, Inc.

Consolidated Statements of Convertible Preferred Stock and Stockholders Equity (Deficit)

(In Thousands, except Per Share Amounts)

	Series A Convertible Preferred Stock		Series B Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount				
Balance at December 31, 2006	30,775	$ 27,110	$		1,138	$ 1	$ 10	$ 3	$ (5,399)	$ (5,385)
Comprehensive loss:										
Unrealized loss on investments								(1)		(1)
Net loss									(27,680)	(27,680)
Comprehensive loss										(27,681)
Issuance of Series A-1 convertible preferred stock for cash at $1.00 per share, net of issuance costs of $20	38,025	38,005								
Issuance of Series A-2 convertible preferred stock for cash at $1.10 per share, net of issuance costs of $63	9,091	9,937								
Adjustment to the estimated fair value of call right		1,903								
Beneficial conversion feature-deemed dividend on the issuance of Series A-1 and Series A-2 convertible preferred stock							18,360			18,360
Reduction of additional paid-in capital for the deemed dividend since the Company has an accumulated deficit							(18,360)			(18,360)
Issuance of common stock in conjunction with the exercise of stock options					213		9			9
Repurchase of founder s common stock					(6)					
Stock-based compensation							131			131
Balance at December 31, 2007	77,891	$ 76,955	$		1,345	$ 1	$ 150	$ 2	$ (33,079)	$ (32,926)

Zogenix, Inc.

Consolidated Statements of Convertible Preferred Stock and Stockholders Equity (Deficit) (Continued)

(In Thousands, except Per Share Amounts)

	Series A Convertible Preferred Stock		Series B Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount				
Balance at December 31, 2007	77,891	$ 76,955		$	1,345	$ 1	$ 150	$ 2	$ (33,079)	$ (32,926)
Comprehensive loss:										
Unrealized loss on investments								(2)		(2)
Net loss									(45,570)	(45,570)
Comprehensive loss										(45,572)
Issuance of common stock in conjunction with the exercise of stock options					1		2			2
Vesting of early exercised stock options							43			43
Stock-based compensation							919			919
Balance at December 31, 2008	77,891	76,955			1,346	1	1,114		(78,649)	(77,534)
Net loss and comprehensive loss									(45,889)	(45,889)
Issuance of Series B convertible preferred stock for cash at $1.10 per share, net of issuance costs of $774			50,636	54,930						
Issuance of Series B convertible preferred stock from conversion of convertible notes, net of issuance costs of $30			13,871	15,228						
Beneficial conversion feature from issuance of convertible notes				3,009						
Issuance of warrants for Series B convertible preferred stock				(810)						
Issuance of common stock in conjunction with the exercise of stock options					98		97			97
Stock-based compensation							1,026			1,026
Balance at December 31, 2009	77,891	76,955	64,507	72,357	1,444	1	2,237		(124,538)	(122,300)
Net loss and comprehensive loss (unaudited)									(71,429)	(71,429)
Issuance of common stock in conjunction with the exercise of stock options (unaudited)					6		3			3
Vesting of early exercised stock options (unaudited)							52			52
Stock-based compensation (unaudited)							1,712			1,712
Beneficial conversion feature from issuance of convertible notes							8,182			8,182
Balance at September 30, 2010 (unaudited)	77,891	$ 76,955	64,507	$ 72,357	1,450	$ 1	$ 12,186	$	$ (195,967)	$ (183,780)

See accompanying notes.

Zogenix, Inc.

Consolidated Statements of Cash Flows

(In Thousands)

	Year Ended December 31,			Nine Months Ended September 30,	
	2007	2008	2009	2009	2010
				(Unaudited)	
Operating activities					
Net loss	$ (27,680)	$ (45,570)	$ (45,889)	$ (39,743)	$ (71,429)
Adjustments to reconcile net loss to net cash used in operating activities:					
Stock-based compensation	131	919	1,026	740	1,712
Depreciation and amortization	407	755	1,017	715	1,046
Provision of inventory reserve			2,497	5,106	378
Amortization of debt issuance costs and non-cash interest	98	349	4,297	4,091	3,763
Change in fair value of preferred stock warrant liability	107	(1,119)	755	505	12,833
Beneficial conversion feature from issuance of convertible notes			3,009	3,009	
Loss on disposal and impairment of property and equipment		346	11	8	3
Accretion of discounts on investments, net of amortization premiums		(77)			
Other financing income	(906)				
Changes in operating assets and liabilities:					
Trade accounts receivable					(2,165)
Inventory			(15,657)	(6,307)	(4,816)
Prepaid expenses and other current assets	(1,045)	391	(1,769)	(134)	(125)
Other assets	(312)	(285)	(176)	68	(5,506)
Accounts payable and accrued expenses	2,380	2,834	(396)	(2,066)	4,847
Deferred rent	20	169	(86)	(63)	(26)
Deferred revenue			19,000	14,000	993
Net cash used in operating activities	(26,800)	(41,288)	(32,361)	(20,071)	(58,492)
Investing activities:					
Purchases of property and equipment	(4,018)	(4,615)	(2,059)	(1,203)	(2,084)
Purchases of short-term investments	(9,798)	(7,828)			
Sales and maturities of short-term investments	14,821	9,650			
Proceeds from sale of long-lived assets			2		
Net cash provided by (used in) investing activities	1,005	(2,793)	(2,057)	(1,203)	(2,084)
Financing activities:					
Proceeds from the issuance of convertible preferred stock, net	47,942		54,930	20,033	
Proceeds from bridge loan, net			14,770	14,800	15,000
Proceeds from borrowings of long-term debt	4,383	17,802			25,000
Proceeds from revolving credit facility					2,702
Payments on borrowings of long-term debt	(483)	(1,006)	(4,691)	(3,035)	(15,367)
Proceeds from the issuance of common stock	130	2	95	35	3
Net cash provided by financing activities	51,972	16,798	65,104	31,833	27,338
Net increase (decrease) in cash and cash equivalents	26,177	(27,283)	30,686	10,559	(33,238)
Cash and cash equivalents at beginning of period	15,331	41,508	14,225	14,225	44,911
Cash and cash equivalents at end of period	$ 41,508	$ 14,225	$ 44,911	$ 24,784	$ 11,673
Supplemental disclosure of cash flow information:					
Cash paid for interest	$ 251	$ 1,091	$ 1,894	$ 1,459	$ 1,569
Noncash investing and financing activities:					
Purchase of property and equipment in accounts payable	$	$ 305	$ 213	$ 108	$ 191

Acquisition of leasehold paid by landlord	$	$	$	$	$ 305
Conversion of bridge loan and related interest to convertible preferred stock	$	$	$ 15,258	$ 15,258	$
Vesting of early exercised stock options	$	$ 43	$ 54	$ 39	$ 52
Warrants issued in connection with debt and convertible preferred stock	$ 151	$ 1,327	$ 3,819	$ 3,009	$ 2,427
Beneficial conversion feature from issuance of convertible notes	$	$	$	$	$ 8,182
Deemed dividend for the beneficial conversion feature on the issuance of Series A-1 and Series A-2 convertible preferred stock	$ (18,360)	$	$	$	$

See accompanying notes.

Zogenix, Inc.

Notes to Consolidated Financial Statements

1. Organization and Basis of Presentation

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

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

The Company has incurred significant net losses since inception and has relied on its ability to fund its operations through private equity financings, debt financings and proceeds from business collaborations. As the Company continues to incur losses, successful transition to profitability is dependent upon achieving a level of revenues adequate to support the Company s cost structure. This may not occur and, unless and until it does, the Company will continue to need to raise additional cash. Based on the Company s operating plan, existing working capital is not sufficient to meet the cash requirements to fund planned operating expenses through December 31, 2010 without additional sources of cash. These conditions raise substantial doubt about the Company s ability to continue as a going concern. The accompanying financial statements have been prepared assuming that the Company will continue as a going concern and do not include any adjustments that might result from the outcome of this uncertainty. This basis of accounting contemplates the recovery of the Company s assets and the satisfaction of liabilities in the normal course of business.

Management expects operating losses and negative cash flows to continue for at least the next several years as the Company continues to incur costs related to the continued development of its product candidates and commercialization of its approved product. Management may pursue additional equity or debt financings if required to help support its planned operations through December 31, 2010. There can be no assurance that the Company will be able to obtain any source of financing on acceptable terms, or at all.

2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States (GAAP) requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results may differ from those estimates.

Principles of Consolidation

The consolidated financial statements include the accounts of Zogenix, Inc. and its wholly owned subsidiary Zogenix Europe Limited, which was incorporated under the laws of England and Wales in June 2010. All intercompany transactions and investments have been eliminated in consolidation.

Unaudited Interim Financial Results

The accompanying interim consolidated balance sheet as of September 30, 2010, the consolidated statements of operations and cash flows for the nine months ended September 30, 2009 and 2010 and consolidated statement of convertible preferred stock and stockholders equity (deficit) for the nine

months ended September 30, 2010, and the related information contained in the notes to the consolidated financial statements are unaudited. These unaudited interim consolidated financial statements and notes have been prepared on the same basis as the audited financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary to present fairly the Company s consolidated financial position as of September 30, 2010 and its consolidated results of operations and cash flows for the nine months ended September 30, 2009 and 2010. The results of operations for the nine months ended September 30, 2010 are not necessarily indicative of the results to be expected for the year ending December 31, 2010 or for any other interim period or for any other future year.

Unaudited Pro Forma Stockholders Equity (Deficit)

The unaudited pro forma stockholders equity (deficit) as of September 30, 2010 reflects the automatic conversion of all outstanding shares of convertible preferred stock and convertible bridge loans from related parties as of September 30, 2010, into 14,239,797 and 3,873,756 shares of common stock, respectively, upon the closing of the initial public offering (IPO) contemplated by the Company s filing of its registration statement on Form S-1 with the Securities and Exchange Commission (SEC) in September 2010, based on a public offering price of $4.00 per share and assuming that the Company s IPO closes on November 29, 2010. The shares of common stock issued in the IPO and its estimated net proceeds are excluded in such pro forma information. In addition, the Company has outstanding warrants to purchase 200,000 shares of Series A-1 convertible preferred stock, 777,273 shares of Series A-2 convertible preferred stock, and 1,590,910 shares of Series B convertible preferred stock, which will become warrants to purchase 20,000, 77,726 and 159,090 shares of common stock, respectively, at $10.00, $11.00 and $11.00 per share, respectively, upon the closing of the IPO. The liability of $20,301,000 related to these warrants has been reclassified to additional paid-in capital as these warrants will no longer be exercisable for convertible preferred shares.

Cash and Cash Equivalents

The Company considers cash equivalents to be only those investments which are highly liquid, readily convertible to cash and which mature within three months from date of purchase.

Restricted Cash

During 2008 and 2009, the Company had a certificate of deposit for $209,000 as collateral for a letter of credit issued in connection with an operating lease. In December 2009, the requirement for the letter of credit was released in connection with the amendment of the operating lease. In December 2009, the Company issued a letter of credit for $200,000 in connection with another operating lease. The letter of credit is collateralized by a certificate of deposit in the same amount. Restricted cash of $209,000 and $200,000 at December 31, 2008 and 2009, respectively, is included in other assets on the balance sheet.

Fair Value Measurements

The carrying amount of financial instruments consisting of cash, accounts receivable, prepaid expenses and other current assets, accounts payable, accrued liabilities, accrued compensation and

Zogenix, Inc.

Notes to Consolidated Financial Statements (Continued)

current portion of debt included in the Company s financial statements are reasonable estimates of fair value due to their short maturities. Based on the borrowing rates currently available to the Company for loans with similar terms, management believes the fair value of long-term debt approximates its carrying value.

Effective January 1, 2008, the Company adopted authoritative guidance for fair value measurements. This authoritative guidance establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

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

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

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

Assets and liabilities measured at fair value on a recurring basis as of December 31, 2008 and 2009 and September 30, 2010 are as follows (in thousands):

	Fair Value Measurements at Reporting Date Using			
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
At December 31, 2008				
Assets				
Money market fund shares(1)	$ 13,300	$	$	$ 13,300
Liabilities				
Convertible preferred stock warrant liability(2)	$	$	$ 467	$ 467
At December 31, 2009				
Assets				
Money market fund shares(1)	$ 44,111	$	$	$ 44,111
Liabilities				
Convertible preferred stock warrant liability(2)	$	$	$ 5,041	$ 5,041
At September 30, 2010				
Assets				
Money market fund shares(1)	$ 115	$	$	$ 115
Liabilities				
Convertible preferred stock warrant liability(2)	$	$	$ 20,301	$ 20,301

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

(2) Convertible preferred stock warrants are measured at fair value using either the Black-Scholes option pricing valuation model or a binomial model depending on the characteristics of the warrants.

Zogenix, Inc.

Notes to Consolidated Financial Statements (Continued)

The following table provides a reconciliation of liabilities measured at fair value using significant unobservable inputs (Level 3) for the years ended December 31, 2008 and 2009 and the nine months ended September 30, 2010 (in thousands):

	Convertible Preferred Stock Warrant Liability
Balance at December 31, 2007	$ 259
Issuance of convertible preferred stock warrants	1,327
Changes in fair value of warrants	(1,119)
Balance at December 31, 2008	467
Issuance of convertible preferred stock warrants	3,819
Changes in fair value of warrants	755
Balance at December 31, 2009	5,041
Issuance of convertible preferred stock warrants	2,427
Changes in fair value of warrants	12,833
Balance at September 30, 2010 (unaudited)	$ 20,301

Concentration of Credit Risk, Sources of Supply and Significant Customers

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

The Company sells its products primarily to established wholesale distributors in the pharmaceutical industry. Credit is extended based on an evaluation of the customer s financial condition, and collateral is not required. Approximately 95.0% of the accounts receivable balance as of September 30, 2010 represents amounts due from three wholesale distributors. The Company evaluates the collectability of its accounts receivable based on a variety of factors including the length of time the receivables are past due, the financial health of the customer and historical experience. Based upon the review of these factors, the Company did not record an allowance for doubtful accounts at September 30, 2010.

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

Astellas Pharma US, Inc. (Astellas) provides a significant amount of funding for the advertising and promotional costs for Sumavel DosePro and co-promotes the product in the United States. See Note 3 for more detailed information regarding this collaboration.

Zogenix, Inc.

Notes to Consolidated Financial Statements (Continued)

Inventory

Inventory is stated at the lower of cost or market. Cost, which includes amounts related to materials, labor and overhead, is determined in a manner which approximates the first-in, first-out (FIFO) method. The Company capitalizes inventory produced in preparation for product launches upon FDA approval when costs are expected to be recoverable through the commercialization of the product. The Company provides reserves for potentially excess, dated or obsolete inventories based on an analysis of inventory on hand and on firm purchase commitments compared to forecasts of future sales.

Property and Equipment, Net

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

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

Impairment of Long-Lived Assets

The Company reviews its long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. There were immaterial charges as a result of impairment losses through December 31, 2009.

Warrants for Convertible Preferred Stock

In accordance with accounting guidance for warrants for shares in redeemable securities, the Company classifies warrants for convertible preferred stock as liabilities on the balance sheet. The Company adjusts the carrying value of these convertible preferred stock warrants to their estimated fair value at each reporting date with the increases or decreases in the fair value of such warrants recorded as change in fair value of warrant liability in the statement of operations.

Revenue Recognition

The Company recognizes revenue from the sale of Sumavel DosePro and from license fees and milestones earned on collaborative arrangements. Revenue is recognized when (i) persuasive evidence of an arrangement exists, (ii) delivery has occurred and title has passed, (iii) the price is fixed or determinable and (iv) collectability is reasonably assured.

Product Revenue

The Company sells Sumavel DosePro product to wholesale pharmaceutical distributors, and on a limited basis to retail pharmacies, or collectively the Company s customers, subject to rights of return within a period beginning six months prior to, and ending 12 months following, product expiration. Given the limited sales history of Sumavel DosePro, the Company currently cannot reliably estimate expected returns of the product at the time of shipment. Accordingly, the Company defers recognition of revenue on product shipments of Sumavel DosePro until the right of return no longer exists, which occurs at the earlier of the time Sumavel DosePro units are dispensed through patient prescriptions or expiration of the right of return. Units dispensed are generally not subject to return, except in the rare cases where the product malfunctions or the product is damaged in transit. The Company estimates

patient prescriptions dispensed using an analysis of third-party information, including third- party market research data, information obtained from certain wholesalers with respect to inventory levels at wholesalers and inventory movement and retail pharmacy re-stocking activity. Sumavel DosePro was launched in January 2010 and, accordingly, the Company does not have significant history estimating the number of patient prescriptions dispensed. If the Company underestimates or overestimates patient prescriptions dispensed for a given period, adjustments to revenue may be necessary in future periods.

As a result of this policy, the Company recognized $11,828,000 in Sumavel DosePro product revenue for the nine months ended September 30, 2010, which is net of estimated wholesaler and retail pharmacy discounts, stocking allowances, prompt pay discounts, chargebacks, rebates and patient discount programs. The Company has a deferred revenue balance of $2,802,000 at September 30, 2010 for Sumavel DosePro product shipments, which is net of estimated wholesaler and retail pharmacy discounts, stocking allowances, prompt pay discounts, chargebacks, rebates and patient discount programs.

The Company will continue to recognize revenue upon the earlier to occur of prescription units dispensed or expiration of the right of return until it can reliably estimate product returns, at which time the Company will record a one-time increase in net revenue related to the recognition of revenue previously deferred. In addition, the costs of manufacturing Sumavel DosePro associated with the deferred revenue are recorded as deferred costs, which are included in inventory, until such time the related deferred revenue is recognized.

Product Sales Allowances

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

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

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

Chargebacks. The Company provides discounts to authorized users of the Federal Supply Schedule (FSS) of the General Services Administration under an FSS contract negotiated by the Department of Veterans Affairs. These federal entities purchase products from the wholesale distributors at a discounted price, and the wholesale distributors then charge back to the Company the difference between the current retail price and the price the federal entity paid for the product. The Company estimates and accrues chargebacks based on estimated wholesaler inventory levels, current contract prices and historical chargeback activity.

Zogenix, Inc.

Notes to Consolidated Financial Statements (Continued)

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

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

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

Contract Revenue

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

Collaborative Arrangements

Effective January 1, 2009, the Company implemented new authoritative guidance related to accounting for collaborative arrangements. The new guidance requires that certain transactions between collaborators be recorded in the income statement on either a gross or net basis within revenues or operating expenses, depending on the characteristics of the collaboration relationship, and provides for enhanced disclosure of collaborative relationships. The Company evaluated its collaborative agreements for proper classification of shared expenses, license fees, milestone payments and any reimbursed costs within the statement of operations based on the nature of the underlying activity. If payments to and from collaborative partners are not within the scope of other authoritative accounting literature, the statement of operations classification for the payments is based on a reasonable, rational analogy to authoritative accounting literature that is applied in a consistent manner. For collaborations relating to commercialized products, if the Company acts as the principal in the sale of goods or services it records revenue and the corresponding operating costs in its respective line items within its statement of operations based on the nature of the shared expenses. Per authoritative accounting guidance, the principal is the party who is responsible for delivering the product to the customer, has latitude with establishing price and has the risks and rewards of providing product to the customer, including inventory and credit risk.

Zogenix, Inc.

Notes to Consolidated Financial Statements (Continued)

Research and Development Expenses

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

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

Advertising Expense

The Company records the cost of its advertising efforts when services are performed or goods are delivered. The Company incurred approximately $0, $0, $1,072,000, $144,000 and $3,506,000 in advertising costs for the years ended December 31, 2007, 2008 and 2009 and the nine months ended September 30, 2009 and 2010, respectively. At December 31, 2008 and 2009 and September 30, 2010, the Company capitalized advertising costs of $0, $203,000 and $106,000 in prepaid and other current assets, respectively.

Income Taxes

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

Foreign Currency Transactions

Gains or losses resulting from transactions denominated in foreign currencies are included in other income (expense) in the statements of operations. The Company recorded gains and losses from foreign currency transactions in other income (expense) of $25,000, $63,000, $(416,000), $(350,000) and $(113,000) for the years ended December 31, 2007, 2008 and 2009 and the nine months ended September 30, 2009 and 2010, respectively.

Stock-Based Compensation

Stock-based compensation cost is measured at the grant date, based on the estimated fair value of the award, and is recognized as expense over the employee s requisite service period on a straight-line basis. As of December 31, 2009 and September 30, 2010, there were no outstanding equity awards with market or performance conditions. Equity awards issued to non-employees are recorded at their fair value on the measurement date and are periodically re-measured as the underlying awards vest unless the instruments are fully vested, immediately exercisable and nonforfeitable on the date of grant.

Zogenix, Inc.

Notes to Consolidated Financial Statements (Continued)

Comprehensive Loss

Comprehensive loss represents all changes in stockholders equity except those resulting from investments or contributions by stockholders. The Company s other comprehensive loss for 2007 and 2008 consisted of unrealized losses on available-for-sale securities and is reported in stockholders equity.

Net Loss per Share

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

Pro forma basic and diluted net loss per share has been computed to give effect to the assumed conversion of all outstanding convertible preferred stock into shares of common stock which will occur upon the closing of the Company s initial public offering.

Zogenix, Inc.

Notes to Consolidated Financial Statements (Continued)

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

	Year Ended December 31,			Nine Months Ended September 30,	
	2007	2008	2009	2009	2010
Historical net loss per share					
Numerator					
Net loss attributable to common stockholders	$ (46,040)	$ (45,570)	$ (45,889)	$ (39,743)	$ (71,429)
Denominator					
Weighted average common shares outstanding	1,228	1,346	1,359	1,355	1,446
Weighted average shares subject to repurchase	(658)	(481)	(239)	(264)	(106)
Weighted average shares outstanding, basic and diluted	570	865	1,120	1,091	1,340
Basic and diluted net loss per share	$ (80.77)	$ (52.68)	$ (40.97)	$ (36.43)	$ (53.31)
Pro forma net loss per common share (unaudited)					
Numerator					
Net loss attributable to common stockholders			$ (45,889)		$ (71,429)
Pro forma adjustment to eliminate changes in fair value of convertible preferred warrant liability			755		12,833
Pro forma adjustment related to interest expense on convertible notes payable					300
Net loss used to compute pro forma net loss per share			$ (45,134)		$ (58,296)
Denominator					
Weighted average shares outstanding, basic and diluted			1,120		1,340
Pro forma adjustment to reflect assumed weighted average effect of conversion of convertible preferred stock			8,937		14,240
Pro forma adjustment to reflect assumed weighted average effect of conversion of convertible notes payable					1,230
Weighted average pro forma shares outstanding, basic and diluted net loss per share			10,057		16,810
Pro forma net loss per share, basic and diluted			$ (4.49)		$ (3.47)

Zogenix, Inc.

Notes to Consolidated Financial Statements (Continued)

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

	Year Ended December 31,			Nine Months Ended September 30,	
	2007	2008	2009	2009	2010
Convertible preferred stock	7,789	7,789	14,240	11,058	14,240
Convertible preferred stock warrants	20	98	1,389	434	1,548
Common stock subject to repurchase	627	360	190	212	24
Common stock options	294	582	808	831	1,483
	8,730	8,829	16,627	12,535	17,295

Segment Reporting

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

Recent Accounting Pronouncements

Effective July 1, 2009, the Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC or Codification) became the authoritative source of GAAP. All existing FASB accounting standards and guidance were superseded by the ASC. Instead of issuing new accounting standards in the form of statements, staff positions and Emerging Issues Task Force abstracts, the FASB now issues Accounting Standards Updates that update the Codification. Rules and interpretive releases of the SEC under authority of federal securities laws continue to be additional sources of authoritative GAAP for SEC registrants.

In January 2010, the FASB issued a new accounting standard which amends guidance on fair value measurements and disclosures. The new guidance requires disclosure of transfers into and out of Level 1 and Level 2 fair value measurements, and also requires more detailed disclosure about the activity within Level 3 fair value measurements. This standard is effective for annual and interim reporting periods beginning after December 15, 2009, except for the requirements related to Level 3 disclosures, which are effective for annual and interim reporting periods beginning after December 15, 2010. The Company adopted the relevant provisions of this guidance, and the adoption did not have a material impact on the Company s financial statements.

In February 2010, the FASB issued a new accounting standard which amends guidance on subsequent events. The new guidance requires evaluation of subsequent events through the date the financial statements are issued for SEC filers, amends the definition of SEC filer, and changes required disclosures. This standard is effective on February 24, 2010 and did not have a material financial impact on the Company s financial statements upon adoption.

In March 2010, the FASB Emerging Issues Task Force (EITF) ratified a new accounting standard which amends guidance on the milestone method of revenue recognition. The EITF concluded that the milestone method is a valid application of the proportional performance model when applied to

research or development arrangements. This guidance eliminates the requirement to establish the fair value of undelivered products and services and instead provides for separate revenue recognition based upon management s estimate of the selling price for an undelivered item when there is no other means to determine the fair value of that undelivered item. This standard allows an entity to make an accounting policy election to recognize a payment that is contingent upon the achievement of a substantive milestone in its entirety in the period in which the milestone is achieved. This standard is effective for fiscal years beginning on or after June 15, 2010 with early adoption permitted. The guidance may be applied prospectively for milestones achieved after the adoption date or retrospectively for all periods presented. The Company does not expect this guidance to have a material impact on the Company s financial position, results of operations or cash flows.

3. Collaboration, License and Purchase Agreements

Astellas Pharma US, Inc. Co-Promotion Agreement

In July 2009, the Company entered into the Co-Promotion Agreement with Astellas. Under the terms of the agreement, the Company granted Astellas the co-exclusive right (with the Company) to market and sell Sumavel DosePro in the United States (excluding Puerto Rico and the other territories and possessions of the United States) until June 30, 2013. Astellas has the option to extend the term of the agreement by an additional year in its sole discretion contingent upon Astellas payment to the Company of a predetermined option fee. In addition, Astellas has a right to opt-in to the commercialization of potential line extensions of Sumavel DosePro. Under the agreement, both Astellas and the Company are obligated to collaborate and fund the marketing of Sumavel DosePro and to provide annual minimum levels of sales effort directed at Sumavel DosePro during the term. In 2011 and throughout the remainder of the term, these minimum sales efforts are set forth as a minimum number of annual primary detail equivalents. The Company is responsible for the manufacture, supply, and distribution of commercial product for sale in the United States. In addition, the Company will supply product samples to Astellas, and Astellas will pay the Company for such samples, at an agreed upon transfer price.

Astellas may terminate the agreement for any reason or no reason upon 180-days written notice to the Company after September 30, 2010 or at any time in the event the Company undergoes a change of control (as defined in the agreement). In addition, Astellas may terminate the agreement if a governmental authority takes action that prevents or makes it unlawful for Astellas to perform its obligations under the agreement, in the event of the Company s inability to supply commercial product, under certain circumstances where a third party asserts that the making or selling of Sumavel DosePro infringes the intellectual property rights of a third party, or if the Company materially breaches its minimum sales effort obligations and does not cure such breach within a specified period. In the event a termination pursuant to the reasons set forth in the previous sentence takes place prior to July 31, 2011, the Company would be required to pay Astellas a specified royalty on net sales of Sumavel DosePro up to an aggregate specified dollar amount. Any such payments would be in lieu of the annual tail payments described below. The Company may terminate the agreement in the event that Astellas materially breaches its minimum sales effort obligations and does not cure such breach within a specified period. Either party may terminate the agreement upon the occurrence of a large scale recall or market withdrawal of Sumavel DosePro, a failure of the Sumavel DosePro brand to achieve certain minimum sales levels in 2010 or 2011, a material uncured breach by the other party, insolvency or bankruptcy of the other party, or other event which affects the other party s ability to perform its obligations under the agreement.

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Notes to Consolidated Financial Statements (Continued)

In connection with execution of the Co-Promotion Agreement, Astellas made a non-refundable up-front payment of $2,000,000 and agreed to make an additional $18,000,000 of payments to the Company upon the achievement of a series of milestones. As of December 31, 2009, Astellas paid a total of $19,000,000 to the Company. The remaining $1,000,000 was paid to the Company in March 2010. Under certain circumstances, the milestone payments made by Astellas to the Company are refundable; however, Astellas right to require this refund expired on July 31, 2010. In consideration for Astellas performance of its commercial efforts, the Company is required to pay Astellas a service fee on a quarterly basis that represents a fixed percentage of between 45% and 55% of Sumavel DosePro net sales to primary care physicians, OB/GYNs, emergency medicine physicians, and urologists in the United States (Astellas Segment). Astellas is not compensated for Sumavel DosePro sales to neurologists, any other prescribers not included in the Astellas Segment or for non-retail sales. In addition, upon completion of the co-promotion term, Astellas will be eligible to receive two additional annual tail payments calculated as decreasing fixed percentages (ranging from a mid-twenties down to a mid-teen percentage) of net sales in the Astellas Segment in the last 12 months of its active promotion.

In accordance with accounting guidance for revenue arrangements with multiple deliverables, the Company identified the deliverables in the Co-Promotion Agreement and divided them into separate units of accounting as follows: (i) co-exclusive right to promote Sumavel DosePro combined with the manufacturing and supply of commercial and sample product and (ii) sales support of Sumavel DosePro. The Company concluded both units of accounting require recognition ratably through the term of the Co-Promotion Agreement beginning with the date of the launch of Sumavel DosePro (January 2010) and which remains in effect through June 30, 2013, subject to a one-year extension at Astellas option upon Astellas payment of a pre-determined fee to the Company, and therefore, the allocation of the up-front and milestone financial consideration is not necessary. Consequently, the Company has recorded the $19,000,000 in upfront and milestone payments received from Astellas as deferred revenue in the balance sheet at December 31, 2009. The final $1,000,000 milestone payment was recorded as deferred revenue when received in March 2010. Beginning with the launch of Sumavel DosePro in January 2010, the Company began amortizing the upfront and milestone payments as contract revenue in the statement of operations over the term of the Co-Promotion Agreement. For the nine months ended September 30, 2010, the Company recognized $2,810,000 of contract revenue. As of September 30, 2010, the remaining balance of these payments in deferred revenue was $17,191,000.

Amounts received from Astellas for shared marketing costs and sample product are reflected as a reduction of selling, general and administrative expenses, and amounts payable to Astellas for shared marketing expenses and service fees are reflected as selling, general and administrative expenses.

For the years ended December 31, 2007, 2008 and 2009 and the nine months ended September 30, 2009 and 2010, the Company recognized shared marketing expense of $0, $0, $2,213,000, $489,000 and $3,490,000, respectively, under the Co-Promotion Agreement. There were no service fee costs incurred during the years ended 2009, 2008 and 2007. For the nine months ended September 30, 2009 and 2010, the Company recorded $0 and $2,236,000, respectively, of service fee costs.

Elan Pharma International Limited License Agreement

In November 2007, the Company entered into a License Agreement with Elan Pharma International Ltd. (Elan), which was amended in September 2009. Under the terms of this License Agreement, Elan granted the Company an exclusive license in the United States and its possessions and territories, with defined sub-license rights to third parties other than certain technological competitors of Elan, to certain Elan intellectual property rights related to the Company s ZX002 product candidate. The License Agreement grants the Company the exclusive right under certain Elan patents and patent applications

to import, use, offer for sale and sell oral controlled-release capsule or tablet formulations of *hydrocodone*, where *hydrocodone* is the sole active ingredient, for oral prescriptions in the treatment or relief of pain, pain syndromes or pain associated with medical conditions or procedures in the United States. This right enables the Company to exclusively develop and sell ZX002 in the United States. Elan has retained the exclusive right to take action in the event of infringement or threatened infringement by a third party of Elan s intellectual property rights under the License Agreement. The Company has the right to pursue an infringement claim against the alleged infringer should Elan decline to take or continue an action.

Under the terms of the License Agreement, the Company and Elan agreed that, subject to the future negotiation of a commercial manufacture and supply agreement, Elan, or an affiliate of Elan, will have the sole and exclusive right to manufacture and supply finished commercial product of ZX002 to the Company under agreed upon financial terms.

Elan also granted the Company, in the event that Elan is unwilling or unable to manufacture or supply commercial product to the Company, a non-exclusive license to make product under Elan s intellectual property rights. This non-exclusive license also includes the right to sublicense product manufacturing to a third party, other than certain technology competitors of Elan.

Under the License Agreement, the Company paid an upfront fee of $500,000 to Elan, which was recorded as research and development expense. As of December 31, 2009, the Company may be obligated to pay Elan up to $4,500,000 in total future milestone payments with respect to ZX002 depending upon the achievement of various development and regulatory events. The Company is also required to pay a mid single-digit percentage royalty on net sales of the product for an initial royalty term equal to the longer of the expiration of Elan s patents covering the product in the United States, or 15 years after commercial launch, if Elan does not have patents covering the product in the United States. After the initial royalty term, the license agreement will continue automatically for three-year rolling periods during which the Company will continue to pay royalties to Elan on net sales of the product at a reduced low single-digit percentage rate in accordance with the terms of the license agreement.

Either party may terminate the agreement upon a material, uncured default or certain insolvency events of the other party or upon 12 months written notice prior to the end of the initial royalty term or any additional three-year rolling period. Elan may terminate the agreement in the event that the Company fails to meet specified development and commercialization milestones within specified time periods. The Company may terminate the agreement if the sale of ZX002 is prohibited by regulatory authorities, or if, despite commercially reasonable efforts, the Company is unable to obtain regulatory approval for ZX002. The Company may also terminate the agreement, with or without cause, at any time upon six months written notice prior to NDA approval for ZX002 and at any time upon 12 months prior written notice after NDA approval for ZX002.

Aradigm Corporation Asset Purchase Agreement

On August 25, 2006, the Company entered into an asset purchase agreement with Aradigm Corporation (Aradigm). Under the terms of the agreement, Aradigm assigned and transferred to the Company all of its right, title and interest to tangible assets and intellectual property related to the DosePro (formerly known as Intraject) needle-free drug delivery system. Aradigm also granted to the Company a non-exclusive, fully paid, worldwide, perpetual, irrevocable, transferable, sublicensable license under all other intellectual property of Aradigm that was owned, controlled or employed by Aradigm prior to the closing of the asset purchase and that is necessary or useful to the development, manufacture or commercialization of the DosePro delivery system. Aradigm also retained a worldwide, royalty-free, non-exclusive license, with a right to sublicense, under all transferred intellectual property

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Notes to Consolidated Financial Statements (Continued)

rights solely for purposes of the pulmonary field, and the Company granted Aradigm a license under other intellectual property rights solely for use in the pulmonary field.

The Company paid Aradigm $4,000,000 at the closing of the asset purchase and was required to make an additional $4,000,000 milestone payment to Aradigm upon the U.S. commercialization of Sumavel DosePro (which payment was made in February 2010). The Company is also required to pay a 3% royalty on global net sales of Sumavel DosePro, by the Company or one of the Company s future licensees, if any, until the later of January 2020 or the expiration of the last valid claim of the transferred patents covering the manufacture, use, or sale of the product. The Company has recorded the second milestone payment as other assets in the balance sheet and is amortizing the milestone over the estimated life of the technology. For the nine months ended September 30, 2010, the Company recorded $598,000 of expense related to the amortization of the milestone and royalties from net sales of Sumavel DosePro.

In addition, in the event the Company or one of its future licensees, if any, commercializes a non-*sumatriptan* product in the DosePro delivery system, the Company will be required to pay Aradigm, at the Company s election, either a 3% royalty on net sales of each non-*sumatriptan* product commercialized, or a fixed low-twenties percentage of the royalty revenues received by the Company from the licensee, if any, until the later of the ten year anniversary of the first commercial sale of the product in the United States or the expiration of the last valid claim of the transferred patents covering the manufacture, use or sale of the product. Royalty revenues under this agreement include, if applicable, running royalties on the net sales of non-*sumatriptan* products, license or milestone fees not allocable to development or other related costs incurred by the Company, payments in consideration of goods or products in excess of their cost, or payments in consideration for equity in excess of the then fair market value of the equity.

4. Balance Sheet Details

Inventory (in thousands)

	December 31, 2008	December 31, 2009	September 30, 2010
Raw materials	$	$ 2,356	$ 5,018
Work in process		7,838	8,475
Finished goods		2,966	4,106
	$	$ 13,160	$ 17,599

Prepaid Expenses and Other Current Assets (in thousands)

	December 31, 2008	December 31, 2009	September 30, 2010
Receivable from collaboration partner for shared expenses	$	$ 1,267	$
Prepaid clinical costs		454	1,298
Value added tax receivable	590	276	830
Prepaid insurance	130	48	18
Prepaid other	299	743	767
	$ 1,019	$ 2,788	$ 2,913

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Notes to Consolidated Financial Statements (Continued)

Property and Equipment, Net (in thousands)

	December 31, 2008	December 31, 2009	September 30, 2010
Machinery, equipment and tooling	$ 5,409	$ 9,696	$ 9,987
Construction in progress	6,572	4,064	5,392
Computer equipment and software	578	840	1,037
Furniture and fixtures	213	433	555
Leasehold improvements	150	138	777
Property and equipment, at cost	12,922	15,171	17,748
Less accumulated depreciation	(1,172)	(2,180)	(3,226)
	$ 11,750	$ 12,991	$ 14,522

Depreciation expense for the years ended December 31, 2007, 2008 and 2009 and the nine months ended September 30, 2009 and 2010 was $407,000, $755,000, $1,017,000, $715,000 and $1,046,000, respectively.

Accrued Expenses (in thousands)

	December 31, 2008	December 31, 2009	September 30, 2010
Accrued interest expense	$ 301	$ 521	$ 560
Contract manufacturing fees		429	914
Accrued clinical expense		386	2,398
Accrued discounts and allowances			571
Accrued service fee			791
Other accrued expenses	1,137	1,155	2,338
	$ 1,438	$ 2,491	$ 7,572

5. Commitments

Operating Leases

In March 2007, the Company entered into a non-cancelable operating lease that expired in May 2010. This office space is located in San Diego, California and was used for general and administrative and sales and marketing operations and personnel. The office lease, subject to a 3.0% increase each year for the duration of the lease, provided the Company the ability to extend the lease for an additional 17 months upon six months prior written notice and an option to expand into additional space. Effective November 2008, the Company relocated its operations and subsequently entered into a sublease agreement with a third party for a term of 35 months. The Company recorded an expense of approximately $54,000 to reflect the exit costs associated with this property, which is reflected in operating expenses in the statement of operations.

Effective October 1, 2009, both the office lease and the sublease were terminated and the Company did not incur any material additional costs associated with the early termination.

In August 2008, the Company entered into a 20-month operating lease for office facilities in San Diego, California commencing on September 1, 2008. Monthly rental payments are adjusted on an annual basis, and the office lease expires, as extended, in July 2011.

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Notes to Consolidated Financial Statements (Continued)

The Company also leases office space for its supply chain and inventory management and research and product development operations in Emeryville, California under a non-cancelable operating lease that expires in November 2011. The base rent is subject to a 3.0% increase each year for the duration of the lease. In October 2009, the Company amended the lease in order to acquire adjacent space. Under the terms of the amendment, the lease term was extended to September 2015 and the Company received an option to expand into additional space. The Company also received free rent for two months and a tenant improvement allowance of $305,000.

In August 2009, the Company entered an operating lease agreement to lease up to 95 vehicles. Each vehicle has a lease term of 36 months with a fixed monthly rental payment. As security for the vehicle leases, the lessor required a letter of credit for $200,000, which is collateralized by a certificate of deposit in the same amount.

The Company recognizes rent expense on a straight-line basis over the non-cancelable term of its operating leases. Rent expense for the years ended December 31, 2007, 2008 and 2009 was $316,000, $672,000 and $799,000, respectively.

Future minimum lease payments as of December 31, 2009 are as follows (in thousands):

2010	$ 1,463
2011	1,420
2012	1,200
2013	638
2014 and thereafter	954
Total	$ 5,675

Manufacturing and Supply Agreements

The Company has a manufacturing services agreement with Patheon UK Limited (Patheon) for the aseptic capsule assembly, filling and inspection, final device assembly and purchasing of Sumavel DosePro, as well as other manufacturing and support services, which agreement expires on October 31, 2013. The Company has manufacturing and supply agreements with several third-party suppliers for the production of key components of Sumavel DosePro, which expire on various dates between 2012 and 2020. As of December 31, 2009, the Company has non-cancellable purchase orders for 2010 totaling approximately $4,139,000 under these arrangements. In addition, the Company is required to pay Patheon a monthly manufacturing fee of £283,000, or approximately $451,000 (based on the exchange rate as of December 31, 2009). As of December 31, 2009, the Company was committed to pay Patheon a total manufacturing fee of £13,033,000, or approximately $20,756,000 (based on the exchange rate as of December 31, 2009), which is payable monthly over the remaining 46 months of the Patheon manufacturing services agreement.

6. Debt

Bridge Loans

In February 2009, the Company entered into a Note and Warrant Purchase Agreement, pursuant to which certain investors agreed to loan the Company up to $14,800,000 (the Bridge Financing). During 2009, the Company drew down the entire $14,800,000 available under the Bridge Financing in four tranches. Outstanding balances under the Bridge Financing accrued interest at a rate of 8% per annum compounded annually. The Company issued to investors in the Bridge Financing subordinated

unsecured convertible promissory notes (Convertible Promissory Notes) under which all the then outstanding principal and interest amounts were due one year from the date of issuance. Upon the occurrence of a Qualified Financing (as defined in the Convertible Promissory Notes), the Convertible Promissory Notes and related accrued interest were convertible into shares issued in conjunction with the Qualified Financing at a conversion rate of $1.10 per share. In September 2009, the Company completed a Qualified Financing with the close of the first tranche of its Series B convertible preferred stock financing (Series B Financing see Note 7) at which time all the Convertible Promissory Notes and related accrued interest converted into shares of Series B convertible preferred stock.

In connection with the Bridge Financing, the loan investors also received warrant coverage equal to 25% of the shares to which the Convertible Promissory Notes convert, based on the original principal amount of the Convertible Promissory Notes. The warrants are exercisable into the same equity instrument issued in the Qualified Financing and have a seven year term. With the close of the Company s Series B Financing in September 2009 and the resulting conversion of the Convertible Promissory Notes, the warrants became exercisable into 3,363,619 shares of Series B convertible preferred stock at an exercise price of $1.10 per share.

In addition to warrant coverage, the holders of the Convertible Promissory Notes received the benefit of a deemed conversion price of the Convertible Promissory Notes that was below the estimated fair value of the Series B convertible preferred stock at the time of their conversion. As a result, in 2009, the Company recorded $3,009,000 in interest expense in the statement of operations to reflect the value of this beneficial conversion feature.

In July 2010, the Company entered into a Note Purchase Agreement, pursuant to which the Company borrowed an aggregate of $15,000,000 from certain existing investors. Outstanding balances under the Note Purchase Agreement accrue interest at a rate of 8% per annum. The Company issued to these investors subordinated unsecured convertible promissory notes (2010 Notes) under which all the then outstanding principal and interest amounts are due one year from the date of issuance. The principal amount of the 2010 Notes and accrued interest thereon will automatically convert into shares of the Company s common stock upon completion of the Company s IPO at a conversion price equal to the Company s IPO price. If a deemed liquidation event (as defined in the Company s amended and restated certificate of incorporation) occurs prior to the completion of the IPO or the maturity date of the 2010 Notes, the holders of the 2010 Notes may elect to (i) receive the repayment of the notes and accrued interest thereon or (ii) convert the notes and accrued interest thereon into shares of Series B convertible preferred stock at a conversion rate of $1.10 per share. If the Company s IPO does not occur prior to the maturity date of the 2010 Notes, the holders of the 2010 Notes may elect to (i) receive the repayment of the notes and accrued interest thereon or (ii) convert the notes and accrued interest thereon into shares of Series B convertible preferred stock at a conversion rate of $1.10 per share.

The holders of the 2010 Notes received the benefit of a deemed conversion price of the 2010 Notes that was below the estimated fair value of the Series B convertible preferred stock at the time of their issuance. The fair value of this beneficial conversion feature was estimated to be $8,182,000. The fair value of this beneficial conversion feature was recorded to debt discount and is being amortized to interest expense using the effective interest method over the term of the 2010 Notes. The Company recorded $2,987,000 of interest expense related to the beneficial conversion feature during the nine months ended September 30, 2010.

Term Debt

In June 2008, the Company entered into and borrowed $18,000,000 under the Oxford Agreement with Oxford and CIT. The obligations under the Oxford Agreement were collateralized by personal

property excluding certain intellectual property and all equipment pledged to secure the equipment financing facility described below. The borrowings under the Oxford Agreement bore an interest rate of 9.76%. The monthly repayment schedule included interest only payments for the first 10 months followed by principal and interest payments for the subsequent 36 months. The Oxford Agreement required a final payment of $990,000, in addition to principal repayments, at the loan maturity date. This final payment was being accrued as additional interest expense over the term of the loan.

The Company has the option to prepay the outstanding balance of the term loan in full, subject to a prepayment fee of 3% of the principal amount prepaid and the $990,000 final payment. In the event the Company becomes in default (as defined in the Oxford Agreement) of the Oxford Agreement, the lender has the right under a control agreement to assume control over the Company s bank accounts, and also has the right to seize and sell the collateral pledge to secure the agreement. The outstanding principal balance of the Oxford Agreement as of December 31, 2009 is $14,441,000. In September 2009, Oxford Finance invested $500,000 in the Company s Series B convertible preferred stock financing.

In July and October 2010, the Company amended and restated the Oxford Agreement with Oxford and CIT, and Oxford and Silicon Valley Bank are now party to the Amended Oxford Agreement. The Amended Oxford Agreement consists of a $25,000,000 term loan and a $10,000,000 revolving credit facility. The obligations under the Amended Oxford Agreement are collateralized by the Company s personal property (including, among other things, accounts receivable, equipment, inventory, contract rights, rights to payment of money, license agreements, general intangibles and cash) but excluding, among other things, copyrights, patents, patent applications, trademarks, service marks, trade secret rights and equipment pledged to secure the GE Capital facility. The Amended Oxford Agreement includes financial covenants relating to the Company s performance against revenue projections and was conditioned on the Company completing a subordinated debt financing of at least $15,000,000 in conjunction with the closing of the Amended Oxford Agreement (see the discussion of the 2010 Notes above), and additionally requires the Company to complete an equity or subordinated debt financing of at least $10,000,000 prior to November 30, 2010.

The $25,000,000 term loan bears an interest rate of 12.06% per annum. The monthly repayment schedule includes interest only payments for the first 12 months followed by principal and interest payments for the subsequent 30 months. The term loan requires a final payment of $1,200,000, in addition to principal repayments, at the loan maturity date, which is January 1, 2014. The Company has the option to prepay the outstanding balance of the term loan in full, subject to the $1,200,000 final payment and a prepayment fee of either 2% or 3% of the principal amount prepaid depending upon when the prepayment occurs.

Under the terms of the revolving credit facility, the Company may borrow up to $10,000,000 based on eligible accounts receivable and inventory balances, as defined within the Amended Oxford Agreement. Amounts outstanding under the revolving credit facility accrue interest, payable monthly, at a floating rate per annum equal to the greater of 3.29% above Silicon Valley Bank s prime rate or 7.29%. In addition, the Company pays a monthly fee equal to 0.5% per annum of the average unused portion of the revolving credit facility. The revolving credit facility requires a final payment of $100,000, in addition to principal and interest repayments, at the loan maturity date. The Company has the option to terminate the revolving credit facility prior to the loan maturity date and repay the outstanding balance in full, subject to a termination fee between $100,000 and $300,000 depending upon when the termination occurs. As of September 30, 2010, the Company had $2,702,000 outstanding under the revolving credit facility, and $7,298,000 was available for future borrowings.

In connection with the Amended Oxford Agreement, $12,757,000 of proceeds borrowed was used to repay the outstanding balance of the Oxford Agreement consisting of principal, accrued interest, prepayment fee and contractual settlement fee.

Zogenix, Inc.

Notes to Consolidated Financial Statements (Continued)

Equipment Financing

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

There are no financial covenants under the terms of the GE Agreement; however, GE Capital maintains the right to determine, in its sole discretion, if the Company has experienced a material adverse change in its business and, in that event, require immediate settlement of the outstanding balance of the loan.

The Company has the option to prepay the outstanding balance of the promissory notes in full, subject to a prepayment fee as defined in the GE Agreement. The outstanding principal balance of the GE Agreement as of December 31, 2009 is $1,925,000.

Maturities of long-term debt as of December 31, 2009, are as follows (in thousands):

2010	$ 8,332
2011	7,620
2012	3,332
2013	
2014	
Total minimum payments	19,284
Less amount representing interest	(2,918)
Present value of net minimum payments	16,366
Less unamortized discount	(1,030)
Total long-term debt	15,336
Less current portion	(6,558)
Long-term portion	$ 8,778

Interest expense related to long-term debt for the years ended December 31, 2007, 2008 and 2009 was $377,000, $1,718,000 and $2,712,000, respectively.

7. Convertible Preferred Stock and Stockholders Equity

Convertible Preferred Stock

Under the Company s amended and restated certificate of incorporation, the Company s convertible preferred stock is issuable in series. The Company s board of directors is authorized to determine the rights, preferences and terms of each series.

The Company initially recorded each series of convertible preferred stock at their fair values on the dates of issuance, net of issuance costs. A redemption event will only occur upon the liquidation or winding up of the Company, a greater than 50% change of control or sale of

substantially all of the

assets of the Company. As the redemption event is outside the control of the Company, all shares of convertible preferred stock have been presented outside of permanent equity in accordance with accounting guidance for redeemable securities. Further, the Company has also elected not to adjust the carrying values of the convertible preferred stock to the redemption value of such shares, since it is uncertain whether or when a redemption event will occur. Subsequent adjustments to increase the carrying values will be made when it becomes probable that such redemption will occur.

Series A-1 Convertible Preferred Stock Financing

During August 2006, the Company entered into agreements with several investors who collectively purchased 30,775,000 shares of Series A-1 convertible preferred stock (Series A-1) at $1.00 per share for net cash proceeds of approximately $30,000,000 and the conversion of $500,000 in bridge financing. In September and December 2007, the Company sold an additional 38,025,000 shares of Series A-1 to the same group of investors, resulting in net cash proceeds of approximately $38,005,000.

Series A-2 Convertible Preferred Stock Financing

In December 2007, the Company sold 9,090,909 shares of Series A-2 convertible preferred stock (Series A-2) at $1.10 per share to a new investor, resulting in net cash proceeds of approximately $9,937,000.

The December 2007 sale of Series A-1 and Series A-2 was issued at prices per share below the estimated fair value of the underlying common stock. Accordingly, the Company recorded a deemed dividend on the Series A-1 and Series A-2 of $18,360,000 in the statement of operations for the year ended December 31, 2007. This deemed dividend is equal to the number of shares of Series A-1 and Series A-2 sold multiplied by the difference between the estimated fair value of the underlying common stock and the Series A-1 and Series A-2 conversion price per share.

Series B Convertible Preferred Stock Financing

In September 2009, the Company sold 32,689,062 shares of Series B convertible preferred stock (Series B) at $1.10 per share to five existing investors and one new investor. The Company received aggregate net cash proceeds of approximately $34,770,000, which includes proceeds of $14,770,000 received in connection with amounts borrowed under the Convertible Promissory Notes that were converted into shares of Series B. In December 2009, the Company sold an additional 31,818,171 shares of Series B to the same group of investors and one new investor, resulting in net cash proceeds of approximately $34,930,000.

The following is a summary of total gross proceeds raised under the Series A-1, Series A-2 and Series B financings (in thousands):

Series A-1	$ 68,800
Series A-2	10,000
Series B	70,958
Total	$ 149,758

Right Issued with Series A-1 Convertible Preferred Stock

Included in the terms of the Series A-1 shares were certain rights granted to the holders which obligated the Company to deliver additional shares of convertible preferred stock at a specified price in the future based on the achievement of a milestone or at the option of the investors in the series of

convertible preferred shares (the Right). The Right related to the Series A-1 was exercised during 2007. Other income of $906,000 was recorded during 2007 related to the change in the fair value of this Right.

Rights, Preference and Privileges of Convertible Preferred Stock

Under the Company s amended and restated certificate of incorporation, as of December 31, 2009, the Company is authorized to issue 156,416,317 shares of preferred stock, consisting of 69,000,000 shares of Series A-1, 10,000,000 shares of Series A-2 and 77,416,317 shares of Series B (collectively referred to as convertible preferred stock), with a $0.001 par value. The rights, preferences and privileges of the Company s convertible preferred stock are as follows:

Dividends

The holders of Series A-1, Series A-2 and Series B are entitled to receive noncumulative dividends at a rate of 8.0%, 8.8% and 8.8%, respectively, per annum and are payable only when and if declared by the board of directors. Through December 31, 2009, the board of directors has not declared any dividends. Convertible preferred stock dividends are payable in preference and in priority to any dividends on common stock.

Liquidation Preference

In the event of liquidation, dissolution, or winding up of the Company, the holders of the Series A-1, Series A-2 and Series B shall be entitled to receive, prior and in preference to any distribution of any of the assets or surplus funds of the Company to the holders of shares of common stock, an amount per share equal to $1.00, $1.10 and $1.10, respectively, for each outstanding share of convertible preferred stock (as adjusted for stock splits, stock dividends, combinations or other recapitalizations). Thereafter, if assets remain in the Company, the holders of common stock and convertible preferred stock shall receive all remaining assets pro rata based on the number of common stock (calculated on an as-converted basis) held by each holder. If available assets are insufficient to pay the full liquidation preference, the available assets will be distributed ratably to the holders in proportion to the amounts that would be payable to such holders if such assets were sufficient to permit payment in full. The aggregate distributions made to the preferred shareholders in a liquidation cannot exceed an amount equal to 2.5 times the liquidation preference plus any declared but unpaid dividends.

Conversion Rights

Each share of convertible preferred stock is convertible at the option of the holder into an equal number of shares of common stock based on the original issue price, subject to certain anti-dilution adjustments. Each share of convertible preferred stock will automatically convert into shares of common stock at the effective conversion price for each such share immediately upon the earlier of (i) the Company s sale of its common stock in a firm commitment underwritten public offering pursuant to a registration statement under the Securities Act of 1933, as amended, in which the per share price is at least $30.00 (as adjusted for recapitalizations), and the gross proceeds are at least $40,000,000 or (ii) upon receipt by the Company of a written request of such conversion from the holders of 67% of the then outstanding shares of convertible preferred stock.

Voting Rights

The holders of convertible preferred stock are entitled to one vote for each share of common stock into which such convertible preferred stock could then be converted; and with respect to such vote, such holder shall have full voting rights and powers equal to the voting rights and powers of the holders of common stock.

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Notes to Consolidated Financial Statements (Continued)

Anti-Dilution Provisions

Each share of convertible preferred stock is convertible at the option of the holder into an equal number of shares of common stock based on the original issue price, subject to certain anti-dilution adjustments. These anti-dilution adjustments consist of adjustments for subsequent issuances of common stock or convertible preferred stock to other investors and any stock dividend, stock split, combination of shares, reorganization, recapitalization, reclassification or other similar event. For subsequent issuances of common stock or convertible preferred stock, the Series B conversion price will be adjusted to the issuance price of the new stock, while the Series A-1 and Series A-2 conversion prices will be adjusted based upon a predetermined formula. For all other anti-dilution adjustments, the conversion price will be adjusted proportionally to account for the impact of such adjustment.

Common Stock

Under the Company s amended and restated certificate of incorporation, as of December 31, 2009, the Company is authorized to issue 183,982,947 shares of common stock with a $0.001 par value. Each share of common stock is entitled to one vote. The holders of common stock are also entitled to receive dividends whenever funds are legally available and when declared by the board of directors, subject to the prior rights of holders of convertible preferred stock.

In May and August 2006, in conjunction with the founding of the Company, 1,138,500 shares of common stock were issued to the founders (Founder s Stock) at a price of $0.01 per share for total proceeds of $11,000. Of the total Founder s Stock issued, 1,120,000 shares vest over periods between two and four years and the Company has the option to repurchase any unvested shares at the original purchase price upon any voluntary or involuntary termination. There were 239,000, 87,000 and 0 unvested shares of common stock at December 31, 2008 and 2009 and September 30, 2010, respectively.

Common stock reserved for future issuance is as follows (in thousands):

	December 31, 2009	September 30, 2010
Conversion of convertible preferred stock	14,240	14,240
Stock options outstanding	808	1,483
Warrants to purchase convertible preferred stock (as if converted)	1,389	1,548
Shares authorized for future issuance under the 2006 Plan	15	234
	16,452	17,505

8. Convertible Preferred Stock Warrants

In connection with the execution of the Amended Oxford Agreement in July 2010, which was subsequently amended in October 2010, the Company issued warrants to Oxford and Silicon Valley Bank to purchase 1,145,455 and 445,455 shares, respectively, of Series B convertible preferred stock at an exercise price of $1.10 per share. In the event the Company completes its next private financing at a price per share of less than $1.10, the warrantholders may make a one-time election to have the warrants become exercisable for shares of the Company s preferred stock at that lower price. The warrants expire upon the earlier of the tenth anniversary of the issuance date or five years following the effective date of the Company s initial public offering. In accordance with accounting guidance for

warrants for shares in redeemable securities, the Company classified these warrants for convertible preferred stock as liabilities on the balance sheet. The Company adjusts the carrying value of these convertible preferred stock warrants to their estimated fair value at each reporting date with the increases or decreases in the fair value of such warrants recorded as change in fair value of warrant liability in the statement of operations. The fair value of the warrants was estimated to be $2,427,000 at the date of issuance using a binomial model. The fair value of the warrants was recorded to debt discount and is being amortized to interest expense using the effective interest method over the term of the loan.

In connection with the issuance of the Convertible Promissory Notes from February to July 2009, the Company issued warrants to the lenders to purchase a total of 3,363,619 shares of Series B convertible preferred stock (the Bridge Loan Warrants). The Bridge Loan Warrants have an exercise price of $1.10 and expire between February and July 2016, subject to their earlier termination upon the completion of the Company s initial public offering and certain mergers, acquisitions and similar transactions. The fair value of the Bridge Loan Warrants was estimated to be $3,009,000 at the date of issuance using the Black-Scholes valuation model. The fair value of the Bridge Loan Warrants was recorded to debt discount and was fully amortized to interest expense upon the conversion of the Convertible Promissory Notes in September 2009.

In connection with the closing of the second tranche of the Series B Financing in December 2009, the Company issued warrants to the participating Series B investors to purchase a total of 9,545,447 shares of Series B convertible preferred stock (the Series B Warrants), which warrants were amended in October 2010 to allow for their current exercisability. The Series B Warrants have an exercise price of $1.10 and expire in December 2016, subject to their earlier termination upon the completion of the Company s initial public offering and certain mergers, acquisitions and similar transactions.

In connection with the execution of the Oxford Agreement in June 2008, the Company issued warrants to Oxford Finance and CIT Healthcare to purchase 410,227 and 367,046 shares, respectively, of Series A-2 convertible preferred stock (the Series A-2 Warrants). The warrants have an exercise price of $1.10 per share and expire in June 2018. The fair value of the warrants was estimated to be $1,327,000 at the date of issuance using the Black-Scholes valuation model. The fair value of the warrants was recorded to debt discount and is being amortized to interest expense using the effective interest method over the term of the loan.

In connection with the execution of the GE Agreement in March 2007, the Company issued a warrant to GE Capital to purchase 200,000 shares of Series A-1 convertible preferred stock (the Series A-1 Warrants). The warrant has an exercise price of $1.00 per share and expires in March 2014. The fair value of the warrant was estimated to be $151,000 at the date of issuance using the Black-Scholes valuation model. The fair value of the warrant was recorded to debt discount and is being amortized to interest expense using the effective interest method over the term of the loan.

At December 31, 2008 and 2009 and September 30, 2010, the estimated fair value of the Series A-1, Series A-2, and Series B warrants was calculated using either the Black-Scholes option pricing valuation model or a binomial model depending on the characteristics of the warrants, resulting in an aggregate carrying value of $467,000, $5,041,000 and $20,301,000, respectively, and was based on the estimated fair value of the convertible preferred stock.

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Notes to Consolidated Financial Statements (Continued)

The warrant valuation was based on the following inputs**:**

	Black-Scholes			Binomial
	December 31,		September 30,	September 30,
	2008	2009	2010	2010
Assumed volatility	85.0%	84.0% to 98.3%	89.1% to 90.4%	91.8%
Expected life (years)	5.2 to 9.5	4.2 to 8.5	3.4 to 7.8	9.9
Assumed risk-free interest rate	1.5% to 2.4%	2.2% to 3.6%	1.0% to 2.2%	2.5%
Expected dividend yield	0%	0%	0%	0%

The following is a summary of warrants outstanding as of December 31, 2009 and September 30, 2010:

	# of Shares	Exercise Price
Series A-1	200,000	$ 1.00
Series A-2	777,273	$ 1.10
Series B	14,499,976	$ 1.10
Total	15,477,249	

9. Stock Option Plan

During 2006, the Company adopted the 2006 Equity Incentive Award Plan (as amended, the 2006 Plan) under which 1,134,000 shares of common stock were reserved for issuance to employees, directors and consultants of the Company at December 31, 2009. The 2006 Plan provides for the grant of incentive stock options, non-qualified stock options and rights to purchase restricted stock to eligible recipients. Recipients of stock options shall be eligible to purchase shares of the Company s common stock at an exercise price equal to no less than the estimated fair market value of such stock on the date of grant. The maximum term of options granted under the 2006 Plan is ten years. At December 31, 2009 and September 30, 2010, 14,750 and 233,689 shares of common stock were available for future issuance under the 2006 Plan, respectively.

The 2006 Plan is intended to encourage ownership of stock by employees, consultants and non-employee directors of the Company and to provide additional incentives for them to promote the success of the Company s business. The board of directors is responsible for determining the individuals to receive equity grants, the number of shares subject to each grant, the exercise price per share and the exercise period of each option. Options granted pursuant to the 2006 Plan generally vest over four years and vest at a rate of 25% upon the first anniversary of the vesting commencement date and 1/48th per month thereafter. The 2006 Plan allows the option holders to exercise their options early and acquire option shares, which are then subject to repurchase by the Company at the original exercise price of such options. At December 31, 2008 and 2009 and September 30, 2010 there were 121,000, 102,000 and 24,000, respectively, of unvested shares of common stock issued to employees of the Company in connection with the early exercise of stock option grants which the Company has recorded as a liability in the accompanying balance sheets.

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Notes to Consolidated Financial Statements (Continued)

Information with respect to the number and weighted average exercise price of stock options under the 2006 Plan is summarized as follows (number of shares in thousands):

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2008	582	$ 2.59		
Granted	346	2.50		
Exercised	(98)	0.96		
Canceled/Forfeited	(23)	3.90		
Outstanding at December 31, 2009	807	$ 2.71	8.96	$ 769
Granted	710	4.09		
Exercised	(6)	0.50		
Canceled/Forfeited	(29)	3.59		
Outstanding at September 30, 2010	1,482	$ 3.36	8.90	$ 14,289
Exercisable at September 30, 2010	1,250	$ 3.60	8.65	$ 11,712
Vested at September 30, 2010	468	$ 2.60	8.10	$ 4,852

(1) Includes awards with early exercise provisions that permit optionee to exercise unvested options.

The intrinsic values above represent the aggregate value of the total pre-tax intrinsic value based upon a common stock price of $3.60 and $13.00 at December 31, 2009 and September 30, 2010, respectively, and the contractual exercise prices. At December 31, 2009, the weighted average fair value of options outstanding was $2.19 per share.

	Year Ended December 31,		
	2007	2008	2009
Weighted average grant date fair value	$ 2.50	$ 6.80	$ 3.30
Total fair value of shares vested	$ 67,000	$ 159,000	$ 414,000

Stock-Based Compensation

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

	Year Ended December 31,			Nine Months Ended September 30,	
	2007	2008	2009	2009	2010
Risk free interest rate	3.5% to 4.8%	2.7% to 3.2%	2.3% to 2.8%	2.3% to 2.8%	1.8% to 2.3%
Expected term	1.0 to 6.1 years	5.0 to 6.1 years	5.0 to 6.1 years	5.0 to 6.1 years	5.0 to 6.1 years

Expected volatility	64.4% to 78.1%	80.6% to 86.0%	105.6% to 107.6%	102.7% to 107.6%	94.2% to 95.7%
Expected dividend yield	0.0%	0.0%	0.0%	0.0%	0.0%
Fair value of underlying stock	$0.50 to $16.00	$3.50 to $19.10	$3.20 to $3.60	$3.20	$13.00 to $13.50

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Notes to Consolidated Financial Statements (Continued)

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

Historically, the fair value of the Company s common stock has been determined contemporaneously by the Company s board of directors on the date of grant. At the time of the issuances of stock options, the Company believed its estimates of the fair value of its common stock were reasonable and consistent with methods outlined in the American Institute of Certified Public Accountants Practice Aid, *Valuation of Privately-Held Company Equity Securities Issued as Compensation*, and the Company s understanding of how similarly situated companies in its industry were valued. In August 2010, the Company commenced the initial public offering process. In connection with the preparation of the financial statements necessary for inclusion in the registration statement related to this offering, the Company reassessed the estimated fair value of its common stock for financial reporting purposes for each quarter in 2009 and 2010. The reassessment included both the determination of the appropriate valuation models and related inputs. For the reassessed periods prior to June 30, 2010, the Company did not forecast or anticipate a liquidity event in the near term and, as such, utilized the option pricing method. These reassessments did not result in any significant difference in the estimated fair value of the common stock from those estimated by the Company s contemporaneous valuations. As a result of the greater clarity available to the Company to define likely outcomes and the proximity to a liquidity event (i.e., this offering), the Company concluded that the probability weighted expected return method (PWERM) was more appropriate than the previously used option pricing model and provided a more refined estimate of the likely value of the Company s common stock as of June and September 30, 2010. The type and timing of each potential liquidity event for the June and September 30, 2010 valuations were heavily influenced by the commencement of the initial public offering process while each prior reassessed valuation was based on the Company s estimate of type and timing of liquidity event at that time. The reassessed fair value of the Company s common stock as of June 30, 2010 was estimated to be $13.50 per share, an increase of $9.50 per share from the $4.00 fair value and as of September 30, 2010 was estimated to be $13.00 per share, an increase of $6.80 per share from the $6.20 fair value determined in good faith by the Company s board of directors.

The Company recognized stock-based compensation expense as follows (in thousands):

	Year Ended December 31,			Nine Months Ended September 30,	
	2007	2008	2009	2009	2010
Cost of sales	$	$	$	$	$ 73
Research and development	45	227	310	228	262
Selling, general and administrative	86	692	716	512	1,377
Total	$ 131	$ 919	$ 1,026	$ 740	$ 1,712

The aggregate intrinsic value of options exercised for the years ended December 31, 2007, 2008 and 2009 was approximately $202,000, $17,000 and $256,000, respectively. As of December 31, 2009, there was approximately $2,850,000 of total unrecognized compensation costs related to outstanding options, which is expected to be recognized over a weighted average period of 2.35 years.

At December 31, 2009, all consultant stock options outstanding were vested. In accordance with accounting guidance for stock-based compensation, the Company periodically re-measured the fair

value of stock option grants to non-employees and recognized the related income or expense during their vesting period. Expense recognized for consultant stock options was immaterial for the years ended December 31, 2007, 2008 and 2009, respectively. Consultant stock option expense is included within research and development expense in the statement of operations.

10. Employee Benefit Plan

Effective February 1, 2007, the Company has established a defined contribution 401(k) plan (the Plan) for all employees who are at least 21 years of age. Employees are eligible to participate in the Plan beginning on the first day of the month following one month of employment. Under the terms of the Plan, employees may make voluntary contributions as a percentage of compensation. The Company s contributions to the Plan are discretionary, and no contributions have been made by the Company to date.

11. Income Taxes

In July 2006, the FASB issued a new accounting standard which clarifies the accounting for uncertainty in income taxes recognized in an entity s financial statements and prescribes a recognition threshold and measurement attributes to financial statement disclosure of tax positions taken or expected to be taken on a tax return. Under this guidance, the impact of an uncertain income tax position on the income tax return must be recognized 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. Additionally, this standard provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition.

The Company adopted this new accounting standard on January 1, 2009. There were no unrecognized tax benefits as of the date of adoption, and there are no unrecognized tax benefits included in the balance sheets at December 31, 2008 and 2009, 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 no accrued interest or penalties on the balance sheets at December 31, 2008 and 2009 and has recognized no interest and/or penalties in the statements of operations through the year ended December 31, 2009.

The Company is subject to taxation in the U.S. and state jurisdictions. The Company s tax years for 2006 and forward can be subject to examination by the United States and state tax authorities due to the carry forward of net operating losses.

At December 31, 2009, the Company had federal and California income tax net operating loss carryforwards of approximately $108,355,000 and $105,069,000, respectively. The federal tax loss carryforwards will begin expiring in 2026 unless previously utilized, and the California tax loss carryforwards will begin expiring in 2016 unless previously utilized. In addition, the Company has federal and California research and development income tax credit carryforwards of $884,000 and $921,000, respectively. The federal research and development income tax credit carryforwards will begin to expire in 2026 unless previously utilized. The California research and development income tax credit carryforwards will carry forward indefinitely until utilized.

The Company has completed an analysis under Internal Revenue Service Code (IRC) Sections 382 and 383 to determine if the Company s net operating loss carryforwards and research and development

credits are limited due to a change an ownership. The Company has determined that as of December 31, 2009 the Company had one ownership change, as defined by IRC Sections 382 and 383, which occurred in August 2006 upon the issuance of the Series A-1 shares. As a result of this ownership change, the Company has reduced its net operating loss carryforwards by $1,900,000 and research and development income tax credits by $8,000. Pursuant to IRC Section 382 and 383, use of the Company s net operating loss and research and development income tax credit carryforwards may be limited in the event of a future cumulative change in ownership of more than 50% within a three-year period.

Significant components of the Company s deferred tax assets as of December 31, 2009 and 2008 are listed below. A valuation allowance of $47,195,000 and $32,141,000 for the years ended December 31, 2009 and 2008, respectively, has been established to offset the deferred tax assets as realization of such assets is uncertain. The components of the deferred tax assets are as follows (in thousands):

	December 31,	
	2008	**2009**
Deferred tax assets:		
Net operating losses	$ 29,938	$ 42,971
Research and development	1,031	1,489
Depreciation and amortization	646	348
Start-up/organization costs	168	153
Accrued vacation	157	242
Deferred rent	75	40
Inventory reserve and UNICAP		1,515
Accrued expenses	77	335
Other, net	49	102
Total deferred tax assets	32,141	47,195
Less valuation allowance	(32,141)	(47,195)
Net deferred tax assets	$	$

12. Subsequent Events

The Company has evaluated all subsequent events through the filing date of its registration statement on Form S-1 with the SEC, to ensure that this filing includes appropriate disclosure of events both recognized in the financial statements as of September 30, 2010, and events which occurred subsequently but were not recognized in the financial statements.

On October 25, 2010, the Board of Directors approved an amendment to its amended and restated certificate of incorporation effecting a 1-for-10 reverse stock split of its common stock. The par value and the authorized shares of the common stock were not adjusted as a result of the reverse stock split. All issued and outstanding common stock, and per share amounts contained in the financial statements have been retroactively adjusted to reflect this reverse stock split for all periods presented. The reverse stock split became effective on November 3, 2010.

In November 2010, the Company was awarded a non-taxable grant of approximately $489,000 under the Qualifying Therapeutic Discovery Project program included in the Patient Protection and Affordable Health Care Act of 2010.

14,000,000 Shares

Common Stock

PROSPECTUS

November 22, 2010

Wells Fargo Securities

Leerink Swann

Oppenheimer & Co.

Stifel Nicolaus Weisel

Through and including December 17, 2010 (25 days after the commencement of this offering), all dealers that effect transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This delivery is in addition to a dealer s obligation to deliver a prospectus when acting as an underwriter and with respect to their unsold allotments or subscriptions.