AFFYMAX INC
Form 10-Q
November 09, 2011
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended September 30, 2011

or

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

For the transition period from to

Commission File Number 001-33213

AFFYMAX, INC.

(Exact name of registrant as specified in its charter)

Delaware	**77-0579396**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)

4001 Miranda Avenue
Palo Alto, CA 94304
(650) 812-8700

(Address, including zip code, and telephone number, including area code, of registrant s principal executive offices)

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

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

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

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

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

As of October 31, 2011, 35,730,339 shares of the registrant s common stock, $0.001 par value, were outstanding.

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PART I FINANCIAL INFORMATION

Item 1. Financial Statements

AFFYMAX, INC.

CONDENSED BALANCE SHEETS

(in thousands)

	September 30, 2011 (Unaudited)	December 31, 2010
Assets		
Current assets		
Cash and cash equivalents	$ 66,025	$ 63,499
Short-term investments	49,222	33,582
Receivable from Takeda	5,452	
Deferred tax assets	438	438
Prepaid expenses and other current assets	1,753	2,023
Total current assets	122,890	99,542
Property and equipment, net	3,071	3,982
Restricted cash	1,135	1,135
Long-term investments		19,876
Deferred tax assets, net of current	6,802	6,802
Other assets	351	50
Total assets	$ 134,249	$ 131,387
Liabilities and Stockholders Equity		
Current liabilities		
Accounts payable	$ 2,579	$ 321
Accrued liabilities	11,359	11,594
Accrued clinical trial expenses	3,251	11,247
Payable to Takeda		5,958
Deferred revenue		18,497
Total current liabilities	17,189	47,617
Long-term income tax liability	10,378	10,249
Advance from Takeda	2,835	
Other long-term liabilities	914	974
Total liabilities	31,316	58,840
Commitments and contingencies (Note 7)		
Stockholders equity		
Common stock: 35,645,926 and 25,451,338 shares issued and outstanding at September 30, 2011 and December 31, 2010, respectively	36	25

Additional paid-in capital		523,715		461,425
Accumulated deficit		(420,860)		(388,934)
Accumulated other comprehensive income		42		31
Total stockholders equity		102,933		72,547
Total liabilities and stockholders equity	$	134,249	$	131,387

The accompanying notes are an integral part of these condensed financial statements.

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AFFYMAX, INC.

CONDENSED STATEMENTS OF OPERATIONS

(in thousands, except per share data)

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	**2010**	**2011**	**2010**
Revenue:				
Collaboration revenue	$ 13,204	$ 16,784	$ 44,029	$ 105,771
License and royalty revenue	5	6	14	15
Total revenue	13,209	16,790	44,043	105,786
Operating expenses:				
Research and development	14,863	21,118	51,606	83,120
General and administrative	8,172	7,781	24,426	25,372
Total operating expenses	23,035	28,899	76,032	108,492
Loss from operations	(9,826)	(12,109)	(31,989)	(2,706)
Interest income	45	47	136	227
Interest expense	(38)	(35)	(111)	(104)
Other income (expense), net	3	67	39	(1)
Net loss before provision for income taxes	(9,816)	(12,030)	(31,925)	(2,584)
Provision for income taxes			(1)	
Net loss	$ (9,816)	$ (12,030)	$ (31,926)	$ (2,584)
Net loss per share:				
Basic and diluted	$ (0.28)	$ (0.49)	$ (0.98)	$ (0.11)
Weighted-average number of shares used in computing basic and diluted net loss per share	35,578	24,369	32,474	24,168

The accompanying notes are an integral part of these condensed financial statements.

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AFFYMAX, INC.

CONDENSED STATEMENTS OF CASH FLOWS

(in thousands)

(Unaudited)

	Nine Months Ended September 30,	
	2011	**2010**
Cash flows from operating activities		
Net loss	$ (31,926)	$ (2,584)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,696	1,663
Amortization of discount/premium on investments	1	594
Stock-based compensation expense	7,872	8,005
Loss (gain) on disposal of property and equipment	(26)	8
Changes in operating assets and liabilities:		
Receivable from Takeda	(5,452)	14,212
Income taxes receivable		1,443
Prepaid expenses and other current assets	270	4,121
Other assets	(301)	192
Accounts payable	2,258	1,077
Accrued liabilities	(234)	(2,944)
Accrued clinical trial expenses	(7,996)	(10,600)
Payable to Takeda	(5,958)	
Deferred revenue	(18,496)	(40,785)
Long-term income tax liability	129	
Advance from Takeda	2,835	
Other long-term liabilities	(60)	(11)
Net cash used in operating activities	(55,388)	(25,609)
Cash flows from investing activities		
Purchases of property and equipment	(801)	(449)
Purchases of investments	(14,215)	(110,225)
Proceeds from sales of investments		16,042
Proceeds from maturities of investments	18,461	51,515
Proceeds from sale of property and equipment	41	(3)
Net cash provided by (used in) investing activities	3,486	(43,120)
Cash flows from financing activities		
Proceeds from issuance of common stock upon exercise of stock options	438	2,242
Proceeds from issuance of common stock under employee stock purchase plan	365	628
Proceeds from common stock issued upon public offering, net of issuance cost	53,625	
Repayment of UBS loan		(9,192)
Net cash provided by (used in) financing activities	54,428	(6,322)
Net increase (decrease) in cash and cash equivalents	2,526	(75,051)
Cash and cash equivalents at beginning of the period	63,499	125,296
Cash and cash equivalents at end of the period	$ 66,025	$ 50,245

The accompanying notes are an integral part of these condensed financial statements.

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AFFYMAX, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS

(Unaudited)

1. The Company

Affymax, Inc., a Delaware corporation, was incorporated on July 20, 2001. We are a biopharmaceutical company committed to developing novel drugs to improve the treatment of serious and often life-threatening conditions. We completed Phase 3 clinical trials of our product candidate, peginesatide (Hematide), to treat anemia associated with chronic kidney disease in early 2010. In May 2011, we submitted our New Drug Application, or NDA, to the U.S. Food and Drug Administration, or FDA, seeking approval for peginesatide to treat adult dialysis patients with anemia associated with chronic kidney disease. Our NDA is currently under review with the FDA, with an action date of March 27, 2012 under the Prescription Drug User Fee Act. Peginesatide is a synthetic peptide-based erythropoiesis stimulating agent, or ESA, designed to stimulate production of red blood cells.

2. Summary of Significant Accounting Policies

Basis of Presentation

Our accompanying condensed financial statements have been prepared following the requirements of the Securities and Exchange Commission, or SEC, for interim reporting. As permitted under those rules, certain footnotes or other financial information that are normally required by U.S. generally accepted accounting principles, or GAAP, have been condensed or omitted. The condensed financial statements are unaudited and reflect all adjustments, consisting of only normal recurring adjustments, which in the opinion of management, are necessary to fairly state the financial position at, and the results of operations and cash flows for, the interim periods presented. The financial information included herein should be read in conjunction with our Annual Report on Form 10-K for the year ended December 31, 2010, which includes our audited financial statements and the notes thereto.

Revenues, expenses, assets and liabilities can vary during each quarter of the year. Therefore, the results and trends in the condensed financial statements and accompanying notes may not be indicative of the results for the full year or any future period.

Comprehensive Loss

Comprehensive loss consists of net loss plus the change in unrealized gains and losses on investments. At each balance sheet date presented, our accumulated other comprehensive income (loss) consists solely of unrealized gains and losses on investments. Comprehensive loss for the three and nine months ended September 30, 2011 and 2010 are as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Net loss	$ (9,816)	$ (12,030)	$ (31,926)	$ (2,584)
Increase (decrease) in unrealized gains (losses) on investments	(28)	28	11	129
Comprehensive loss	$ (9,844)	$ (12,002)	$ (31,915)	$ (2,455)

Concentration of Risk and Uncertainties

Financial instruments that potentially subject us to a concentration of credit risk consist of cash, cash equivalents and investments. We deposit excess cash in accounts with two major financial institutions in the U.S. Deposits in these banks may exceed the amount of insurance provided on such deposits. We have not experienced any realized losses on our deposits of cash and cash equivalents.

We have experienced significant operating losses since inception. At September 30, 2011, we had an accumulated deficit of $420.9 million. We have generated no revenue from product sales to date. We have funded our operations to date principally from the sale of equity securities, upfront license fees, milestone payments and

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reimbursement for development and commercial expenses and manufacturing costs under our collaboration agreements with Takeda Pharmaceutical Company Limited, or Takeda, operating and capital lease financing, interest earned on investments and limited license fees and royalties from licensing intellectual property. We expect to incur substantial losses in the future and may need to obtain additional financing in order to complete the development and commercialization of peginesatide. There can be no assurance that such financing will be available or will be at terms acceptable to us.

As of September 30, 2011, we have an accounts receivable balance with Takeda of $5.5 million under the terms of our two separate collaboration agreements, or together, the Arrangement, with Takeda. This receivable was comprised of the amounts due from Takeda for the reimbursement of development and commercial expenses we incurred during the third quarter of 2011 partially offset by amounts due to Takeda for reimbursement of development and commercial expenses they incurred during the same quarter. As of December 31, 2010, we had an accounts payable balance due to Takeda of $6.0 million under the Arrangement. This balance due to Takeda was primarily due to a change in estimate to our clinical trial accrual and related expense in the fourth quarter of 2010, partially offset by amounts due from Takeda for the reimbursement of development and commercial expenses we incurred. We have not experienced any credit losses from our Arrangement with Takeda and do not expect any. We do not require collateral on our receivable.

We are currently developing our first product offering, peginesatide, and have no products that have received regulatory approval. Peginesatide will require approval from the FDA, and/or foreign regulatory agencies prior to commercial sales. There can be no assurance that peginesatide will receive the necessary approvals. If we are denied such approvals or such approvals are delayed, it would have a material adverse effect on us. To achieve profitable operations, we must successfully develop, test, manufacture and commercialize peginesatide. There can be no assurance that peginesatide can be developed successfully or manufactured at an acceptable cost and with appropriate performance characteristics, or that peginesatide will be successfully commercialized. These factors could have a material adverse effect on our future financial results.

Further, some of our suppliers and manufacturing arrangements, including the provision of bulk poly(ethylene) glycol reagent for the manufacture of peginesatide from Nektar Therapeutics AL, Corporation are currently single-sourced, leaving us at greater risk of supply interruptions and potential delays.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Actual results could differ from those estimates.

Investments

Investments are classified as available-for-sale and are carried at their fair market value based upon quoted market prices for these or similar instruments at the balance sheet date. Unrealized gains and losses are reported as a separate component of stockholders equity until realized. The amortized cost of these securities is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization as well as realized gains and losses are included in interest income. We assess our investments for potential other-than-temporary impairment based on

factors including the length of time and extent to which the fair market value has been below our cost basis, the current financial condition of the investee and our intent and ability to hold the investment for a sufficient period of time to allow for any anticipated recovery in market value. If we conclude that an other-than-temporary impairment exists, we recognize an impairment charge to reduce the investment to fair value and record the related charge as a reduction of interest to other income (expense), net. We have elected to use settlement date accounting for purposes of recording transactions.

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Revenue Recognition

Collaboration Revenue

We recognize revenue in accordance with the SEC Staff Bulletin No. 101, *Revenue Recognition in Financial Statement*s, as amended by Staff Accounting Bulletin No. 104, *Revision of Topic 13* and Accounting Standards Codification, or ASC, 605-25, *Multiple Element Arrangements*. When evaluating multiple element arrangements, we consider whether the components of the arrangement represent separate units of accounting as defined in the authoritative guidance for revenue arrangements with multiple deliverables. Application of this guidance requires subjective determinations and requires management to make judgments about the fair value of the individual elements and whether such elements are separable from the other aspects of the contractual relationship.

On January 1, 2011, we adopted Accounting Standards Update, or ASU, No. 2009-13, *Multiple Deliverable Revenue Arrangements*. This update amends the guidance on accounting for arrangements with multiple deliverables to require that each deliverable be evaluated to determine whether it qualifies as a separate unit of accounting. This determination is generally based on whether the deliverable has stand-alone value to the customer. This update also establishes a selling price hierarchy for determining how to allocate arrangement consideration to identified units of accounting. The selling price used for each unit of accounting will be based on vendor-specific objective evidence, or VSOE, if available, third-party evidence if VSOE is not available, or estimated selling price if neither VSOE nor third-party evidence is available. We may be required to exercise considerable judgment in determining whether a deliverable is a separate unit of accounting and the estimated selling price of identified units of accounting for new agreements. The adoption of ASU No.2009-13 did not impact our financial position or results of operations as of and for the nine month period ended September 30, 2011. The potential future impact of the adoption of this update will depend on the nature of any new arrangements or material modifications of existing arrangements that we enter into in the future.

During the development period under the Arrangement, which ended in May 2011, upon submission of our NDA to the FDA, we recognized collaboration revenue using Contingency Adjusted Performance Model, or CAPM. Under CAPM, revenue was eligible for recognition in the period the payment was earned under the Arrangement including amounts that were either received or due from Takeda. Revenue initially recognized was based on the percentage of time elapsed from inception of the Arrangement in June 2006 to the period in which the payment was earned in relation to the total projected development period. The remaining portion of the payment was then recognized on a straight-line basis over the remaining estimated duration of the development period of the Arrangement. Payments during the development period included amounts due for upfront license fees, milestone payments earned, purchases of active pharmaceutical ingredient or API and reimbursement of development expenses. Our obligations under the agreement consisted primarily of actively developing our product candidate, peginesatide, for the treatment of anemia for chronic kidney disease through the end of the development period which occurred upon our submission of our NDA.

Beginning in June 2011, we have moved into the commercialization period as defined under our Arrangement with Takeda. Per the Arrangement, this includes all activities undertaken before and after regulatory approval relating specifically to pre-marketing, launch, promotions, marketing, sale and distribution of peginesatide. Prior to approval of the product and commencement of profit sharing payments, our primary source of revenue in the commercialization period will likely consist of reimbursement of ongoing efforts related to regulatory activities for FDA approval of peginesatide and commercial activities in preparation of the launch of our product. The Arrangement provides us with multiple payment streams, including reimbursement of third party development and commercialization expenses, reimbursement of expenses for full-time employee equivalent or FTE services related to commercialization (which commenced on July 1 2011), the potential to earn at risk milestone payments upon achievement of contractual criteria and profit sharing payments subsequent to product launch if approved. During the commercialization period, our obligations include ongoing regulatory work to obtain FDA approval and commercial efforts related to our product launch.

Where there are multiple deliverables combined as a single unit of accounting, revenues are deferred and recognized over the period that we remain obligated to perform services. The specific methodology for the recognition of the revenue (e.g., straight-line or according to specific performance criteria) is determined on a case-by-case basis according to the facts and circumstances applicable in the Arrangement.

During the commercialization period of the Arrangement, for each source of collaboration revenue, we apply the following revenue recognition criteria:

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- Revenues related to reimbursement by Takeda of third-party development expenses (70/30 split per the Arrangement) and commercial expenses (shared equally 50/50 per the Arrangement) are recognized as revenue, in the period incurred.

- Revenues related to reimbursement of costs of FTEs engaged in commercial activities are recognized as revenue in the period incurred. Such reimbursement is based on contractually negotiated reimbursement rates for each FTE as specified in the Arrangement.

- Revenue resulting from a milestone payment that is contingent upon the achievement of a substantive event or milestone is recognized in its entirety in the period in which the milestone is achieved and collectability is assured. A milestone is an event (i) that can only be achieved based in whole or in part on either our performance or on the occurrence of a specific outcome resulting from our performance, (ii) for which there is substantive uncertainty at the date the Arrangement is entered into that the event will be achieved and (iii) results in additional payments being due to us. Milestones are considered substantive when the consideration earned from the achievement of the milestone (i) is commensurate with either our performance to achieve the milestone or the enhancement of value of the item delivered as a result of a specific outcome resulting from our performance; (ii) relates solely to past performance and (iii) is reasonable relative to all deliverable and payment terms in the Arrangement.

- Other payments received, such as payments due under the launch allowance (see Note 8 in the Notes to Condensed Financial Statements), for which such payments are contingent solely upon future events are recognized as revenue when earned in accordance with the contract terms and when such payments can be reasonably estimated and collectability is reasonably assured.

We account for milestones under ASU 2010-17, *Milestone Method of Revenue Recognition*. Under the milestone method, contingent consideration received from the achievement of a substantive milestone is recognized in its entirety in the period in which the milestone is achieved, which we believe is more consistent with the substance of our performance under our collaboration agreement. A milestone is defined as an event (i) that can only be achieved based in whole or in part on either the entity s performance or on the occurrence of a specific outcome resulting from the entity s performance, (ii) for which there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved, and (iii) that would result in additional payments being due to the entity. A milestone is substantive if the consideration earned from the achievement of the milestone is consistent with our performance required to achieve the milestone or the increase in value to the collaboration resulting from our performance, relates solely to our past performance, and is reasonable relative to all of the other deliverables and payments within the arrangement.

License and Royalty Revenue

Royalties are recognized as earned in accordance with contract terms, when third party results are reported and collectability is reasonably assured. Royalties received under agreements that were acquired by us in the 2001 spin out from GlaxoSmithKline, or Glaxo, are recorded net of the 50% that we are required to remit to Glaxo.

Clinical Trial Expense and Accruals

We record expense for estimated clinical study external costs, which until 2011, were a significant component of research and development, or R&D, expense. These clinical trial costs were $(1.1) million and $3.1 million during the three months ended September 30, 2011 and 2010, respectively, and $0.3 million and $26.3 million for the nine months ended September 30, 2011 and 2010, respectively. Clinical trials are administered by clinical research organizations, or CROs. CROs typically perform most of the total start-up activities for the trials, including document preparation, site identification pre-study visits, training as well as on-going program management. For the Phase 3 studies, which represented the vast majority of the clinical trial expense, the expense recorded is based on reporting received from CROs and internal analyses. We accrue costs for work performed by CROs based on the achievement of contracted activities during the period. Expense for investigator fees, which include patient costs, is based on internal estimates of activities using patient enrollment and contractual or estimated rates. For the Phase 2 studies, the expense is activities-based such as patient monitoring as reported by the CROs and achievement of milestones. Other costs such as testing and drug materials are expensed as incurred. For all studies, CRO reporting is reviewed by us for appropriateness.

During Q3 2011 we have been working with our CROs on final close-out activities regarding site billings for investigator grants on our Phase 3 trials. We recently received notification from one of our CROs that they had completed their close-out work and they provided the final amounts due relating to work performed on our Phase 3 studies for which they were responsible. As a result of this new information, we recorded a change in estimate to decrease our clinical trial accruals for these trials. As a result, we reversed $1.4 million of clinical trial accrual in the third quarter of 2011. In addition, as a result of the conclusion of negotiations with our CROs on various billing disputes, we further reduced our clinical trial accrual by $0.7 million as the ultimate settlement was more favorable than our initial estimates. The aggregate change in estimate during the period decreased expense by $2.1 million for the three months ended September 30, 2011.

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Additional changes in estimate or adjustments may result as the final trial close-out audits and fee negotiations are completed relating to our clinical trials which could impact R&D expense, collaboration revenues and amounts due to or from Takeda in subsequent periods.

Recent Accounting Pronouncements

In June 2011, the Financial Accounting Standards Board or FASB, issued ASU No. 2011-05, which is an update to Topic 220, *Presentation Of Comprehensive Income*. This update amends current comprehensive income guidance and eliminates the option of presenting the components of other comprehensive income as part of the statement of stockholders equity. This update presents an entity with the option to present the total of comprehensive income, the components of net income, and the components of other comprehensive income either in a single continuous statement of comprehensive income or in two separate but consecutive statements. In both choices, an entity is required to present each component of net income along with total net income, each component of other comprehensive income along with a total for other comprehensive income, and a total amount for comprehensive income. The amendments in this update do not change the items that must be reported in other comprehensive income or when an item of other comprehensive income must be reclassified to net income. The new guidance was originally proposed to be effective for fiscal years, and interim periods within those years, beginning after December 15, 2011 and applied retrospectively. In October 2011, the FASB proposed to defer the effective date of certain provisions in the guidance related to the presentation of reclassification adjustments. No effective date has been announced. As ASU No. 2011-05 relates only to the presentation of comprehensive income, we do not expect that the adoption of this update will have a material effect on our financial statements.

In May 2011, the FASB issued ASU No. 2011-04, which is an update to Topic 820, *Fair Value Measurement*. This update establishes common requirements for measuring fair value and related disclosures in accordance with GAAP and international financial reporting standards. This amendment did not require additional fair value measurements. ASU No. 2011-04 is effective for all interim and annual reporting periods beginning after December 15, 2011. We do not believe there will be a significant impact on our financial statements from the adoption of ASU No. 2011-04

Net Loss Per Common Share

Basic net loss per share is computed by dividing net loss by the weighted-average number of shares of common stock outstanding during the period.

Diluted net loss per share is computed similarly to basic net loss per share, except that the denominator is increased to include all dilutive potential common shares using the treasury stock method. For purposes of this calculation, options to purchase common stock, common stock issuable pursuant to the 2006 Employee Stock Purchase Plan, restricted stock units and warrants are considered to be potential common shares and are only included in the calculation of diluted loss per share when their effect is dilutive. The computations for basic and diluted net loss per share were as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	**2010**	**2011**	**2010**
Numerator:				

Net loss	$ (9,816)	$ (12,030)	$ (31,926)	$ (2,584)
Denominator:				
Weighted-average shares outstanding used in computing basic and diluted net loss per share	35,578	24,369	32,474	24,168
Basic and diluted net loss per share	$ (0.28)	$ (0.49)	$ (0.98)	$ (0.11)

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The following shares were excluded from the computation of diluted net loss per common share for the periods presented because including them would have an antidilutive effect (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Options to purchase common stock	4,233	3,873	4,233	3,873
Common stock issuable pursuant to the 2006 Employee Stock Purchase Plan	100	34	100	34
Restricted stock units	375	509	375	509
Warrants to purchase common stock	426	426	426	426

3. Stock-Based Compensation

During the quarter ended September 30, 2011, we granted 403,124 stock options and 113,356 RSUs to our employees and board of directors with a weighted average grant date fair value of $4.44 and $7.04 per share, respectively. The stock options generally vest over a four year period and the RSUs vest annually over a three year period.

We measure and recognize all stock-based compensation expense under the authoritative guidance for share-based payments.

Stock-based compensation was recorded in the condensed statements of operations as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Research and development	$ 1,025	$ 1,313	$ 3,668	$ 2,969
General and administrative	1,186	1,864	4,204	5,036
Total	$ 2,211	$ 3,177	$ 7,872	$ 8,005

Included in the amounts in the table above for the nine months ended September 30, 2011 are compensation costs related to the January 31, 2011 resignation of our former Chief Executive Officer, Arlene M. Morris. Under the terms of Ms. Morris separation agreement, consistent with her 2008 employment agreement, she has a post-termination exercise period for vested stock options ending on the earlier of one year following the date of termination or the expiration of the option. As part of the separation agreement, Ms. Morris is obligated to provide consulting services through September 30, 2011. Effective upon her resignation, Ms. Morris status changed from an employee to a consultant and her options and awards continued to vest until the end of her consulting arrangement in September 2011. In accordance with ASC 718, *Shared Based Payments*, we recorded $268,000 of stock-based compensation expense related to her separation and consulting arrangement during the quarter ended March 31, 2011. Given the nature of the consulting agreement, all costs were accrued and expensed in the quarter ended March 31, 2011.

In March 2011, our board of directors approved an amendment to our 2006 Equity Incentive Plan to extend the post-termination exercise period from 90 days to two years for non-employee board members options vested as of such director s termination date. No other terms of the awards were modified. This amendment applies to all existing and future option grants to non-employee board members.

As of September 30, 2011, unrecognized compensation costs related to employee and director stock options and restricted stock units totaled $16.0 million. The cost is expected to be recognized over a weighted-average amortization period of 2.7 years.

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4. Investments

The following is a summary of our available-for-sale marketable securities (in thousands):

	As of September 30, 2011				
	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Other-Than Temporary Impairment	Fair Value
Short-term investments:					
Certificates of deposit	$ 996	$	$	$	$ 996
Government securities	48,183	43			48,226
Total short-term investments	$ 49,179	$ 43	$	$	$ 49,222
Long-term investments:					
Government securities	$	$	$	$	$
Total long-term investments	$	$	$	$	$

	As of December 31, 2010				
	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Other-Than Temporary Impairment	Fair Value
Short-term investments:					
Certificates of deposit	$ 1,448	$	$	$	$ 1,448
Government securities	32,080	58	(4)		32,134
Total short-term investments	$ 33,528	$ 58	$ (4)	$	$ 33,582
Long-term investments:					
Government securities	$ 19,899	$ 5	$ (28)	$	$ 19,876
Total long-term investments	$ 19,899	$ 5	$ (28)	$	$ 19,876

Investments held at September 30, 2011 mature between October 2011 and August 2012.

5. Fair Value Measurements

We measure certain financial assets at fair value on a recurring basis, including cash equivalents and available for sale securities. The fair value of these assets was determined based on a three-tier hierarchy under the authoritative guidance for fair value measurements and disclosures that 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 quoted prices in active markets that are observable either directly or indirectly through corroboration with observable market data.

- Level 3 unobservable inputs in which there is little or no market data, which would require us to develop our own assumptions.

Our cash equivalents and investments are classified within Level 1 or Level 2 of the fair value hierarchy because they are valued using quoted market prices in active markets, broker or dealer quotations, or alternative pricing sources with reasonable levels of price transparency. The types of investments that are generally classified within Level 1 of the fair value hierarchy include money market securities. The valuation technique we used to measure fair value of our Level 1 money market securities is a market approach, using prices and other relevant information generated by market transactions involving identical securities. The types of investments that are generally classified within Level 2 of the fair value hierarchy include corporate securities, certificates of deposits and U.S. government securities. The valuation technique we used to measure fair value of our Level 2 investments is a market approach, which we review trading activity and pricing for these investments as of the measurement date. When sufficient quoted pricing for identical investments was not available, we used market pricing and other observable market inputs for similar investments obtained from various third party data providers. These inputs

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represent quoted prices for similar investments in active markets or these inputs have been derived from observable market data.

The following table presents our investments measured at fair value on a recurring basis classified by the fair value measurements and disclosures valuation hierarchy (in thousands):

	As of September 30, 2011			
		Fair Value Measurements Using		
	Total	Level 1	Level 2	Level 3
Cash equivalents	$ 51,494	$ 50,249	$ 1,245	$
Short-term investments:				
Certificates of deposit	$ 996	$	$ 996	$
Government securities	48,226		48,226	
Total short-term investments	$ 49,222	$	$ 49,222	$
Long-term investments:				
Government securities	$	$	$	$
Total long-term investments	$	$	$	$

	As of December 31, 2010			
		Fair Value Measurements Using		
	Total	Level 1	Level 2	Level 3
Cash equivalents	$ 61,096	$ 59,353	$ 1,743	$
Short-term investments:				
Certificates of deposit	$ 1,448	$	$ 1,448	$
Government securities	32,134		32,134	
Total short-term investments	$ 33,582	$	$ 33,582	$
Long-term investments:				
Government securities	$ 19,876	$	$ 19,876	$
Total long-term investments	$ 19,876	$	$ 19,876	$

We held investments in auction rate securities or ARS and UBS AG of Series C-2 ARS Rights, or ARS Rights during the quarter ended June 30, 2010, which were classified within Level 3 of the fair value hierarchy because of the lack of observable inputs. The valuation technique we used to measure fair value of our Level 3 ARS and ARS Rights was an income approach and we used a discounted cash flow analysis. As of September 30, 2011 and December 31, 2010, we no longer hold ARS or ARS Rights as these investments were fully redeemed or sold in 2010.

The following table presents changes in Level 3 investments measured at fair value on a recurring basis for the nine months ended September 30, 2011 and 2010 (in thousands):

	Nine Months Ended September 30,	
	2011	2010
Balance at beginning of the period	$	$ 17,883
Included in net loss		695
Total realized loss related to ARS		
Included in net loss		(158)
Total realized losses related to ARS Rights included in net loss		(604)

Settlements		(17,816)
Balance at end of the period	$	$

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Upon the sale and redemptions of our ARS during 2010, we recognized a realized loss of $158,000 for the nine months ended September 20, 2010. The fair value of our ARS Rights was decreased by $604,000 for the nine months ended September 30, 2010 and this reduction was recorded as a charge to other income (expense), net. We also reversed other-than-temporary impairment charges of $695,000 during that period.

6. UBS Loan

In connection with the settlement with UBS AG relating to our ARS, we entered into a loan agreement with UBS Financial Services, Inc., an affiliate of UBS AG, and we obtained a loan of approximately $9.2 million in December 2009. This no net cost loan bore interest at a rate not to exceed the average rate of interest paid on the pledged ARS. For the three and nine months ended September 30, 2010, we paid $2,000 and $56,000 of interest expense associated with the loan, respectively and received $6,000 and $150,000 in interest income from the collateralized ARS, respectively. As required by UBS, for the nine months ended September 30, 2010, we applied the net interest earned of $94,000 and $9.1 million from the sales and redemptions of ARS to the principal of the loan. As part of our redemption of ARS Rights in July 2010, we repaid our outstanding loan balance.

7. Commitments and Contingencies

In October 2010, the arbitration panel in our binding arbitration with certain subsidiaries of Johnson & Johnson Pharmaceutical Research & Development, L.L.C. and Ortho-McNeil Pharmaceutical, Inc., or J&J, decided the ownership of a number of U.S. and international patents and patent applications related to certain erythropoietin receptor agonists, or collectively the intellectual property in dispute. The decision maintained J&J s sole inventorship and sole ownership of U.S. Patent No. 5,767,078, or the 078 Patent, and certain related foreign patents and patent applications, including European Patent application EP96/918,317. The arbitrators determined that we and J&J jointly own the remainder of the intellectual property in dispute.

In November 2010, we filed in the U.S. District Court for the Northern District of Illinois, or District Court, a motion to vacate the arbitration award with respect to the ownership of the 078 Patent and related foreign cases. In December 2010, J&J filed its response and requested that the court confirm the arbitration award.

In March 2011, the District Court issued its decision to vacate in part the arbitrators award relating to sole ownership by J&J of the European Patent EP96/918,317 and other foreign counterpart patents and patent applications to the 078 Patent. As a consequence, the District Court remanded the issues of inventorship and ownership of such foreign patents and patent applications to the arbitration panel. The District Court denied our motion to vacate in part and maintained the arbitration award with respect to the sole ownership by J&J of the 078 Patent in the U.S. In May 2011, we filed a notice of appeal relating to the District Court s decision as to the 078 Patent in the U.S. which remains pending with the Court of Appeals for the Federal Circuit. Concurrently, J&J filed an appeal with the Seventh Circuit Court of Appeals, and in October 2011, the Seventh Circuit Court reversed the District Court with the result that it remanded with instruction to confirm the arbitration award in full and set forth its view that the Court of Appeals for the Federal Circuit lacked jurisdiction.

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In November 2011, we entered into a settlement agreement with J&J. or Settlement Agreement, under which we obtain a non-exclusive license to the intellectual property in dispute, a covenant not to sue and a release of all claims associated with the arbitration and dispute. The Settlement Agreement also provides for the dismissal of all pending proceedings.

The Settlement Agreement provides for upfront payments by us to J&J of $6 million within 30 days of execution thereof, $2 million by June 30, 2012, a $2.5 million milestone payment upon FDA regulatory approval of peginesatide, and a $2.5 million milestone payment upon regulatory approval of peginesatide in the first major European country. In addition, we pay royalties to J&J on sales of peginesatide in Europe, Japan and certain other countries outside of the United States until mid-2016.

Concurrent with the execution of the Settlement Agreement, we and Takeda entered into an amendment to the Arrangement in connection with the above settlement payments to J&J, pursuant to which Takeda will reimburse us up to 50% of upfront and milestone payments to J&J or $6.5 million in total contingent upon the accomplishment of certain milestones related to peginesatide regulatory approvals and commercial events. We are solely responsible for the royalty payment to J&J.

8. Development and Commercialization Agreements with Takeda

We entered into two separate collaboration agreements with Takeda, which have been combined for accounting purposes due to their proximity of negotiation. Consideration from these collaboration agreements includes nonrefundable upfront license fees, reimbursement for sales of API, clinical and regulatory milestone payments, reimbursement of third party U.S. clinical development expenses, product profit share revenues (as co-promotion revenues) and royalties.

In February 2006, we granted an exclusive license to Takeda for development and commercialization of peginesatide in Japan. Pursuant to this agreement, Takeda has paid us approximately $42 million to date, consisting of $17 million in upfront licensing fees, approximately $10 million for the purchase of equity, a $10 million cash milestone payment for the completion of the first Phase 1 trial of peginesatide in Japan, and in March 2010, a $5 million cash milestone payment for the initiation of Phase 3 trial of peginesatide in Japan. In the event of Takeda s successful achievement of clinical development and regulatory milestones, we would be eligible to receive from Takeda up to an additional aggregate of $33 million relating to the renal program. Takeda is responsible for all development and commercialization costs in Japan and will purchase the API for peginesatide from us. In the event peginesatide is approved and launched in Japan, we would receive a royalty from Takeda on peginesatide sales in Japan.

In June 2006, we expanded our collaboration with Takeda to develop and commercialize peginesatide worldwide, which includes the co-development and co-commercialization of peginesatide in the U.S. Takeda received an exclusive license to develop and commercialize peginesatide outside of the U.S. During the development period of the collaboration, beginning January 1, 2007, Takeda was responsible for the first $50 million of third party expenses related to development in pursuit of U.S. regulatory approval of peginesatide, which was fully utilized through the first quarter of 2008. Thereafter, Takeda has borne 70% of the third party U.S. development expenses while we have been responsible for 30% of third party expenses. We retain responsibility for 100% of our internal development expenses, most notably employee-related expenses.

During the commercialization period, which commenced upon submission of our NDA to the FDA, Takeda will continue to bear responsibility for 70% of all third-party expenses related to U.S. development and 50% of all third party expenses related to the commercialization of peginesatide in the U.S. However, during the commercialization period, certain internal employee-related expenses supporting preparation for commercialization of peginesatide in the U.S. are also shared equally. By mutual agreement of the parties, the equal sharing of certain FTE expenses commenced July 1, 2011.

Per the terms of the Arrangement, we are also entitled to a launch allowance to help fund the initial costs associated with preparing to launch the product in the U.S. Under the terms of the launch allowance, Takeda is responsible for 100% of the first $20 million of U.S. commercial expenses, whether third-party costs or employee-related expenses, as opposed to the 50% for which they would otherwise be responsible. The costs that they bear on our behalf (up to $10 million) as a result of this launch allowance is non-refundable; however, in the event the product is approved for sale in the U.S., Takeda is entitled to deduct up to 8% of net sales from the profit share each period until they have recouped an amount equal to $11 million. As a result of the potential reductions in profit sharing post-launch stemming from the launch allowance, we have reflected amounts we receive under the terms of

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the launch allowance as a liability on our condensed balance sheets. As of September 30, 2011, we have received $2.8 million of benefit as a result of the launch allowance, which is reflected in the caption Advance from Takeda in the condensed balance sheets. In the event our product is ultimately approved, we would expect to recognize the amounts being deferred as collaboration revenue as Takeda takes deductions from net sales in recoupment of the launch allowance.

Under the June 2006 agreement, Takeda paid us an upfront license fee of $105 million, and we have received milestone payments upon completion of database lock of the Phase 3 clinical trials of $30 million for dialysis and non-dialysis. In addition, we earned a $10 million milestone in July 2011, as a result of the FDA acceptance for review of our NDA, which was deemed to be at risk and recognized immediately upon achievement of the milestone. Further, upon the successful achievement of clinical development and regulatory milestones, we are eligible to receive from Takeda an additional aggregate of $75 million relating to the renal program, including a $50 million milestone payment upon approval by the FDA in the dialysis indication. We and Takeda will share equally in the net profits and losses of peginesatide in the U.S., which include expenses related to the marketing and launch of peginesatide.

The Arrangement establishes a joint steering committee to oversee the development, regulatory approval and commercialization of peginesatide. We share responsibility with Takeda for clinical development activities required for U.S. regulatory approval of peginesatide. Specifically, we have primary responsibility for peginesatide s clinical development plan and clinical trials in the dialysis indication, and the non-dialysis indication to the extent of any further development, while Takeda has primary responsibility in the chemotherapy induced anemia and anemia of cancer indications to the extent any such indication is developed. We and Takeda have agreed to suspend the development of peginesatide to treat chemotherapy-induced anemia as well as anemia in chronic kidney disease patients not on dialysis and to focus all development efforts for peginesatide in the U.S. on the treatment of chronic kidney disease anemia in dialysis patients. We are responsible for U.S. regulatory filings in the dialysis and any other indications we pursue, including holding the NDAs for those indications. Takeda is responsible for regulatory filings outside the U.S. and the creation of a global safety database.

Takeda will have primary responsibility and bear all costs for peginesatide clinical development in support of regulatory approval and commercialization activities for all territories outside the U.S either directly or through sublicensees and will pay us a variable royalty based on annual net sales of peginesatide outside the U.S.

We are also responsible for the manufacture and supply of all quantities of API to be used in the development and commercialization of peginesatide worldwide. Takeda is responsible for the fill and finish steps in the manufacture of peginesatide worldwide.

We and Takeda will jointly develop the initial commercial marketing plan for peginesatide in the U.S. pursuant to which we and Takeda will divide peginesatide promotional responsibilities in the U.S. We and Takeda will jointly decide on promotional responsibility for markets outside of these initial indications if any.

Under the February 2006 agreement, Takeda also obtained a right of first negotiation to certain backup products for peginesatide developed by us or our third party partners. Specifically, during the first 10 years of the agreement, if we or third party partners develop a product that advances to Phase 2 clinical trials and competes with peginesatide in the renal or oncology indications, we are obligated to offer to Takeda the right to develop and commercialize such product in Japan before offering the product opportunity in Japan to any other third party.

We recognized $13.2 million and $16.8 million of collaboration revenue in the quarters ended September 30, 2011 and 2010, respectively and $44.0 million and $105.8 million for the nine months ended September 30, 2011 and 2010, respectively. As of September 30, 2011, we have a net receivable balance from Takeda of $5.5 million that is reflected on the accompanying condensed balance sheet under the caption Receivable from Takeda.

In July 2011, as a result of the FDA acceptance of our NDA for review, we earned a $10 million milestone payment from Takeda which we recorded as collaboration revenue during the quarter ended September 30, 2011. Going forward, we expect collaboration revenue to be directly affected by milestone payments and expenses that are eligible for reimbursement from Takeda under the Arrangement in future periods. We do not expect to recognize

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any revenue related to commercial product sales under our Arrangement with Takeda, and do not expect to recognize any product profit sharing until after the product is approved by the FDA.

In November 2011, as contemplated under our Arrangement, we and Takeda executed a Commercial API Supply Agreement which formalizes our respective responsibilities as it relates to the manufacture of peginesatide API by Affymax and the purchase of that API by Takeda for commercial manufacturing and sales of the product. Under the terms of the Commercial API Supply Agreement, Takeda has agreed to pay an aggregate of $10.8 million in deposits against API shipments of existing inventory to be delivered by Affymax to Takeda, $7.2 million of which is payable in the fourth quarter of 2011.

In November 2011, concurrent with the execution of the Settlement Agreement, we and Takeda entered into an amendment to the Arrangement in connection with the above settlement payments to J&J, pursuant to which Takeda will reimburse us up to 50% of upfront and milestone payments to J&J or $6.5 million in total contingent upon the accomplishment of certain milestones related to peginesatide regulatory approvals and commercial events.

9. Public Stock Offering

In March 2011, we completed the issuance and sale to the public of an aggregate of 9,745,762 shares of our common stock, par value $0.001 per share at $5.90 per share. We received net proceeds of approximately $53.6 million, after deducting underwriting discounts and commissions and offering expenses.

10. Restructuring Charge

As a result of the May 2010 amendment to our operating lease, we took possession of approximately 16,000 square feet of additional office space adjacent to our corporate headquarters in Palo Alto, California in May 2011. During the quarter ended June 30, 2011, management concluded that we would not occupy this additional office space, and we are actively seeking to sublease this space. Given these plans and the fact that this space is adequately separable from our existing facilities, in the second quarter of 2011 we recorded a restructuring charge of $659,000, which represents the present value of the estimated future facility costs for which we will obtain no future economic benefit over the term of our lease, net of estimated future sublease income. The initial $659,000 charge, as well as $16,000 of accretion was recorded during the quarter ended June 30, 2011 in general and administrative or G&A expenses in the condensed statement of operations.

The estimates underlying the fair value of the lease-related restructuring liability involve significant assumptions regarding the time required to contract with a subtenant, the amount of space we may be able to sublease, the range of potential future sublease rates and the level of leasehold improvements expenditures that we may incur to sublease the property. We have evaluated a number of potential sublease scenarios with differing assumptions and have probability weighted these scenarios and calculated the present value of cash flows based on management s judgment. We will continue to monitor and update the liability balance when future events impact our cash flow estimates related to this excess space.

In August 2011, we initiated a restructuring plan to lower annual operating expenses that included a planned reduction in force of 22 positions. As a result, we recorded a restructuring charge in the quarter ended September 30, 2011 of $698,000 related to severance and benefits, of which $655,000 was reflected as R&D expense and $43,000 as G&A expense in the condensed statement of operations.

The following table summarizes the accrual balance and utilization by type for the restructuring (in thousands):

	Facilities Related	Employee Related	Total
Balance as of June 30, 2011	$ 569	$	$ 569
Restructuring charges accrued		698	698
Cash payments	(163)	(475)	(638)
Accretion	20		20
Balance at September 30, 2011	426	223	649
Less Current Portion	265	223	488
Long-term portion as of September 30, 2011	$ 161	$	$ 161

The current portion of the total restructuring accrual balance is included in the caption Accrued liabilities and the non-current portion is included in the caption Other long-term liabilities in the condensed balance sheets.

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

You should read the following discussion and analysis by our management of our financial condition and results of operations in conjunction with our audited financial statements and related notes thereto included as part of our Annual Report on Form 10-K for the year ended December 31, 2010 and our unaudited condensed financial statements for the nine month period ended September 30, 2011.

Forward-Looking Statements

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, which are subject to the safe harbor created by those sections. Forward-looking statements are based on our management s beliefs and assumptions and on information currently available to our management. In some cases, you can identify forward-looking statements by terms such as may, will, should, could, would, expect, intend , plan, anticipate, believe, estimate, project, predict, potential and similar expressions intended to identify forward-looking statements. These forward-looking statements include, but are not limited to, statements regarding the timing, design and results of our clinical trials and drug development program and registration strategy, our ability to obtain and maintain regulatory approval of peginesatide (Hematide) and any other product candidates we pursue, the continuation and success of our collaboration with Takeda Pharmaceutical Company Limited, or Takeda, collaboration revenue and payment streams during the commercialization period, including reimbursements of third party commercialization expenses, under our agreements with Takeda, the timing and likelihood of the commercialization of peginesatide and the size and potential of the commercial opportunity. These statements involve known and unknown risks, uncertainties and other factors, which may cause our actual results, performance, time frames or achievements to be materially different from any future results, performance, time frames or achievements expressed or implied by the forward-looking statements. We discuss many of these risks, uncertainties and other factors in this Quarterly Report on Form 10-Q under Item 1A Risk Factors, including risks relating to the approvability and comprehensiveness of the new drug application, risks relating to timing of and regulatory requirements for approvals, including the U.S. Food and Drug Administration s, or FDA s, interpretation and evaluation of the data from the Phase 3 studies of peginesatide, in particular with respect to the secondary analyses in the non-dialysis population, risks relating to data quality and integrity particularly in non-inferiority designed trials, risks related to the continued safety and efficacy of peginesatide in clinical development, the potential for once per month dosing and room temperature stability, the timing of patient accrual in ongoing and planned clinical trials, regulatory requirements and approvals, research and development efforts, the factors affecting the commercial potential of peginesatide, industry and competitive environment, controversy surrounding the class of erythropoiesis stimulating agents, reimbursement coverage, intellectual property rights and disputes and potential costs, disruptions and consequences of litigation, financing requirements and ability to access capital, and other matters. Given these risks, uncertainties and other factors, you should not place undue reliance on these forward-looking statements. Also, these forward-looking statements represent our estimates and assumptions only as of the date of this filing. You should read this Quarterly Report on Form 10-Q completely and with the understanding that our actual future results may be materially different from what we expect. We hereby qualify our forward-looking statements by these cautionary statements. Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

Overview

We are a biopharmaceutical company committed to developing novel drugs to improve the treatment of serious and often life-threatening conditions. The New Drug Application, or NDA, for our product candidate, peginesatide for treatment of adult dialysis patients with anemia associated with chronic kidney disease is currently under review by the FDA. Anemia is a serious condition in which blood is deficient in red blood cells and hemoglobin. It is common in patients with chronic kidney disease, cancer, heart failure, inflammatory diseases and other critical illnesses, as well as in the elderly. If left untreated, anemia may lead to chronic fatigue or increase the risk of other diseases or death. Currently

recombinant EPO, or rEPO, is used to manage the anemia of dialysis, non-dialysis and

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cancer patients. Peginesatide is a synthetic peptide-based erythropoiesis stimulating agent, or ESA, designed to stimulate production of red blood cells. Peginesatide is designed to be longer acting than currently marketed ESAs in the U.S. and therefore has the potential to offer reduced cost and complexity for healthcare providers.

In late June 2010, we announced preliminary top-line results from our peginesatide Phase 3 clinical program for the treatment of patients with anemia associated with chronic kidney disease. Our Phase 3 clinical program included four open-label, randomized controlled clinical trials. Of these trials, two trials, called PEARL 1 and PEARL 2, were conducted in non-dialysis patients and designed to evaluate the safety and efficacy of peginesatide compared to darbepoetin alfa to correct anemia and maintain hemoglobin in a corrected range over time. The other two trials, called EMERALD 1 and EMERALD 2, were conducted in dialysis patients and designed to evaluate the safety and efficacy of peginesatide and its ability to maintain hemoglobin levels in a corrected range compared to epoetin alpha or epoetin beta when switched to peginesatide. Analysis of efficacy and safety for all of the Phase 3 studies were based on primarily assessments of non-inferiority to the comparator drugs. The primary efficacy endpoint, the mean change in hemoglobin from baseline, in each of the four Phase 3 studies met the statistical criteria for non-inferiority. In addition, peginesatide met the statistical criterion for non-inferiority for the assessment of safety for the cardiovascular composite safety endpoint, or CSE, which was composed of death, stroke, myocardial infarction, congestive heart failure, unstable angina and arrhythmia from a pooled safety database across the four Phase 3 studies. However, some differences were observed when secondary analyses were conducted as previously described in our Current Report on Form 8-K dated June 21, 2010.

In October 2010, we met with the FDA to discuss the regulatory path for peginesatide based on the initial analysis of the Phase 3 data. Based on these discussions with the FDA, we submitted a NDA, to the FDA, for treatment of anemia in chronic kidney disease patients on dialysis in May 2011. In July 2011, the FDA accepted our submission and filed the NDA for review, with an action date of March 27, 2012 under the Prescription Drug User Fee Act.

Despite meeting the primary efficacy endpoints and the CSE for peginesatide, the differences observed in the Phase 3 secondary analyses present risks to our ability to obtain regulatory approval for peginesatide particularly in view of the heightened concerns surrounding safety of ESAs. Any negative perception of peginesatide s safety relative to other ESAs would significantly reduce the likelihood of obtaining regulatory approval for peginesatide. The issues arising from the Phase 3 results have caused significant delay and may continue to negatively impact the timelines for development and the likelihood, scope or conditions surrounding regulatory approval. Any or all of these factors may significantly reduce the ultimate commercial potential of peginesatide.

Effective January 31, 2011, our former Chief Executive Officer, Arlene M. Morris, resigned from her position as well as from our board of directors. As part of her separation agreement, Ms. Morris was obligated to provide consulting services through September 30, 2011. Under the terms of her severance arrangement, she received severance benefits in the form of cash, reimbursement of COBRA premiums, continued vesting of existing stock-based awards until September 30, 2011, and additional time to exercise vested stock-based awards after September 30, 2011. We recorded $935,000 of expense in the quarter ended March 31, 2011 related to the severance and consulting arrangement with Ms. Morris. Given the nature of the consulting arrangement, all costs were accrued and expensed in the quarter ended March 31, 2011.

In March 2011, we sold an aggregate of 9,745,762 shares of our common stock to the public at $5.90 per share. We received net proceeds of approximately $53.6 million, after deducting underwriting discounts and commissions and offering expenses.

To date, we have not generated any product revenue. We have funded our operations primarily through the sale of equity securities, reimbursement for development expenses and active pharmaceutical ingredient, or API, production, license fees and milestone payments from

collaborative partners, operating and capital lease financings, interest earned on investments and limited license fees and royalties from licensing intellectual property. As of September 30, 2011, we had an accumulated deficit of $420.9 million. Due to the recognition of revenues from milestone payments from our collaboration with Takeda, or the Arrangement, we were profitable in the three and six months ended June 30, 2010 and may have profitable quarters from time to time if we are successful in obtaining FDA approval for peginesatide. We continue to expect to incur substantial losses in order to complete the development and commercialization of peginesatide.

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We believe that our existing cash, cash equivalents and investments together with the interest thereon will enable us to maintain our currently planned operations for at least the next 12 months. However, further challenges or delays to approval and commercialization of peginesatide may require us to raise additional funding to complete the development and commercialization of peginesatide. Since the announcement of our Phase 3 data in late June 2010 and the arbitration decision in October 2010, we have experienced a severe decline in our stock price, which has impaired our ability to access capital on potentially favorable terms. In contrast, our funding needs have only increased as the peginesatide development program has suffered delays, the potential loss of milestone payments from Takeda associated with the non-dialysis indication and the potential for future legal proceedings and costs. There can be no assurance we can raise the additional funds to support our continuing operations and maintain current regulatory timelines, and funding may not be available to us on acceptable terms, or at all. Our failure to raise capital if and when needed may harm our business and operating results.

Critical Accounting Policies and Significant Judgments and Estimates

Our management s discussion and analysis of our financial condition and results of operations is based on our condensed financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles, or GAAP. The preparation of these condensed financial statements requires us to make estimates, assumptions and judgments that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenues and expenses during the reporting periods. On an ongoing basis, we evaluate our estimates and judgments related to revenue recognition and clinical development costs. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Our critical accounting policies and the use of estimates are consistent with those noted in our Annual Report on Form 10-K for the year ended December 31, 2010 except as noted below:

Revenue recognition

Collaboration Revenue

We recognize revenue in accordance with the Securities and Exchange Commission, or SEC, Staff Bulletin No. 101, *Revenue Recognition in Financial Statement*s, as amended by Staff Accounting Bulletin No. 104, *Revision of Topic 13* and Accounting Standards Codification 605-25, *Multiple Element Arrangements*. When evaluating multiple element arrangements, we consider whether the components of the arrangement represent separate units of accounting as defined in the authoritative guidance for revenue arrangements with multiple deliverables. Application of this guidance requires subjective determinations and requires management to make judgments about the fair value of the individual elements and whether such elements are separable from the other aspects of the contractual relationship.

On January 1, 2011, we adopted Accounting Standards Update, or ASU, No. 2009-13, *Multiple Deliverable Revenue Arrangements*. This update amends the guidance on accounting for arrangements with multiple deliverables to require that each deliverable be evaluated to determine whether it qualifies as a separate unit of accounting. This determination is generally based on whether the deliverable has stand-alone value to the customer. This update also establishes a selling price hierarchy for determining how to allocate arrangement consideration to identified units

of accounting. The selling price used for each unit of accounting will be based on vendor-specific objective evidence, or VSOE, if available, third-party evidence if VSOE is not available, or estimated selling price if neither VSOE nor third-party evidence is available. We may be required to exercise considerable judgment in determining whether a deliverable is a separate unit of accounting and the estimated selling price of identified units of accounting for new agreements. The adoption of ASU No.2009-13 did not impact our financial position or results of operations as of and for the nine month period ended September 30, 2011. The potential future impact of the adoption of this update will depend on the nature of any new arrangements or material modifications of existing arrangements that we enter into in the future.

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During the development period under the Arrangement, which ended in May 2011 upon submission of our NDA to the FDA, we recognized collaboration revenue using Contingency Adjusted Performance Model, or CAPM. Under CAPM, revenue is eligible for recognition in the period the payment is earned under the Arrangement including amounts that are either received or due from Takeda. Revenue initially recognized is based on the percentage of time elapsed from inception of the Arrangement in June 2006 to the period in which the payment is earned in relation to the total projected development period. The remaining portion of the payment is then recognized on a straight-line basis over the remaining estimated duration of the development period of the Arrangement. Payments during the development period included amounts due for upfront license fees, milestone payments earned, purchases of API and reimbursement of development expenses. In exchange for these payments, we continued to actively develop our compound for the treatment of anemia for chronic kidney disease through the end of the development period which occurred upon our submission of our NDA,

Beginning in June 2011, we have moved into the commercialization period as defined under our Arrangement with Takeda. Per the Arrangement, this includes all activities undertaken before and after regulatory approval relating specifically to pre-marketing, launch, promotions, marketing, sale and distribution of peginesatide. Prior to approval of the product and commencement of profit sharing payments, our primary source of revenue during the commercialization period will likely consists of reimbursement of ongoing development efforts related to regulatory activities for FDA approval of peginesatide and commercial activities in preparation of the launch of our product. The Arrangement provides us with multiple payment streams, including reimbursement of third party development and commercialization expenses, reimbursement of expenses for full-time employee equivalent or FTE services related to commercialization (which commenced on July 1, 2011) and the potential to earn at risk milestone payments upon achievement of contractual criteria. During the commercialization period, our obligations include ongoing regulatory work to obtain FDA approval and commercial efforts related to our product launch.

Where there are multiple deliverables combined as a single unit of accounting, revenues are deferred and recognized over the period that we remain obligated to perform services. The specific methodology for the recognition of the revenue (e.g., straight-line or according to specific performance criteria) is determined on a case-by-case basis according to the facts and circumstances applicable in the Arrangement.

During the commercialization period of the Arrangement, for each source of collaboration revenue, we apply the following revenue recognition criteria:

- Revenues related to reimbursements by Takeda of third-party development expenses (70/30 split per the Arrangement) and commercial expenses (shared equally 50/50 per the Arrangement) are recognized as revenue, in the period incurred.

- Revenues related to reimbursement of costs of FTEs engaged in commercial activities are recognized as revenue in the period incurred. Such reimbursement is based on contractually negotiated reimbursement rates for each FTE as specified in the Arrangement.

- Revenue resulting from a milestone payment that is contingent upon the achievement of a substantive scientific or regulatory event or milestone is recognized in its entirety in the period in which the milestone is achieved and collectability is assured. A milestone is an event (i) that can only be achieved based in whole or in part on either our performance or on the occurrence of a specific outcome resulting from our performance, (ii) for which there is substantive uncertainty at the date the Arrangement is entered into that the event will be achieved and (iii) results in additional payments being due to us. Milestones are considered substantive when the consideration earned from the achievement of the milestone (i) is commensurate with either our performance to achieve the milestone or the enhancement of value of the item delivered as a result of a specific outcome resulting from our performance; (ii) relates solely to past performance and (iii) is reasonable relative to all deliverable and payment terms in the Arrangement.

- Other payments received, such as payments due under the launch allowance (see Note 8 in the Notes to Condensed Financial Statements), for which such payments are contingent solely upon future events are recognized as revenue when earned in accordance with the contract terms and when such payments can be reasonably estimated and collectability is reasonably assured.

We account for milestones under ASU 2010-17, *Milestone Method of Revenue Recognition*. Under the milestone method, contingent consideration received from the achievement of a substantive milestone is recognized in its entirety in the period in which the milestone is achieved, which we believe is more consistent with the substance of our performance under our collaboration agreement. A milestone is defined as an event (i) that can only be achieved based in whole or in part on either the entity s performance or on the occurrence of a specific outcome resulting from the entity s performance, (ii) for which there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved, and (iii) that would result in additional payments being due to the entity. A milestone is substantive if the consideration earned from the achievement of the milestone is consistent with our performance required to achieve the milestone or the increase in value to the collaboration resulting from our performance, relates solely to our past performance, and is reasonable relative to all of the other deliverables and payments within the arrangement.

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Clinical Trial Expense and Accruals

We record expense for estimated clinical study external costs, which until 2011, were a significant component of research and development, or R&D, expense. These clinical trial costs were $(1.1) million and $3.1 million during the three months ended September 30, 2011 and 2010, respectively, and $0.3 million and $26.3 million for the nine months ended September 30, 2011 and 2010, respectively. Clinical trials are administered by clinical research organizations, or CROs. CROs typically perform most of the total start-up activities for the trials, including document preparation, site identification pre-study visits, training as well as on-going program management. For the Phase 3 studies, which represented the vast majority of the clinical trial expense, the expense recorded is based on reporting received from CROs and internal analyses. We accrue costs for work performed by CROs based on the achievement of contracted activities during the period. Expense for investigator fees, which include patient costs, is based on internal estimates of activities using patient enrollment and contractual or estimated rates. For the Phase 2 studies, the expense is activities-based such as patient monitoring as reported by the CROs and achievement of milestones. Other costs such as testing and drug materials are expensed as incurred. For all studies, CRO reporting is reviewed by us for appropriateness.

During Q3 2011 we have been working with our CROs on final close-out activities regarding site billings for investigator grants on our Phase 3 trials. We recently received notification from one of our CROs that they had completed their close-out work and they provided the final amounts due relating to work performed on our Phase 3 studies for which they were responsible. As a result of this new information, we recorded a change in estimate to decrease our clinical trial accruals for these trials. As a result, we reversed $1.4 million of clinical trial accrual in the third quarter of 2011. In addition, as a result of the conclusion of negotiations with our CROs on various billing disputes, we further reduced our clinical trial accrual by $0.7 million as the ultimate settlement was more favorable than our initial estimates. The aggregate change in estimate during the period decreased expense by $2.1 million for the three months ended September 30, 2011.

Additional changes in estimate or adjustments may result as the final trial close-out audits and fee negotiations are completed relating to our clinical trials which could impact R&D expense, collaboration revenues and amounts due to or from Takeda in subsequent periods.

Results of Operations

Revenue

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2011	2010	% Increase/ (Decrease)	2011	2010	% Increase/ (Decrease)
	($ amounts in thousands)					
Collaboration revenue	$ 13,204	$ 16,784	(21)%	$ 44,029	$ 105,771	(58)%
License and royalty revenue	5	6	(17)%	14	15	(7)%
Total revenue	$ 13,209	$ 16,790	(21)%	$ 44,043	$ 105,786	(58)%

We recognized $13.2 million and $16.8 million of collaboration revenue during the three months ended September 30, 2011 and 2010, respectively and $44.0 million and $105.8 million for the nine months ended September 30, 2011 and 2010, respectively. The decrease in collaboration revenue for the three and nine months ended September 30, 2011 compared to the three and nine months ended September 30, 2010 was due to a reduction in the amounts eligible for reimbursement under our collaboration arrangement with Takeda as we completed our

Phase 3 clinical trials in early 2010. In addition, we received a $5 million milestone payment from Takeda for the

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initiation of Japan s Phase 3 renal indication in March 2010 and $30 million in milestone payments for the database lock of our non-dialysis and dialysis Phase 3 trials in the second quarter of 2010. During the nine months ended September 30, 2011, we received a $10 million cash milestone payment from Takeda for acceptance for review of our NDA by the FDA in the third quarter of 2011. We expect collaboration revenue to be directly affected by milestone payments and expenses that are eligible for reimbursement from Takeda under the Arrangement in future periods.

Research and Development Expenses

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2011	2010	% Increase/ (Decrease)	2011	2010	% Increase/ (Decrease)
	($ amounts in thousands)					
Research and development expenses	$ 14,863	$ 21,118	(30)%	$ 51,606	$ 83,120	(38)%

Research and development, or R&D, expenses consist of: (i) expenses incurred under agreements with contract research organizations, or CROs, and investigative sites, which conduct a substantial portion of our pre-clinical studies and all of our clinical trials; (ii) payments to contract manufacturing organizations, which produce our API; (iii) payments to consultants; (iv) license fees paid to third parties for use of their intellectual property; (v) employee-related expenses, which include salaries and related costs; and (vi) facilities, depreciation and other allocated expenses, which include direct and allocated expenses for rent and maintenance of facilities and equipment, depreciation of leasehold improvements and equipment and laboratory and other supplies.

The decrease in research and development expenses for the three and nine months ended September 30, 2011 compared to the three and nine months ended September 30, 2010 was primarily due to a change in estimate of our clinical trial accrual and corresponding expense related to final close-out activities with one of our CROs as well as reduced CRO and investigative site costs as a result of the completion of the treatment and follow up of our Phase 3 clinical trials in early 2010. This was partially offset by $655,000 in employee-related restructuring costs recorded in the third quarter of 2011 related to a reduction in force.

General and Administrative Expenses

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2011	2010	% Increase/ (Decrease)	2011	2010	% Increase/ (Decrease)
	($ amounts in thousands)					
General and administrative expenses	$ 8,172	$ 7,781	5%	$ 24,426	$ 25,372	(4)%

General and administrative expenses consist principally of salaries and related costs for personnel in executive, finance, accounting, business development, information technology, legal and human resources functions as well as for personnel in our commercial and medical affairs departments. Other general and administrative expenses include facility costs not otherwise included in R&D expense, patent filing, prosecution and defense costs and professional fees for legal, consulting, auditing and tax services.

The increase in general and administrative expenses for the three months ended September 30, 2011 compared to the three months ended September 30, 2010 was due to higher commercial expenses related to expansion of our commercial capabilities. The decrease in general and administrative expenses for the nine months ended September 30, 2011 compared to the nine months ended September 30, 2010 was due to reductions in legal costs and consulting services partially offset by increased employee compensation costs, which occurred primarily as a result of costs associated with the resignation of our former Chief Executive Officer during the first quarter of 2011 and a facilities-related restructuring charge incurred of $659,000 in the second quarter of 2011 related to unoccupied office space.

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Interest Income (Expense), Net

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2011	2010	% Increase/ (Decrease)	2011	2010	% Increase/ (Decrease)
	($ amounts in thousands)					
Interest income (expense), net	$ 7	$ 12	(42)%	$ 25	$ 123	(80)%

The decrease in interest income (expense), net, was due primarily to lower interest rates and a lower average cash balance during the three and nine months ended September 30, 2011 compared to the same period in 2010.

Other Income (Expense), Net

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2011	2010	% Increase/ (Decrease)	2011	2010	% Increase/ (Decrease)
	($ amounts in thousands)					
Other income (expense), net	$ 3	$ 67	(96)%	$ 39	$ (1)	400%

The decrease in other income (expense), net was due primarily to a $61,000 foreign exchange gain during the three months ended September 30, 2010 compared to the same period in 2011. Other income, net, for the nine months ended September 30, 2011 includes a $26,000 gain on disposal of fixed assets. Other expense, net, for the nine months ended September 30, 2010 includes $95,000 of foreign currency loss partially offset by $0.1 million of realized gain on investments.

Provision for Income Taxes

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2011	2010	% Increase/ (Decrease)	2011	2010	% Increase/ (Decrease)
	($ amounts in thousands)					
Provision for income taxes	$	$	%	$ 1	$	*

* *Calculation is not meaningful*

We are subject to federal and California income taxes. We anticipate being in a net operating loss position for 2011 and therefore have not recorded any federal or California taxes, other than the minimum statutory California tax, for the three and nine months ended September 30, 2011. We also did not record any tax liability for the three and nine months ended September 30, 2010 due to the anticipated tax loss position for the year ended December 31, 2010.

Liquidity and Capital Resources

Our cash, cash equivalents, and investments at September 30, 2011 and December 31, 2010 were as follows (in thousands):

	September 30, 2011	December 31, 2010
	(in thousands)	
Cash and cash equivalents	$ 66,025	$ 63,499
Short-term investments	$ 49,222	$ 33,582
Long-term investments	$	$ 19,876

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	Nine Months Ended September 30,	
	2011	2010
	(in thousands)	
Cash provided by (used in):		
Operating activities	$ (55,388)	$ (25,609)
Investing activities	$ 3,486	$ (43,120)
Financing activities	$ 54,428	$ (6,322)
Capital expenditures (included in investing activities above)	$ (801)	$ (449)

Since our inception, we have financed our operations through sale of capital stock, license fees, milestone payments and reimbursement for development and commercial expenses and manufacturing costs from collaborative partners, operating and capital lease financing, interest earned on investments and limited license fees and royalties from licensing intellectual property. From inception through September 30, 2011, we have received net proceeds of $445.0 million from the issuance of equity securities, including $53.6 million in net proceeds from the sale of 9,745,762 shares of our common stock in a secondary public offering in March 2011. We have also received $122 million of upfront license fees, $55 million in milestone payments and $236.8 million for the reimbursement of development and commercial expenses and purchase of API from our Arrangement with Takeda. Takeda was responsible for the first $50 million of third party expenses related to the development in pursuit of U.S. regulatory approval of peginesatide, which was fully utilized through the first quarter of 2008. Thereafter, Takeda has borne 70% of the third party U.S. development expenses, while we have been responsible for 30% of such expenses. We retain responsibility for 100% of our internal development expenses, most notably employee-related expenses.

During the commercialization period, which commenced upon submission of our NDA to the FDA, Takeda will continue to bear responsibility for 70% of all third-party expenses related to U.S. development and 50% of all third party expenses related to the commercialization of peginesatide in the U.S. However, during the commercialization period, certain internal employee-related expenses supporting preparation for commercialization of peginesatide in the U.S. are also shared equally. By mutual agreement of the parties, the equal sharing of certain FTE expenses commenced July 1, 2011.

Per the terms of the Arrangement, we are also entitled to a launch allowance to help fund the initial costs associated with preparing to launch the product in the U.S. Under the terms of the launch allowance, Takeda is responsible for 100% of the first $20 million of U.S. commercial expenses, whether third-party costs or employee-related expenses, as opposed to the 50% for which they would otherwise be responsible. The costs that they bear on our behalf (up to $10 million) as a result of this launch allowance is non-refundable; however, in the event the product is approved for sale in the U.S., Takeda is entitled to deduct up to 8% of net sales from the profit share each period until they have recouped an amount equal to $11 million. As a result of the potential reductions in profit sharing post-launch stemming from the launch allowance, we have reflected amounts we receive under the terms of the launch allowance as a liability on our condensed balance sheets. As of September 30, 2011, we have received $2.8 million of benefit as a result of the launch allowance, which is reflected in the caption Advance from Takeda in the condensed balance sheets. In the event our product is approved, Takeda will take deductions related to the launch allowance against net sales and we will recognize those amounts as collaboration revenue.

In November 2011, as contemplated under our Arrangement, we and Takeda executed a Commercial API Supply Agreement which formalizes our respective responsibilities as it relates to the manufacture of peginesatide API by Affymax and the purchase of that API by Takeda for commercial manufacturing and sales of the product. Under the terms of the Commercial API Supply Agreement, Takeda has agreed to pay an aggregate of $10.8 million in deposits against API shipments of existing inventory to be delivered by Affymax to Takeda, $7.2 million of which is payable in the fourth quarter of 2011.

In November 2011, we entered into a settlement agreement with J&J, which requires us to pay to J&J $6 million within 30 days of execution thereof, $2 million by June 30, 2012, a $2.5 million milestone payment upon FDA regulatory approval of peginesatide, and a $2.5 million

milestone payment upon regulatory approval of peginesatide in the first major European country. In addition, we pay royalties to J&J on sales of peginesatide in Europe, Japan and certain other countries outside of the United States until mid-2016. Concurrent with the execution of the Settlement Agreement, we and Takeda entered into an amendment to the Arrangement in connection with the above settlement payments to J&J, pursuant to which Takeda will reimburse us up to 50% of upfront and milestone payments to J&J or $6.5 million in total contingent upon the accomplishment of certain milestones related to peginesatide regulatory approvals and commercial events. We are solely responsible for the royalty payment to J&J.

Net cash used in operating activities for the nine months ended September 30, 2011 was primarily the result of our net loss generated primarily by the development of peginesatide and payments to Takeda related to our outstanding payable as well as payments to third party vendors related to our accrued clinical trial expenses and accrued liabilities. The impact of this loss was reduced in part by non-cash activities including stock-based compensation and depreciation. The $29.8 million decrease in cash used in operating activities in the nine months

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ended September 30, 2011 as compared to the same period in 2010 was primarily due to a $5 million cash milestone payment received from Takeda for the initiation of Japan s Phase 3 renal indication and $30 million of milestone payments for the database lock of non-dialysis and dialysis Phase 3 clinical trials in the nine months ended September 30, 2010. This was partially offset by a $10 million cash milestone payment received from Takeda related to the FDA acceptance of our NDA submission for review in the nine months ended September 30, 2011. Due to the recognition of revenue from these milestone payments in 2010, we were profitable in the six months ended June 30, 2010, but we expect to incur substantial losses in order to complete the development and commercialization of peginesatide. Under our Arrangement with Takeda, we are eligible to receive additional clinical development and regulatory milestones of approximately $108 million relating to the dialysis indication, including a $50 million milestone payment upon approval by the FDA in the dialysis indication.

Net cash provided by investing activities for the nine months ended September 30, 2011 was primarily a result of the maturities of investments offset by purchases of investments. Net cash used in investing activities for the nine months ended September 30, 2010 was a result of the purchase of investments partially offset by maturities and sales of investments.

Net cash provided by financing activities for the nine months ended September 30, 2011 was primarily attributable to net proceeds of $53.6 million received from our March 2011 public offering and proceeds received from the issuance of common stock upon exercise of stock options. Net cash used in financing activities for the nine months ended September 30, 2010 was primarily attributable to repayment of $9.2 million towards our loan from UBS AG offset by the proceeds of $2.9 million from issuance of common stock upon exercise of stock options and our employee stock purchase plan.

We have an equity line of credit arrangement with Azimuth Opportunity, Ltd, or Azimuth, which provides that upon the terms and subject to the conditions set forth in the purchase agreement, as amended, or the Common Stock Purchase Agreement, Azimuth is committed to purchase up to $60.0 million worth of shares of our common stock over the term of the equity facility, due to expire in September 2012.

In October 2010, we closed on the sale of 999,061 shares of common stock to Azimuth under the Common Stock Purchase Agreement for an aggregate purchase price of $5.0 million. Our net proceeds from the sale of these shares were $4.9 million after deducting offering expenses.

Our equity facility is subject to a number of conditions that limit our ability to draw against such facility. For example, Azimuth is not required to purchase our common stock when the price of our common stock is below $4.00 per share. In addition, Azimuth is not obligated to purchase shares of our common stock which, when aggregated with all other shares of our common stock then owned beneficially by Azimuth, would result in the beneficial ownership by Azimuth of more than 9.9% of the then issued and outstanding shares of our common stock. At September 30, 2011, this represents 3,528,947 shares. After deducting the shares purchased in October 2010, assuming that all remaining 2,529,886 shares were sold at the $4.48 closing price of our common stock at September 30, 2011 at the largest possible discount and assuming that Azimuth still owns these shares, the maximum aggregate net proceeds we could receive under the agreement with Azimuth would be approximately $10.6 million.

The issuance of shares of our common stock in our March 2011 public offering resulted in an ownership change, under Section 382 of the Internal Revenue Code of 1986, as amended which, in general, provides that an ownership change occurs if the aggregate stock ownership of certain stockholders increases by more than 50 percentage points during the testing period (generally three years). Under Section 382, a corporation that undergoes an ownership change may be subject to limitations on its ability to utilize its net operating losses, or NOLs, and tax credits accumulated prior to the ownership change to offset future taxable income or tax liabilities. Based on our preliminary analysis, we believe that we did incur an ownership change as defined by the Internal Revenue Code. We are currently in the process of assessing whether the resulting annual limitations on the use of our NOLs will result in an impairment to some portion of the NOLs in place at the time of the

offering.

As of September 30, 2011, we had $116.4 million in cash, cash equivalents, restricted cash and investments. Our cash and investment balances are held in a variety of interest bearing instruments, including obligations of U.S. government agencies, certificates of deposit, and money market funds. Cash in excess of immediate

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requirements is invested in accordance with our investment policy primarily with a view to liquidity and capital preservation.

We believe that our existing cash, cash equivalents and investments together with the interest thereon will enable us to maintain our currently planned operations for at least the next 12 months. However, further challenges or delays to approval and commercialization of peginesatide may require us to raise additional funding to complete the development and commercialization of peginesatide. Since the announcement of our Phase 3 clinical data in late June 2010 and the arbitration decision in October 2010, we have experienced a severe decline in our stock price, which has impaired our ability to access capital on potentially favorable terms. In contrast, our funding needs have only increased as the peginesatide development program has suffered delays, the potential loss of milestone payments from Takeda associated with the non-dialysis indication and the potential for future legal proceedings and costs.

Our current view of the worldwide capital markets is that they are extremely volatile with limited accessibility, and many biotechnology companies have been limited or unsuccessful in obtaining funding in this environment. We intend to evaluate the capital markets from time to time to determine whether to raise additional capital, in the form of equity or otherwise, depending upon market conditions relative to our need for funds at such time. Continuation of this market may significantly limit our ability to raise funds such that there can be no assurance we can raise the additional funds to support our continuing operations and maintain current development timelines, and funding may not be available to us on acceptable terms, or at all. Further, we have had to reduce our research capabilities and efforts, including the elimination of certain research programs, and even some activities related to the support of peginesatide. If we are unable to raise additional funds when needed, we could be required to further delay, scale back or eliminate some or all of our development programs and other operations. We may seek to raise additional funds through public or private financing, strategic partnerships or other arrangements. Any additional equity financing would be dilutive to stockholders and debt financing, if available, may involve restrictive covenants. Further, any strategic or licensing arrangements, if available, may require us to relinquish product rights that we would otherwise seek to develop or commercialize ourselves. Our failure to raise capital when needed may harm our business and operating results.

Our future capital requirements will depend on many forward looking factors and are not limited to the following:

- the progress, timing and completion of clinical development for peginesatide;
- our ability to fulfill our obligations under our collaboration agreements with Takeda and to achieve the milestones contained therein;
- costs related to litigation;
- outcome, timing and cost of regulatory approvals;
- delays that may be caused by changing regulatory requirements;

- the number of drug candidates that we pursue;

- the costs involved in filing and prosecuting patent applications and enforcing and defending patent claims;

- timing and terms of future in-licensing and out-licensing transactions;

- the cost and timing of establishing our commercial infrastructure including sales, marketing and distribution capabilities;

- cost of procuring clinical and commercial supplies of peginesatide and future product candidates, if any; and

- the extent to which we acquire or invest in businesses, products or technologies, although we currently have no commitments or agreements relating to any of these types of transactions.

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Contractual Obligations and Significant Commitments

There were no material changes in our contractual obligations in the nine months ended September 30, 2011 from those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2010. Please see Item 7 *Management s Discussion and Analysis of Financial Condition and Results of Operations Contractual Obligations and Significant Commitments* in our Form 10-K for a description of contractual obligations as of December 31, 2010.

Recent Accounting Pronouncements

In June 2011, the Financial Accounting Standards Board, or FASB, issued ASU No. 2011-05, which is an update to Topic 220, presentation of comprehensive income. This update amends current comprehensive income guidance and eliminates the option of presenting the components of other comprehensive income as part of the statement of stockholders equity. This update presents an entity with the option to present the total of comprehensive income, the components of net income, and the components of other comprehensive income either in a single continuous statement of comprehensive income or in two separate but consecutive statements. In both choices, an entity is required to present each component of net income along with total net income, each component of other comprehensive income along with a total for other comprehensive income, and a total amount for comprehensive income. The amendments in this update do not change the items that must be reported in other comprehensive income or when an item of other comprehensive income must be reclassified to net income. The new guidance was originally proposed to be effective for fiscal years, and interim periods within those years, beginning after December 15, 2011 and applied retrospectively. In October 2011, the FASB proposed to defer the effective date of certain provisions in the guidance related to the presentation of reclassification adjustments. No effective date has been announced. As ASU No. 2011-05 relates only to the presentation of comprehensive income, we do not expect that the adoption of this update will have a material effect on our financial statements.

In May 2011, the FASB issued ASU No. 2011-04, which is an update to Topic 820, fair value measurement. This update establishes common requirements for measuring fair value and related disclosures in accordance with GAAP and international financial reporting standards. This amendment did not require additional fair value measurements. ASU No. 2011-04 is effective for all interim and annual reporting periods beginning after December 15, 2011. We do not believe there will be a significant impact on our financial statements from the adoption of ASU No. 2011-04

Item 3. Quantitative and Qualitative Disclosure About Market Risk

Interest Rate Risk

Our exposure to market risk is confined to our cash, cash equivalents and investments. We do not use derivative financial instruments in our investment portfolio. The goals of our investment policy are preservation of capital, fulfillment of liquidity needs and fiduciary control of cash and investments. We also seek to maximize income from our investments without assuming significant risk. To achieve our goals, we maintain a portfolio of cash equivalents and investments in a variety of securities of high credit quality. The securities in our investment portfolio are not leveraged, are classified as available for sale and are subject to minimal interest rate risk. We currently do not hedge interest rate exposure. We do not believe that a decrease in interest rates would have a material negative impact on the value of our investment portfolio. During the nine months ended September 30, 2011, there were no material changes to our interest rate disclosures as set forth in Part II, Item 7A, *Quantitative*

and Qualitative Disclosure About Market Risk, of our Annual Report on Form 10-K for the year ended December 31, 2010.

Foreign Exchange Risk

We have no investments denominated in foreign currencies, and therefore our investments are not subject to foreign currency exchange risk. At each quarter end, we may have liabilities for costs incurred by overseas suppliers of goods or services and clinical trial programs that are denominated in foreign currencies that are not hedged

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because of their relatively small size, uncertainty of payment date, and/or short time until settlement. An increase or decrease in exchange rates on these unhedged exposures may affect our operating results.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures. An evaluation was performed by our Chief Executive Officer and Chief Financial Officer of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act as of September 30, 2011. Disclosure controls and procedures are those controls and procedures designed to provide reasonable assurance that the information required to be disclosed in our Exchange Act filings is (1) recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission s rules and forms, and (2) accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of September 30, 2011, our disclosure controls and procedures were effective at the reasonable assurance level.

Limitations on the effectiveness of controls. Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our procedures or our internal controls will prevent or detect all errors and fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within an organization have been detected. We continue to implement, improve and refine our disclosure controls and procedures and our internal control over financial reporting.

Changes in Internal Control over Financial Reporting. There were no changes in our internal control over financial reporting during our quarter ended September 30, 2011 that have materially affected, or are reasonably likely to materially affect our internal control over financial reporting.

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PART II OTHER INFORMATION

Item 1. Legal Proceedings

In October 2010, the arbitration panel in our binding arbitration with certain subsidiaries of Johnson & Johnson Pharmaceutical Research &Development L.L.C and Ortho-McNeil Pharmaceutical, Inc., or J&J, decided the ownership of a number of U.S. and international patents and patent applications related to certain erythropoietin receptor, EPO-R, agonists, or collectively, the intellectual property in dispute. The decision maintained J&J s sole inventorship and sole ownership of U.S. Patent No. 5,767,078, or the 078 Patent, and certain related foreign patents and patent applications, including European Patent application EP96/918,317. The arbitrators determined that we and J&J jointly own the remainder of the intellectual property in dispute.

In November 2010, we filed in the U.S. District Court for the Northern District of Illinois, or District Court, a motion to vacate the arbitration award with respect to the ownership of the 078 Patent and related foreign cases. In December 2010, J&J filed its response and requested that the court confirm the arbitration award.

In March 2011, the District Court issued its decision to vacate in part the arbitrators award relating to sole ownership by J&J of the European Patent EP96/918,317 and other foreign counterpart patents and patent applications to the 078 Patent. As a consequence, the District Court remanded the issues of inventorship and ownership of such foreign patents and patent applications to the arbitration panel. The District Court denied our motion to vacate in part and maintained the arbitration award with respect to the sole ownership by J&J of the 078 Patent in the U.S. In May 2011, we filed a notice of appeal relating to the District Court s decision as to the 078 Patent in the U.S. which remains pending with the Court of Appeals for the Federal Circuit. Concurrently, J&J filed an appeal with the Seventh Circuit Court of Appeals, and in October 2011, the Seventh Circuit Court reversed the District Court with the result that it remanded with instruction to confirm the arbitration award in full and set forth its view that the Court of Appeals for the Federal Circuit lacked jurisdiction.

In November 2011, we entered into a Settlement Agreement with J&J under which we obtain a non-exclusive license to the intellectual property in dispute, a covenant not to sue and a release of all claims associated with the arbitration and dispute. The Settlement Agreement also provides for the dismissal of all pending proceedings.

From time to time, we are involved in legal proceedings arising in the ordinary course of business. We believe there is no other litigation pending that could have, individually or in the aggregate, a material adverse effect on our financial position, results of operations or cash flows.

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Item 1A. Risk Factors

You should carefully consider the risks described below, which we believe are the material risks of our business before making an investment decision. If any of these risks actually occurs, our business, financial condition, results of operations or cash flow could be seriously harmed. This could cause the trading price of our common stock to decline, resulting in a loss of all or part of your investment. In assessing these risks, you should also refer to the other information contained in this Quarterly Report on Form 10-Q, including our financial statements and related notes. The risks and uncertainties described below are not the only ones facing us. Additional risks and uncertainties not presently known to us, or that we currently see as immaterial, may also harm our business.

Risks Related to Our Business

We are dependent on the success of peginesatide (HematideTM). Peginesatide is a new chemical entity and currently our only product candidate. We cannot give any assurance the development program for peginesatide will be successful or completed in a timely or effective manner. Our previously announced Phase 3 results present challenges to our ability to obtain regulatory approval for peginesatide particularly in view of the heightened concerns surrounding safety of erythropoiesis stimulating agents, or ESAs. Our failure to demonstrate the safety and effectiveness of peginesatide to the satisfaction of the U.S. Food and Drug Administration, or FDA, will prevent us from receiving regulatory approval and would have a material and adverse impact on our business. Even if the FDA does ultimately approve our new drug application, or NDA, submission, the length of the review process may be longer than anticipated or the FDA may impose requirements, conditions and restrictions that could significantly increase costs or delay and limit our ability to successfully commercialize peginesatide or otherwise severely harm our business.

Peginesatide, an ESA, is a new chemical entity and currently our only product candidate. In order to commercialize peginesatide, we will be required to establish that peginesatide is sufficiently safe and effective to obtain regulatory approvals, which we may fail to do.

In late June 2010, we announced preliminary top-line results from the peginesatide Phase 3 clinical program for the treatment of patients with anemia associated with chronic kidney disease. Our Phase 3 clinical program included four open-label, randomized controlled clinical trials. Of these trials, two trials, called PEARL 1 and PEARL 2, were conducted in non-dialysis patients and designed to evaluate the safety and efficacy of peginesatide compared to darbepoetin alfa to correct anemia and maintain hemoglobin in a corrected range over time. The other two trials, called EMERALD 1 and EMERALD 2, were conducted in dialysis patients and designed to evaluate the safety and efficacy of peginesatide and its ability to maintain hemoglobin levels in a corrected range compared to epoetin alpha or epoetin beta when switched to peginesatide. Analysis of efficacy and safety for all of the Phase 3 studies were based primarily on assessments of non-inferiority to the comparator drugs. The primary efficacy endpoint, the mean change in hemoglobin from baseline, in each of the four Phase 3 studies met the statistical criteria for non-inferiority. In addition, peginesatide met the statistical criterion for non-inferiority for the assessment of safety for the cardiovascular composite safety endpoint, or CSE, which was composed of death, stroke, myocardial infarction, congestive heart failure, unstable angina and arrhythmia from a pooled safety database across the four Phase 3 studies. However, some differences were observed when secondary analyses were conducted, including a difference in a subgroup analysis conducted in the PEARL trials where the frequency of CSE events was higher in the peginesatide group relative to the comparator in these non-dialysis patients, as previously described in our Current Report on Form 8-K dated June 21, 2010 and in Part I, Item 1. *Business* of our Annual Report on Form 10-K for the year ended December 31, 2010.

The differences observed in the Phase 3 secondary analyses present risks to our ability to obtain regulatory approval for peginesatide particularly in view of the heightened concerns surrounding safety of ESAs. Based on our discussions with the FDA, we submitted an NDA for treatment of

anemia in chronic kidney disease patients on dialysis in May 2011. Although the NDA has been filed and accepted for review, any negative perception of peginesatide s safety relative to other ESAs would significantly limit the likelihood of obtaining regulatory approval for peginesatide. The issues arising from the Phase 3 results have caused significant delay and may continue to

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negatively impact the timelines for development and the likelihood, scope or conditions surrounding regulatory approval. Any or all of these factors may significantly reduce the ultimate commercial potential of peginesatide.

Regardless of whether peginesatide met the statistical criteria for non-inferiority to the comparator drugs, peginesatide could still fail to establish that it is sufficiently safe for regulatory approval for any indication. In addition to data from clinical trials, extensive data from pre-clinical studies, including carcinogenicity studies, has been submitted as part of the NDA. As peginesatide is the first ESA to undergo carcinogenicity studies, the regulatory requirements and standards for review remain uncertain and may increase the risk for regulatory approval. The results from earlier pre-clinical testing and prior clinical trials may not be predictive of results obtained in other pre-clinical models, later clinical trials or in a practice setting. In addition, the approval of our NDA may be delayed or fail for many reasons, including:

- safety issues, including serious adverse events associated with peginesatide, and concerns surrounding use of ESAs generally;

- difficulties arising from administration, data gathering and analysis of our large and complex Phase 3 clinical program for peginesatide, which involved numerous third parties, approximately 2,600 patients and over 300 sites in the U.S. and Europe, compliance with a variety of government regulations, and a number of significant new initiatives and processes for which we did not have any prior experience implementing, including the adjudication of cardiovascular events by an independent review committee;

- risks associated with non-inferiority trials, which are studies devised and statistically powered to show that the test drug is not inferior to the comparator drug;

- risks associated with data integrity and difficulty in obtaining complete and accurate data on a timely basis which may result from our large and complex Phase 3 trial design for a variety of other reasons, including shortage of resources, delays in data entry, inaccurate or inconsistent data entry, failure to follow the clinical trial protocols, inadequate monitoring or training of sites, inadequate oversight of third party clinical research organizations, or CROs, delays or failures to establish adequate procedures, remediations or corrective actions that regulatory agencies may not find sufficient, problems maintaining contact with patients after treatment or as a consequence of the open-label, non-inferiority design of the Phase 3 trials;

- suspension or termination of clinical trials for various reasons, including exposure of the participating patients to unacceptable health risks or noncompliance with regulatory requirements;

- manufacturing issues or failure to manufacture or obtain from third parties materials of sufficient quality;

- inadequate effectiveness or safety concerns arising from clinical trials or pre-clinical studies, including the carcinogenicity studies;

- the failure of patients to complete clinical trials due to death or the length of our clinical program, side effects, dissatisfaction with peginesatide or other reasons including adverse medical effects unrelated to treatment with peginesatide;

- our lack of experience as an organization in obtaining regulatory approvals;

- governmental or regulatory delays and changes in regulatory requirements, policy and guidelines; and

- varying interpretation of data by FDA and similar foreign regulatory agencies.

Further analysis, regulatory review or inspections or additional data may reveal further issues associated with the Phase 3 results. For example, negative imbalances in safety events, which could give rise to safety concerns whether or not they are statistically significant, or potential issues surrounding data quality, which may be of greater concern for non-inferiority designed trials, may negatively impact the ultimate acceptability of the data for regulatory approval. As noted in the FDA s March 2010 draft Guidance for Industry Non-inferiority Clinical Trials, there is a critical need for particular attention to study quality and conduct when planning and executing a non-inferiority study, as poor quality can sometimes lead to an apparent finding of non-inferiority that is incorrect. The FDA appears to be increasing its focus on clinical data quality which may delay or increase the risk of failure to

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obtain regulatory approval. For example, in late 2009, Basilea Pharmaceutica AG failed to obtain approval for ceftobiprole from the FDA as the agency cited unreliable or unverifiable data and inadequate monitoring on the part of sponsor Johnson & Johnson as the basis for the agency s decision. As the sponsor of the peginesatide clinical trials, the FDA holds us accountable for oversight of our clinical trials, including monitoring performed by our CROs. To the extent the FDA determines that we failed to properly oversee our clinical trials and the CROs, the FDA may find our Phase 3 results or other clinical data unreliable. Our failure to adequately demonstrate the safety and effectiveness of peginesatide or the integrity of the data will prevent us from receiving regulatory approval and will have a material adverse impact on our business.

Obtaining approval of a NDA by the FDA is highly uncertain and like many product candidates, we may fail to obtain approval even though our NDA for peginesatide has been filed and accepted for review. The NDA review process is extensive, lengthy, expensive and uncertain, and the FDA may delay action on the NDA significantly beyond the March 27, 2012 date assigned under the Prescription Drug User Fee Act, limit or deny approval of peginesatide for many reasons, including:

- we may not be able to demonstrate to the satisfaction of the FDA that peginesatide is safe and effective for any indication;

- the data arising from the clinical trials, including the Phase 3 results, the development program or the NDA for peginesatide may not be satisfactory to the FDA;

- the FDA may disagree with the number, design, size, conduct or implementation of our clinical trials or conclude that the data fails to meet statistical or clinical significance;

- the FDA may have difficulties approving a dosing regimen for peginesatide in view of the FDA s safety concerns surrounding hemoglobin variability, rates of rise and excursions with ESAs as a class;

- the FDA may not find the data from preclinical studies, including our carcinogenicity studies, and clinical studies sufficient to demonstrate that peginesatide s clinical and other benefits outweighs its safety risks;

- the FDA may disagree with our interpretation of data from preclinical studies or clinical trials;

- the FDA may not accept data generated at our clinical trial sites and monitored by third party CROs;

- the FDA may determine that we did not properly oversee third party CROs and our clinical trials;

- the FDA may have difficulties scheduling an advisory committee in a timely manner;

- an advisory committee, scheduled to review the NDA for peginesatide in December 2011, may recommend against approval of our application or may recommend that the FDA require, as a condition of approval, additional preclinical studies or clinical trials, limitations on approved labeling or distribution and use restrictions or even if an advisory committee makes a favorable recommendation, the FDA may still fail to approve peginesatide;

- the FDA may have difficulties approving a risk evaluation and mitigation strategy, or REMS, or labeling for peginesatide; and

- the FDA may identify deficiencies in our manufacturing processes, facilities or analytical methods or those of our third party contract manufacturers or Takeda.

The FDA may require us to conduct additional studies or trials which could result in our failure to ever bring peginesatide to market. Accordingly, we may not receive the regulatory approvals needed to market peginesatide. Any failure or delay in completion of the development program or the FDA review process would delay or foreclose commercialization of peginesatide and severely harm our business and financial condition.

We have relied and continue to rely on numerous third parties, particularly CROs, to conduct and complete our development program for peginesatide, and to the extent they fail to properly and successfully perform their obligations to us, we may not be able to obtain the necessary regulatory approvals for peginesatide.

Due to the size and limited experience of our organization, we have relied heavily on CROs, contractors and other third parties to assist us in managing, monitoring and otherwise conducting clinical trials. Our Phase 3 clinical

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program for peginesatide was large and complex and conducted at over 300 sites in the U.S. and Europe. Even though we have completed our Phase 3 clinical program and our NDA was accepted for review, we continue to require the assistance of these third parties through the FDA review process and in the future. We have had significant difficulties obtaining the necessary and quality resources. We continue to compete with larger and other companies for the attention and assistance of these third parties. If we are unsuccessful in obtaining the needed assistance, we will have difficulty maintaining our timelines and obtaining approval for peginesatide.

Although we rely on these third parties to conduct our clinical trials, we are responsible for confirming that each of our clinical trials is conducted in accordance with its general investigational plan and protocol. Moreover, FDA and foreign regulatory agencies require us to comply with regulations and standards, commonly referred to as good clinical practices, for conducting, recording and reporting the results of clinical trials to assure that the data and results are credible and accurate and that the trial participants are adequately protected. Our reliance on third parties does not relieve us of these responsibilities and requirements, and regulatory authorities may find remediation efforts by us or our CROs insufficient. Recently, the FDA appears to be increasing its focus on clinical data quality, which may delay or reduce the likelihood of regulatory approval.

We may not be able to maintain our relationships with these CROs or other contractors on acceptable terms. These third parties generally may terminate their engagements with us at any time and if we have to enter into alternative arrangements, these may result in the delay of development and commercialization of peginesatide. As a result, we can control their activities only within certain limits, and they will devote only a certain amount of their time to peginesatide. If these third parties did not or do not successfully carry out their duties under their agreements with us or, or if they otherwise fail to meet expected deadlines, our NDA filing may not meet regulatory requirements. If the quality or accuracy of the data they obtain is compromised due to failure to adhere to clinical protocols, good clinical practices and regulatory requirements, our development activities may be extended or such failure to perform may negatively impact the quality and acceptability of the data. If any of these events occur, or we are otherwise unable to adequately demonstrate the reliability of the data from our Phase 3 results, we may not be able to obtain regulatory approval of peginesatide on a timely basis, if at all.

Results from the Trial to Reduce Cardiovascular Endpoints with Aranesp Therapy, or TREAT, heightens concerns surrounding safety of ESAs and increases the regulatory risk for peginesatide as the class faces greater scrutiny. These concerns may limit the ability to develop and obtain regulatory approval for peginesatide or to do so on a timely basis. The FDA recently announced label changes including additional boxed warnings and more conservative dosing guidelines for ESAs in the treatment of anemia in chronic kidney disease. We cannot predict what future actions the FDA may take that could affect the potential of peginesatide given the uncertain regulatory environment.

In late 2009, Amgen Inc., or Amgen, announced the results of its large, randomized, double-blind, placebo-controlled Phase 3 study of patients with chronic kidney disease (CKD) (not requiring dialysis), anemia and type-2 diabetes (TREAT). In this study, treatment of anemia with Aranesp to a target hemoglobin of 13 g/dL, which was higher than the 10 g/dL 12 g/dL range previously approved by the FDA in the label. Study results reportedly failed to show benefit compared to the control group with regard to composite of time to all-cause mortality or cardiovascular morbidity (including heart failure, heart attack, stroke, or hospitalization for myocardial ischemia) and a composite of time to all-cause mortality or chronic renal replacement. In addition, higher rates of stroke were reported amongst patients treated with Aranesp compared to the control group. Further, among a subgroup of patients with a history of cancer at baseline, a statistically significant increase in deaths from cancer was observed in the Aranesp treated patients compared to placebo treated patients. However, Aranesp treatment reportedly was associated with a statistically significant reduction in blood transfusions and a modest improvement in patient reported fatigue.

In January 2010, FDA officials published an editorial in the New England Journal of Medicine entitled Erythropoiesis-Stimulating Agents Time for a Reevaluation and plans to convene a public advisory committee meeting to evaluate the use of ESAs in the treatment of anemia due to chronic kidney disease. The editorial noted that a number of randomized trials, including TREAT, have attempted to show that using ESAs to

raise hemoglobin concentrations to higher targets improves clinical outcomes but rather have suggested the opposite. Accordingly, the

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article indicates that more conservative hemoglobin targets (well below 12 g/dL), more frequent hemoglobin monitoring, and more cautious dosing, should be evaluated.

In February 2010, the FDA announced that ESAs must be prescribed and used under a risk management program known as a REMS to ensure the safe use of these drugs. As part of the REMS, a medication guide explaining the risks and benefits of ESAs must be provided to all patients receiving ESAs for all indications. In addition, in the case of oncology use, the FDA required ESA manufacturers to implement training for hospitals and healthcare professionals and the signing of a patient informed consent acknowledging the risks of ESA use prior to treatment. As part of any REMS, the manufacturer has reporting and monitoring obligations to ensure compliance.

In October 2010, the FDA convened a cardio-renal advisory committee to review TREAT and to re-evaluate the use of ESAs in the treatment of anemia in chronic kidney disease. Although the advisory panel voted against withdrawal of the indication for Aranesp s use in non-dialysis patients even those with a history of stroke, and voted against the adoption of the TREAT control group dosing regimen (treatment once hemoglobin is below 9 g/dL), the advisory committee discussion included potential areas of concerns regarding the use of ESAs, including hemoglobin variability and rates of excursions associated with current dosing regimens, use by certain subgroups including diabetics and hyporesponders, among others, for further consideration in clinical trials.

In June 2011, the FDA cited increased risks of cardiovascular events as a basis for more conservative dosing guidelines for use of ESAs in chronic kidney disease and announced related changes to ESA labeling. The FDA removed the prior target range of 10-12 g/dL and while separately issuing guidance for non-dialysis patients, the FDA recommended that dialysis patients initiate treatment when the hemoglobin is less than 10 g/dL and to reduce or interrupt dosing if hemoglobin level approaches or exceeds 11 g/dL. The FDA also required Amgen to conduct additional clinical trials to explore dosing strategies, including in dialysis patients to minimize hemoglobin variability, rates of change and excursions while exploring benefit. The FDA may continue to impose further restrictions or requirements on ESAs, including on peginesatide.

The TREAT results and the FDA s recent and potential future actions represent additional challenges to the ESAs as a class and increase the uncertainty associated with peginesatide s regulatory approval. Even prior to these recent events, for the last several years, the FDA, the medical community, and others have recently raised significant safety concerns relating to commercially available ESAs as a result of reports of increased mortality and side effects from a number of clinical trials. These concerns have resulted in a number of negative actions affecting the market for ESAs, including the following:

- As a result of concerns associated with administering ESAs to target higher hemoglobin levels, the FDA required revised warnings, including black box warnings, be added to labels of currently marketed ESAs advising physicians to monitor hemoglobin levels and to use the lowest dose of ESA to increase the hemoglobin concentration to the lowest level sufficient to avoid the need for red blood cell transfusions.

- The FDA also issued a public health advisory statement re-evaluating the safe use of the ESA class and convened its Oncology Drugs Advisory Committee, or ODAC, in May 2007 to consider recent information on risks associated with ESAs for use in the treatment of anemia in cancer patients. The ODAC recommended that the FDA institute restrictions on the usage of currently marketed ESAs, including limitations on the treatment of certain types of cancer and the duration of treatment.

- The FDA also convened a joint meeting in September 2007 of the Cardiovascular and Renal Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee to review the risks and benefits of ESAs.

- The FDA approved revised black box warnings and other safety-related product labeling changes for commercially available ESAs during 2007 and thereafter.

- In addition, the FDA convened another ODAC meeting in March 2008 to review data from more recent clinical trials with breast cancer patients and cervical cancer patients using currently marketed ESAs, and to consider additional action. The ODAC recommended the use of informed consents and further restrictions on the use of currently marketed ESAs for the treatment of chemotherapy-induced anemia, including the exclusion of patients with metastatic breast or head and neck cancer as well as those cancer patients potentially receiving curative treatment.

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- In July 2008, the FDA announced additional safety-related label restrictions for the use of commercially available ESAs including revisions to the black box warnings to provide that ESAs are not indicated for patients undergoing chemotherapy expected to cure their cancer. In addition, the FDA required new prescribing information to assure that ESA therapy is not initiated until the hemoglobin level drops below 10 g/dL.

In 2008, these factors and the uncertain regulatory climate resulted in our and Takeda s decision to suspend the development of peginesatide to treat chemotherapy-induced anemia. Further, in 2010, based on our discussion with the FDA, we and Takeda decided to submit an NDA for treatment of anemia in chronic kidney disease patients for dialysis patients only. These events may have a material adverse effect on our business and future financial results.

We cannot predict what further action, if any, the FDA may take, which may include, among others, additional label restrictions, the use of informed consents, further lowering or removal of target hemoglobin levels, or even the removal of indications from the label altogether. Further, regardless of whether the FDA takes additional action or not, the Centers for Medicare and Medicaid Services, or CMS, and private payors may still decide separately to lower or discontinue reimbursement as CMS has recently proposed changes and continues to evaluate reimbursement policy for ESAs.

The controversy surrounding ESAs and FDA concerns has, and may further negatively affect peginesatide, including the completion of our development program. These safety concerns may increase the risk of not achieving regulatory approval or negatively affect the timing or costs associated with obtaining regulatory approval, including potential risk mitigation activities we may be required to complete either prior to or after product approval. We cannot predict the scope of the REMS we may ultimately be required to implement by the FDA and the impact on the use of peginesatide. Even a small imbalance in safety events or unfavorable signal or trend against peginesatide may increase the risk of or the conditions or limitations associated with approval by the FDA, as regulators are increasingly uncomfortable with the safety of the comparator ESAs. Any of these factors could significantly delay or negatively impact the commercialization of peginesatide.

Our development program for peginesatide may not lead to a commercial drug either because we fail to adequately demonstrate that it is safe and effective in clinical trials and or pre-clinical studies and we therefore fail to obtain necessary approvals from the FDA and similar foreign regulatory agencies, or because we have inadequate financial or other resources to advance peginesatide through development and commercialization. Our analyses of the Phase 3 results remain preliminary and no conclusions as to the safety and efficacy can be drawn as only the FDA has the authority to make such determination. Any significant delay or failure to obtain approval of peginesatide would have a material and adverse impact on our business as we would have to incur substantial expense and it would take a significant amount of time and resources to bring any future product candidate to market, if ever.

Even if peginesatide receives approval by the FDA for treatment of anemia associated with chronic kidney disease in dialysis patients, the market opportunity for peginesatide may be significantly reduced as a result of the increasing controversy surrounding ESAs, the TREAT results and recent and future actions by the FDA and CMS.

Safety concerns have significantly reduced the market for ESAs in recent years. As the perception of the risks of ESA usage continues to increase with the controversy surrounding the recent TREAT results, the concerns are likely to further negatively impact the use of ESAs and the commercial potential of peginesatide. The FDA s recent actions, including the removal of target hemoglobin ranges, may limit the use of ESAs in chronic kidney disease in dialysis patients. In addition to these recent FDA actions, CMS convened a meeting of the Medicare Evidence Development & Coverage Advisory Committee, or MedCAC, to review the available evidence on the use of ESAs to manage anemia in patients who have chronic kidney disease and considered the results of the TREAT study among others. In July 2011, CMS proposed modifications to

reimbursement policy for ESAs including removal of a performance measure focused on maintaining hemoglobin level above 10g/dL in dialysis patients. These recent events and further action by FDA to continue to restrict ESA use or decrease reimbursement coverage by CMS

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could have a materially negative impact on the size of the ESA market in the U.S. and reduce the overall size of the market peginesatide is expected to compete in at the time of launch. Not only may a small imbalance in safety events or unfavorable signal or trend against peginesatide increase FDA approval risk or the risk of peginesatide obtaining reimbursement, but any negative perception of peginesatide s safety relative to other ESAs could keep us from successfully commercializing peginesatide.

We have incurred significant operating losses since inception and anticipate that we will incur continued losses for the foreseeable future, which will require us to obtain substantial additional financing. If we incur significant delays or expenses and are unable to obtain additional financing, we will be unable to complete the development and commercialization of peginesatide and may need to cease operations. Even if we obtain additional financing, when needed, we may never achieve or sustain profitability.

We have experienced significant operating losses since our inception in 2001. Currently, we have no products approved for commercial sale and, to date, we have not generated any revenue from product sales. At September 30, 2011, we had an accumulated deficit of $420.9 million. Due to the recognition of revenues from milestone payments from our collaboration with Takeda, we were profitable for the three and nine months ended June 30, 2010 and may have profitable quarters from time to time if we are successful in obtaining FDA approval for peginesatide. We continue to expect to incur substantial losses in order to complete the development and commercialization of peginesatide. Our operations have consumed substantial amounts of cash since our inception. We expect to continue to spend substantial amounts in order to:

- complete clinical development of peginesatide;
- pursue approval of the NDA for peginesatide through the FDA review process, which is a lengthy and uncertain process;
- prepare for manufacturing process for peginesatide at our contract manufacturers for commercial launch; and
- prepare to launch and commercialize peginesatide, including building our own commercial organization, sales force and infrastructure to address renal markets.

We believe that our existing cash, cash equivalents and investments together with the interest thereon will enable us to maintain our currently planned operations for at least the next 12 months. However, further challenges or delays to approval and commercialization of peginesatide or significant future legal costs may require us to raise additional funding to complete the development and commercialization of peginesatide. Since the announcement of our Phase 3 data in late June 2010 and the arbitration decision in October 2010, we have experienced a severe decline in our stock price, which has impaired our ability to access capital on potentially favorable terms. In contrast, our funding needs have only increased as the peginesatide development program has suffered delays, the potential loss of milestone payments from Takeda associated with the non-dialysis indication and the potential for future legal proceedings and costs. Our failure to raise capital when needed may harm our business and operating results.

The current capital markets have been extremely volatile, and biotechnology companies have been limited or unsuccessful in obtaining funding in this environment. Securing funding has been particularly difficult for companies of our size with limited capital resources. Continuation of this market and the issues arising from our Phase 3 results significantly limit our ability to raise funds such that that there can be no assurance we can raise the additional funds, when needed, to support our continuing operations and maintain current development and commercialization timelines for peginesatide.

To date, our sources of cash have been limited primarily to the proceeds from the sale of our securities to private and public investors and payments by Takeda under our collaboration agreements. We cannot be certain that additional funding will be available on acceptable terms, or at all. To the extent that we raise additional funds by issuing equity securities, if available, our stockholders may experience significant dilution particularly given the stock price decline we experienced subsequent to the announcement of our Phase 3 results. Further, our equity line of credit with Azimuth Opportunity Ltd., or Azimuth, is subject to a number of conditions that limits our ability to draw against such facility. Any debt financing, if available, may involve security interests on our assets or restrictive

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covenants, such as limitations on our ability to incur additional indebtedness, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business.

If we are unable to raise additional funds when required or on acceptable terms, we may have to:

- assume greater risks and significantly delay, scale back, or discontinue the development and/or commercialization of peginesatide;

- relinquish our existing rights to peginesatide;

- eliminate or defer formulation research and development or other manufacturing efforts that may be required to successfully develop or commercially launch peginesatide; or

- pursue merger and acquisition alternatives.

We expect to continue to incur substantial operating losses as we pursue regulatory review and approval of the NDA, add infrastructure and operations to support commercialization of peginesatide, and potentially begin new research and development programs. Our ability to generate revenue depends heavily on our ability to successfully develop and secure regulatory approval for, and commercially launch, our product candidate, peginesatide. If due to lengthy and complicated development, clinical and regulatory requirements or any other reason, we are unable to commercialize peginesatide, we may never be able to commercialize any future product candidates.

Even if we receive regulatory approval of peginesatide, we must successfully commercialize peginesatide before we can become profitable. We anticipate that it will be years before we can commercialize peginesatide and we expect to incur substantial expenses associated with our commercialization efforts as well as share in those of Takeda s even prior to obtaining approval of peginesatide as well as thereafter. Accordingly, we may never generate significant revenues and, even if we do generate revenues, we may never achieve or sustain profitability.

Peginesatide may require extensive additional clinical evaluation and will require regulatory approval, significant marketing efforts and substantial investment before it can provide us or our partners with any revenue. If we or our partners are unable to develop and commercialize peginesatide or even if we receive marketing approval for peginesatide, sales revenue therefrom may be insufficient, and we may not achieve or sustain profitability, and we may be unable to continue our operations.

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Even if peginesatide is approved by the FDA for treatment of anemia associated with chronic kidney disease in dialysis patients, our commercial success depends upon attaining significant market acceptance of peginesatide among physicians, patients, health care payors and the major operators of dialysis clinics as well as reaching an agreement with one or more of such major operators of dialysis clinics.

Peginesatide has not been approved or commercialized for any indication and we are planning to pursue approval from the FDA for treatment of anemia associated with chronic kidney disease in dialysis patients. Even if approved for sale by the appropriate regulatory authorities, physicians may not prescribe peginesatide, in which case we would not generate revenue or become profitable. In particular, the therapeutic indication targeted by peginesatide has been served by our competitors products for many years. These products may now be said to be the standard of care, and it may be difficult to encourage healthcare providers to switch from products with which they and their patients have become comfortable.

The dialysis market, which peginesatide will attempt to penetrate, is highly established and concentrated, with two ESA products serving a significant majority of all dialysis patients on Medicare. In addition, dialysis clinics using ESAs could incur substantial expense in administration and training if they were to switch from current ESAs to peginesatide. The concentration of customers for ESAs within the dialysis market may pose a risk to our ability to obtain revenues or favorable margins on peginesatide, if approved. If we cannot come to agreements with one or more of the major companies operating dialysis clinics in the U.S. or, even if we do and we cannot do so on favorable terms or on a timely basis, the revenue opportunity of peginesatide could be significantly reduced. In October 2006, Amgen, which markets the ESAs EPOGEN and Aranesp, and Fresenius Medical Care, or Fresenius, one of the two largest operators of dialysis clinics in the U.S., announced an agreement whereby Amgen would be the sole supplier of EPO products for Fresenius dialysis business effective immediately through the end of 2011. We are not aware of the specific terms of the Amgen-Fresenius agreement, and cannot project how it may impact the commercial opportunity for peginesatide if and when it is launched. However, agreements between operators of dialysis facilities and marketers of competing ESA products could potentially limit the market opportunity for peginesatide, and adversely impact our ability to generate revenues.

Prior to this year, CMS generally reimbursed ESAs at a rate of 106% of the average ESA sales price, or ASP. This allowed the dialysis facilities to realize a profit on the purchase and administration of ESAs, which constitutes an important component of their economic viability. However, under the 2008 Medicare Legislation a new bundled payment system commenced in January 2011 for facilities that furnish renal dialysis services and home dialysis to Medicare beneficiaries with end-stage renal disease. Under the new system, CMS will make a single bundled payment to the dialysis facility for each dialysis treatment that will cover all renal dialysis services, including ESAs. The bundled payment system is undergoing further rulemaking and may create incentives for significantly lower utilization or dosing of ESAs, including peginesatide, and reduce the commercial potential for peginesatide. We cannot guarantee that peginesatide will be reimbursed by CMS in a manner that will support physician adoption. CMS held MedCAC meetings in March 2010 and January 2011 to review current ESA coverage policy based on the available evidence on the use of ESAs to manage anemia in patients who have chronic kidney disease, and the role of ESAs in successful kidney transplantation, respectively. Independent of any additional action the FDA may take, CMS has proposed modifications to reimbursement policies and may take future actions that further decrease reimbursement coverage of ESA or otherwise reduce the overall size of the market peginesatide is expected to compete in at the time of launch.

In addition, recent studies by manufacturers of ESAs indicate that the higher levels of hemoglobin achieved through administration of ESAs can result in a statistically significant increase in cardiovascular events. This may in turn reduce the growth or cause contraction of the market for ESAs and reduce the potential revenues for peginesatide.

In addition, market acceptance of peginesatide by physicians, healthcare payors and patients will depend on a number of additional factors, including:

- the clinical indication for which peginesatide is approved;
- acceptance by physicians and patients of peginesatide as a safe and effective treatment alternative;
- perceived differences between peginesatide and alternative treatments;
- the cost of treatment in relation to alternative treatments;

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- the availability of adequate reimbursement by third parties;

- the continued use of ESA treatments generally for anemia;

- relative convenience and ease of administration; and

- the prevalence and severity of side effects.

Competition in the pharmaceutical industry is intense. If our competitors are able to develop and market products that are more effective, safer or less costly than peginesatide, our commercial opportunity will be reduced or eliminated.

We face competition from established and emerging pharmaceutical and biotechnology companies, as well as from academic institutions, government agencies and private and public research institutions.

Our commercial opportunity will be reduced or eliminated if our competitors develop and commercialize products that are more effective, have fewer side effects or are less expensive than peginesatide or any other future products that we may develop and commercialize. In addition, significant delays in the development of peginesatide could allow our competitors to bring new products to market before we do and impair our ability to commercialize peginesatide. Competitors may also reduce the price of their ESAs in order to gain market share. These price reductions could force us to lower the price of peginesatide in order to compete effectively, resulting in lower revenues and reduced margins on the sales of peginesatide.

We anticipate that, if approved, for treatment of anemia associated with chronic kidney disease in dialysis patients, peginesatide would compete with EPOGEN and potentially Aranesp, which are both marketed by Amgen, NeoRecormon and Mircera, which are currently marketed outside the U.S. by Roche. PROCRIT, which is marketed by Ortho Biotech Products, L.P. (a subsidiary of J&J), is approved for treatment of anemia in non-dialysis patients as well as for chemotherapy induced anemia. Aranesp is approved for once-monthly dosing for treatment of anemia in non-dialysis patients in Europe. In the U.S., Amgen is reportedly in the process of seeking approval for once-monthly dosing of Aranesp for treatment of anemia in non-dialysis patients. If Amgen is successful in obtaining approval for once-monthly dosing or our competitors products are administered in practice on a less frequent basis than prescribed by their labels, the market for peginesatide may be decreased. In addition, Roche s Mircera has recently launched in Europe. Mircera reportedly has greater plasma stability and is longer acting than any rEPO product that is currently on the market. As a result of the patent litigation between Roche and Amgen, Mircera has been found to infringe several U.S. patents owned by Amgen and has been enjoined from being sold in the U.S. until the expiration of these patents in mid-2014 under a limited license. If Mircera enters the U.S. market before peginesatide or upon its entry, we believe that Mircera will be in direct competition with peginesatide, and therefore could potentially limit the market for peginesatide, because of its ability to be longer acting. Other potential competitors, including FibroGen, Inc., are developing small molecules designed to promote the production of greater levels of naturally-occurring EPO in patients. The introduction of biosimilars into the ESA market, or new market entrants, could also prove to be a significant threat to us as it could not only limit the market for peginesatide, but could also drive down the price of ESAs.

Most of these competitors have substantially greater financial resources and expertise in research and development, manufacturing, pre-clinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Current marketers of ESAs also have the ability to bundle sales of existing ESA products with their other products, potentially disadvantaging peginesatide, which we plan to sell on a stand-alone basis. Established pharmaceutical and large biotechnology companies may invest heavily to discover and develop novel compounds or drug delivery technology that could make peginesatide obsolete. Smaller or early-stage companies may also prove to be significant competitors, particularly through strategic partnerships with large and established companies. These third parties may compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies and technology licenses complementary to our programs or advantageous to our business. Our competitors may succeed in obtaining patent or other intellectual property protection, receiving FDA approval, or discovering, developing and commercializing products before we do.

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The U.S. market opportunity for peginesatide may deteriorate significantly after the entry of biosimilars in the U.S.

The remaining U.S. patents for epoetin alfa, a version of short-acting rEPO, expire from 2012 through 2015. Patents related to epoetin alfa expired in the European Union, or E.U., in 2004. Biosimilars of short-acting rEPO are currently being developed or sold in various markets outside the U.S., including the E.U. We expect that biosimilars, including rEPO, will be sold at a significant discount to existing branded products when they are launched in the U.S. as in the E.U. The introduction of biosimilars into the ESA market in the U.S. could prove to be a significant threat to peginesatide if they are able to demonstrate bioequivalence to existing ESAs. Biosimilars will constitute additional competition for peginesatide, if approved, and are expected to drive its price and sales volume down, which may adversely affect our revenues.

Peginesatide is our only product candidate and we may not develop any other product candidates for the foreseeable future.

Peginesatide is the main focus of our business, which we expect to be the case for the foreseeable future. Accordingly, until we are able to obtain additional financing and resources to develop and commercialize peginesatide, we are unlikely to be able to successfully discover or develop any other product candidates. Further, we have had to reduce our research capabilities and efforts, including the elimination of certain research programs even some activities related to the support of peginesatide. We have limited ability and resources to pursue internal research and programs and strategic collaborations for the development of new products. Research programs to identify new disease targets and product candidates require substantial technical, financial and human resources, whether or not any product candidates are ultimately identified. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for many reasons, including, but not limited to, the following:

- the financial and internal resources may be insufficient and are needed for peginesatide;
- the research methodology used may not be successful in identifying potential product candidates;
- competitors may develop alternatives that render our product candidates obsolete;
- a product candidate may on further study be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory requirements for approval;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; or
- a product candidate may not be accepted by patients, the medical community or third party payors.

The success of peginesatide is dependent upon the strength and performance of our collaboration with Takeda, in particular in the U.S. If we fail to maintain our existing collaboration with Takeda, such termination would likely have a material adverse effect on our ability to continue to develop peginesatide and our business.

The maintenance and successful performance of our strategic collaboration with Takeda for development of peginesatide is an important part of our business model. Our collaboration with Takeda is extremely complex, particularly in the context of our planned U.S. commercial launch with respect to financial provisions, allocations of responsibilities, and the respective rights of the parties in decision making. Accordingly, significant aspects of the development and commercialization of peginesatide require Takeda s agreement or approval prior to implementation, which could cause significant delays that may materially impact the potential success of peginesatide in the U.S. Further, if we are not able to reach agreement with Takeda or maintain our existing collaboration with Takeda on plans and efforts to develop and commercialize peginesatide, our business could be severely and adversely affected. Takeda has the ability to terminate each of the collaboration agreements upon an uncured material breach by us or even in the absence of a material breach with six months notice. Currently, Takeda could terminate either or both of our collaboration agreements, which would likely have a material adverse effect on the advancement of our peginesatide program and our business. Events such as the suspension of the peginesatide oncology program, the impact of the Phase 3 results on the renal program particularly on the non-dialysis indication,

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the arbitration decision relating to the dispute with J&J and the decreased market opportunity for ESAs may increase the possibility that Takeda may elect to terminate the collaboration or limit the resources Takeda is willing to commit to peginesatide on a worldwide basis, particularly in advance of obtaining regulatory approvals for peginesatide. Through the collaboration, Takeda currently provides development and commercialization funding and performs important functions, including conduct of certain clinical trials and manufacturing activities, and is expected to pay us milestone payments upon the completion of certain events, all of which would be unavailable to us in the case of an early termination of the collaboration. Even in the absence of a termination, the significant resources and commitment that may be required to successfully commercialize peginesatide in the U.S. may be limited, and Takeda s failure to provide funding or perform its obligations on a timely basis in anticipation of commercial launch may have a material adverse effect on our business and the success of peginesatide, in particular in the U.S. If we fail to maintain the Takeda collaboration or establish and maintain additional strategic collaborations for any other potential product candidates that we may pursue:

- the development of peginesatide or future product candidates may be terminated or delayed;

- our cash expenditures related to development of our current or future product candidates would increase significantly and we may need to seek additional financing;

- we may be required to hire additional employees or otherwise develop expertise, such as sales and marketing expertise, for which we have not budgeted;

- we will bear all of the risk related to the development of each of our current and future product candidates; and

- we may be unable to meet demand for any future products that we may develop.

Any of these events could have a material adverse effect on our business.

The commercial success of peginesatide in the U.S. depends in significant part on the development and commercialization efforts of Takeda, over which we have limited control in the U.S. Outside of the U.S. in the Takeda territory, we are solely dependent on the efforts and commitments of Takeda, either directly or through third parties, to further develop and commercialize peginesatide. If our collaborations are unsuccessful, our ability to develop and commercialize products through our collaborations, and to generate future revenue from the sale of these products, would be significantly reduced.

Our dependence on Takeda for our global collaboration with peginesatide subjects us to a number of risks, including our ability to successfully develop and commercialize peginesatide in the U.S. and sole reliance on Takeda, either directly or through third parties, to further develop, obtain and maintain regulatory approvals and achieve market acceptance of peginesatide in the Takeda territory.

Under our collaboration with Takeda in the U.S., we co-develop and co-commercialize peginesatide in the U.S. Because we share responsibility with Takeda for clinical development and commercialization activities in the U.S., the conduct and success of the peginesatide program is dependent on the efforts of Takeda over which we have limited or no control. Further, as Takeda has significant rights, responsibilities and decision-making authority over commercialization of peginesatide in the U.S., any failure of Takeda to act in a timely manner or make adequate investments of funds or resources may delay further development or commercialization of peginesatide that may result in a negative impact on our planned timelines, require us to contribute more resources to successfully commercialize peginesatide and decrease the likelihood of commercial success for peginesatide in the U.S.

Outside of the U.S., Takeda holds an exclusive license to develop and commercialize peginesatide and has primary responsibility for filing regulatory submissions and obtaining product approvals in those territories, including in Europe and Japan. As a consequence, any progress and commercial success in those territories is dependent solely on Takeda s efforts and commitment to the program. Takeda may delay, reduce or terminate development efforts relating to peginesatide, independently develop products that compete with peginesatide, or fail to commit sufficient resources to the marketing and distribution of peginesatide. Competing products or programs, either developed by Takeda or to which our collaboration partners have rights or acquire in the future, may result in our partners withdrawal of support for peginesatide.

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In the event that Takeda fails to diligently develop or commercialize peginesatide, our collaboration agreements provide us the right to allege breach and if successfully asserted, terminate our partner s rights in certain instances. However, any such decision would impact the potential success of peginesatide and we may choose not to as we may not be able to find another partner and any new collaboration will likely not provide comparable financial terms to those in our Takeda collaboration agreements. In the event of our termination, this may require us to commercialize peginesatide on our own, which is likely to result in significant additional expense and delay. Significant changes in Takeda s business strategy, resource commitment and the willingness or ability of Takeda to complete its obligations under our collaboration agreements, particularly in advance of obtaining regulatory approvals in the U.S. and abroad could materially affect the potential success of peginesatide.

We have limited ability to control and influence Takeda in its strategic decisions. This is particularly important as we are currently planning for commercialization of peginesatide in the U.S. If Takeda were to breach or terminate either of our collaboration agreements or otherwise inadequately perform or fail to perform its obligations thereunder in a timely manner, the development and commercialization of peginesatide would be delayed, terminated or negatively impacted. Moreover, if Takeda fails to successfully develop and commercialize peginesatide outside of the U.S., our potential to generate future revenue in the Takeda territory would be significantly reduced.

Reimbursement may not be available for peginesatide, which would materially diminish our sales and our ability to sell our products profitably.

Market acceptance and sales of peginesatide will depend on reimbursement policies and may be affected by future health care reform measures. Government authorities and third party payors, such as private health insurers and health maintenance organizations, decide which drugs they will pay for and establish reimbursement levels. We cannot be sure that reimbursement will be available for peginesatide. Also, we cannot be sure that reimbursement amounts will not reduce the demand for, or the price of, peginesatide. We have not commenced efforts to have our peginesatide reimbursed by government or third party payors. If reimbursement is not available or is available only to limited levels, we may not be able to commercialize peginesatide.

In both the U.S. and certain foreign jurisdictions, there have been a number of legislative and regulatory proposals in recent years to change the healthcare system in ways that could impact our ability to sell peginesatide profitably.

In response to the FDA s recent black box warning and public health advisories, CMS has significantly restricted coverage of ESAs. In July 2007, CMS issued its National Coverage Decision Memorandum for Use of Erythropoiesis Stimulating Agents in Cancer and Neoplastic Conditions, or the National Coverage Decision, that determined that ESA treatment was not reasonable or necessary for certain medical conditions, including any anemia of cancer not related to cancer treatment, among others. The National Coverage Decision also established the ESA reimbursement policy for Medicare and other government beneficiaries who are treated for chemotherapy-induced anemia and contains a coverage restriction for hemoglobin levels greater than 10g/dL, which has had a material adverse effect on the use of ESAs. In July 2007, CMS also issued revisions to its reimbursement policies for the use of ESAs for end stage renal disease in cases where hemoglobin levels exceed 13 g/dL and also decreased the monthly dosing limits. In July 2008, CMS announced that ESAs are a potential topic for another National Coverage Decision citing adverse effects in cancer and chronic kidney disease patients, including dialysis patients, while noting the large costs but uncertain benefits. In March 2010, CMS convened a MedCAC meeting to review the available evidence on the use of ESAs to manage anemia in patients who have chronic kidney disease and in January 2011 to review the role of ESAs in successful kidney transplantation. In July 2011, CMS proposed modifications to reimbursement policy for ESAs including removal of a performance measure focused on maintaining hemoglobin level above 10g/dL in dialysis patients. Independent of any additional action the FDA may take as to ESAs, CMS may further decrease coverage or create disincentives which could have a materially negative impact on the size of the ESA market in the U.S. and reduce the overall size of the market peginesatide is expected to compete in at the time of launch.

As a result of these reimbursement and other legislative proposals and the trend towards managed health care in the U.S., third party payors are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement of new drugs. They may also refuse to provide any coverage of approved products for

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medical indications other than those for which the FDA has granted market approvals. In addition, major third party payors have begun to follow CMS s restrictive reimbursement policies, which has further decreased the market for ESAs. As a result, significant uncertainty exists as to whether and how much third party payors will reimburse patients for their use of newly approved drugs, which in turn will put pressure on the pricing of drugs. We expect to experience pricing pressures in connection with the sale of our products due to the trend toward managed health care, the increasing influence of health maintenance organizations and additional legislative proposals.

CMS policies are constantly changing and we cannot guarantee that they will not decrease, limit or deny reimbursement of peginesatide in the future.

CMS, the agency within the Department of Health and Human Services that manages Medicare and will be responsible for reimbursement of the cost of peginesatide administered to Medicare beneficiaries, has asserted the authority of Medicare not to cover particular drugs if it determines that they are not reasonable and necessary for Medicare beneficiaries, or to cover them at a lesser rate, compared to drugs that CMS considers to be therapeutically comparable. We cannot be certain that CMS will not decrease, limit or deny reimbursement of peginesatide for any therapeutic indication we may pursue. Even if CMS ultimately authorizes reimbursement for peginesatide, it may be not do so in a timely manner. As the costs of the Medicare program continue to grow, CMS may be compelled to make difficult decisions regarding the trade-offs of supporting the reimbursement of certain public health expenditures over others. Depending on methods CMS uses to calculate the cost-benefit of treatments competing for share of the Medicare budget, ESAs (including peginesatide) may not be considered to offer sufficient overall health benefit to justify reimbursement at levels that will allow us to achieve and sustain profitability. In addition, as a result of the recent safety concerns relating to ESAs, CMS recently announced policies significantly restricting the coverage of ESAs and has proposed another National Coverage Decision on the topic that may further negatively affect reimbursement of ESAs. CMS has instituted dramatic Medicare reimbursement changes in the past that adversely impacted the businesses of companies in other segments of the healthcare industry, and we cannot determine that CMS will not do the same in the markets in which we operate.

Medicare reimbursement policies under a new bundled payment system could create disincentives for use of ESAs.

Prior to this year, CMS generally reimbursed healthcare providers for use of ESAs at average selling price, or ASP, plus 6%. However, under the 2008 Medicare Legislation a new bundled payment system commenced in January 2011 for facilities that furnish renal dialysis services and home dialysis to Medicare beneficiaries with end-stage renal disease. Under the new bundled payment system, providers are expected to be reimbursed a fixed amount per patient. We cannot guarantee that peginesatide will be reimbursed by CMS or in a manner that will support physician adoption and depending upon the implementation of the bundled payment, may not be favorable to the entry of new ESAs such as peginesatide. In fact, a capitated reimbursement payment methodology may create incentives for significantly lower utilization or dosing of ESAs, including peginesatide, and reduce the commercial potential for peginesatide.

Significant challenges remain with us and Takeda to manufacture peginesatide on a commercial scale. Our dependence upon third parties for manufacture and supply may cause delays in, or prevent us from, successfully developing and commercializing peginesatide. In accordance with the terms of our collaboration, Takeda has responsibility for manufacture of finished product and as a consequence, we have limited ability to control risks associated with that portion of the manufacturing process.

The peginesatide manufacturing process is a complicated, time-consuming process. Manufacture of peginesatide active pharmaceutical ingredient, or API, involves long lead times. We do not currently have the infrastructure or capability internally to manufacture the peginesatide needed to conduct our clinical trials or to commercialize peginesatide. We are and will continue to rely upon contract manufacturers to produce our clinical trial materials and in the future commercial supplies of peginesatide. For the foreseeable future, we expect to continue to rely on

contract manufacturers, partners and other third parties to produce sufficient quantities of peginesatide for all our uses, including completion of our clinical trials and development program. If our contract manufacturers or other third parties fail to deliver materials for the manufacture of peginesatide or peginesatide itself for clinical use or for our registration stability studies on a timely basis, with sufficient quality and at commercially reasonable prices, and if we fail to find replacement manufacturers or to develop our own manufacturing

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capabilities, we may be required to delay or suspend clinical trials or our planned NDA filing or otherwise discontinue development and production.

Peginesatide is a new chemical entity and the manufacturing process for commercial scale production in accordance with applicable regulatory guidelines remains challenging and as such, there are risks associated with the commercial scale manufacture of the API. Similar challenges exist for the manufacture of finished product that must meet a variety of regulatory requirements that vary from country to country and continue to change. Any of these risks and others may prevent or delay us from successfully developing peginesatide, including the following:

- stability or formulation issues including the potential failure of product registration studies to establish sufficient stability to obtain adequate shelf life at refrigerated or room temperature;

- cost overruns, process scale-up, process reproducibility;

- difficulties in maintaining or upgrading equipment and manufacturing facilities on a timely basis; and

- regulatory issues or changes that may cause significant modifications in the manufacturing process or facilities or otherwise impact our ability to offer competitive product presentations or formulations.

We have transferred responsibility of manufacture of peginesatide finished product to Takeda and we therefore have limited control and ability to address risks associated with that portion of the manufacturing process. Further, some of suppliers and manufacturing arrangements, including the provision of bulk poly(ethylene) glycol reagent for the manufacture of peginesatide from Nektar Therapeutics AL, Corporation, or Nektar, are currently single-sourced, leaving us at greater risk of supply interruptions, potential delays and failure to obtain regulatory approvals and commercialize. Unless we are able to successfully negotiate with Nektar, which we may not be able to do on acceptable terms, we may have difficulties under our existing arrangement with Nektar from obtaining proprietary information and additional services from Nektar which may be useful or necessary to obtain regulatory approvals or for commercial manufacture of peginesatide.

We, Takeda, and our third party manufacturers are required to comply with applicable FDA manufacturing practice regulations. If there is any failure by us, Takeda or one of our third party manufacturers or suppliers to maintain compliance with these regulations, the production of peginesatide could be interrupted, resulting in delays and additional costs. Additionally, our third party manufacturers must pass a pre-approval inspection before we can obtain regulatory approval for peginesatide. If for any reason these third parties are unable or unwilling to perform under our agreements or enter into new agreements with us, we may not be able to locate alternative manufacturers or enter into favorable agreements with them in an expeditious manner. We could also experience manufacturing delays if our third party manufacturers, Takeda or suppliers give greater priority to the production of other products over peginesatide. Any inability to acquire sufficient quantities of peginesatide or components thereof in a timely manner from third parties could delay clinical trials or result in product shortages and prevent us from developing and commercializing peginesatide in a cost-effective manner or on a timely basis. Further, our lack of experience providing reliable supply of product may deter health care providers and dialysis centers from selecting or otherwise switching to peginesatide from our competitors products.

It is difficult and costly to protect our proprietary rights, and we may not be able to ensure their protection.

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection of peginesatide and any other product candidates we may pursue, their use and the methods used to manufacture them, as well as successfully defending these patents against third party challenges. Our ability to protect peginesatide from unauthorized making, using, selling, offering to sell or importation by third parties is dependent upon the extent to which we have rights under valid and enforceable patents, or have trade secrets that cover these activities.

We have licensed from third parties rights to numerous issued patents and patent applications. The rights that we acquire from licensors or collaborators are protected by patents and proprietary rights owned by them, and we rely on the patent protection and rights established or acquired by them. The remaining patent terms may not provide meaningful protection. Moreover, third parties may challenge the patents, patent applications and other proprietary rights held by our licensors or collaborators. We generally do not unilaterally control the prosecution of patent

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applications licensed from third parties. Accordingly, we are unable to exercise the same degree of control over this intellectual property as we may exercise over internally developed intellectual property.

Even if we are able to obtain issued patents, any patent may be challenged, invalidated, held unenforceable or circumvented. The existence of a patent will not necessarily protect us from competition or from claims of a third party that our products infringe their issued patents. No consistent policy regarding the breadth of claims allowed in biotechnology patents has emerged to date in the U.S. The biotechnology patent situation outside the U.S. is even more uncertain. Competitors may successfully challenge our patents, produce similar drugs or products that do not infringe our patents, or produce drugs in countries where we have not applied for patent protection or that do not respect our patents. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our licensed patents, in our patents or in third party patents or applications therefor.

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

- others may be able to make similar compounds but that are not covered by the claims of our patents, or for which we are not licensed under our license agreements;

- we or our licensors or collaborators might not have been the first to make the inventions covered by our pending patent application or the pending patent applications and issued patents of our licensors;

- we or our licensors or collaborators 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 without infringing our intellectual property rights;

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

- our issued patents and the issued patents of our licensors or collaborators may not provide us with any competitive advantages, or may be held invalid or unenforceable as a result of legal challenges by third parties;

- we may not develop additional proprietary technologies that are patentable; 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. 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 U.S. are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

Our research and development collaborators may have rights to publish data and other information to which we have rights. In addition, we sometimes engage individuals or entities to conduct research that may be relevant to our business. The ability of these individuals or entities to publish or otherwise publicly disclose data and other information generated during the course of their research is subject to certain contractual limitations. These contractual provisions may be insufficient or inadequate to protect our trade secrets and may impair our patent rights. If we do not apply for patent protection prior to such publication or if we cannot otherwise maintain the confidentiality of our technology and other confidential information, then our ability to receive patent protection or protect our proprietary information may be jeopardized.

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We expect to 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, or use, our technology.

Our ability, and that of our commercial partners, to commercialize any approved product will depend, in part, on our ability to obtain patents, enforce those patents and operate without infringing the proprietary rights of third parties. The patent positions of biotechnology and pharmaceutical companies can be highly uncertain and involve complex legal and factual questions. We have filed multiple U.S. patent applications and foreign counterparts related to peginesatide and other programs as well as underlying platform technologies and may file additional U.S. and foreign patent applications related thereto. There can be no assurance that any issued patents we own or control will provide sufficient protection to conduct our business as presently conducted or as proposed to be conducted, that any patents will issue from the patent applications owned by us, or that we will remain free from infringement claims by third parties.

The failure to obtain adequate patent protection would have a material adverse effect on us and may adversely affect our ability to enter into, or affect the terms of, any arrangement for the further development and marketing of any product. There can also be no assurance that patents owned by us will not be challenged by others. We could incur substantial costs in proceedings, including interference proceedings before the U.S. Patent and Trademark Office and comparable proceedings before similar agencies in other countries in connection with any claims that may arise in the future. These proceedings could result in adverse decisions about the patentability of our inventions and products, as well as about the enforceability, validity or scope of protection afforded by our patents.

Patent applications in the U.S. and elsewhere are published only after 18 months from the priority date. The publication of discoveries in the scientific or patent literature frequently occurs substantially later than the date on which the underlying discoveries were made. Therefore, patent applications relating to products similar to peginesatide and any future products may have already been filed by others without our knowledge. In the event an infringement claim is brought against us, we may be required to pay substantial legal and other expenses to defend such a claim and, if we are unsuccessful in defending the claim, we may be prevented from pursuing related product development and commercialization and may be subject to damage awards.

Any future patent litigation, interference or other administrative proceedings will result in additional expense and distraction of our personnel. An adverse outcome in such litigation or proceedings may expose us or our collaborators to loss of our proprietary position or to significant liabilities, or require us to seek licenses that may not be available from third parties on commercially acceptable terms or at all. In addition, we may be restricted or prevented from manufacturing, developing or commercializing peginesatide or from developing, manufacturing and selling any future products in the event of an adverse determination in a judicial or administrative proceeding or if we fail to obtain necessary licenses. If it is determined that we have infringed an issued patent, we could be compelled to pay significant damages, including punitive damages.

Virtually all of our competitors are 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, in-license technology that we need, out-license our existing technologies or enter into collaborations that would assist in commercially exploiting any technology.

If we are unable either to create sales, marketing and distribution capabilities or enter into agreements with third parties to perform these functions, we will be unable to commercialize peginesatide successfully.

We currently have no sales, marketing or distribution capabilities. To commercialize peginesatide, we must either develop internal sales, marketing and distribution capabilities, which will be expensive and time consuming, or make arrangements with third parties to perform these services. If we decide to market peginesatide directly, we must commit significant financial and managerial resources to develop a marketing and sales force with technical

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expertise and with supporting distribution capabilities. Factors that may inhibit our efforts to commercialize peginesatide directly or indirectly with Takeda include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;

- the inability of sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe our products;

- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and

- unforeseen costs and expenses associated with creating and sustaining an independent sales and marketing organization.

If we, or Takeda through our collaboration, are not successful in recruiting sales and marketing personnel or in building a sales and marketing infrastructure, we will have difficulty commercializing peginesatide, which would adversely affect our business and financial condition. To the extent we rely on other pharmaceutical or biotechnology companies with established sales, marketing and distribution systems to market peginesatide, we will need to establish and maintain partnership arrangements, and we may not be able to enter into these arrangements on acceptable terms. To the extent that we enter into co-promotion or other arrangements, any revenues we receive will depend upon the efforts of third parties, which may not be successful and are only partially in our control. In that event, our product revenues would likely be lower than if we marketed and sold our products directly.

If we fail to attract and keep senior management and key clinical and scientific personnel, we may be unable to successfully develop, conduct our clinical trials and commercialize peginesatide or any other future product candidates.

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel and on our ability to develop and maintain important relationships with leading academic institutions, clinicians and scientists. We are highly dependent upon our senior management and clinical and scientific staff, particularly John Orwin, our Chief Executive Officer, and Dr. Anne-Marie Duliege, our Chief Medical Officer. The loss of services of Mr. Orwin, Dr. Duliege, or one or more of our other members of senior management could delay or prevent the successful completion of our development or the commercialization of peginesatide.

Competition for qualified personnel in the biotechnology and pharmaceuticals field is intense. We will need to hire additional personnel as we expand our clinical development and commercial activities. We may not be able to attract and retain quality personnel on acceptable terms. Our ability to retain or attract qualified personnel has been negatively impacted by the Phase 3 results and the severe decline in our stock price. Each of our officers and key employees may terminate his/her employment at any time without notice and without cause or good reason.

As we evolve from a company primarily involved in research and development to a company also involved in commercialization, we may encounter difficulties in managing our growth and expanding our operations successfully.

As we advance peginesatide through the development stage towards commercialization, we will need to expand our organization, including marketing and sales capabilities or contract with third parties to provide these capabilities for us. As our operations expand, we expect that we will need to manage additional relationships with various collaborative partners, suppliers and other third parties. Future growth will impose significant added responsibilities on members of management. Our future financial performance and our ability to commercialize peginesatide and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to manage our development efforts effectively, and hire, train and integrate additional management, administrative and sales and marketing personnel. We may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successfully growing our company.

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Risks Related to Our Industry

The regulatory approval process is expensive, time consuming and uncertain and may prevent us or our collaboration partners from obtaining approvals for the commercialization of peginesatide.

The research, testing, manufacturing, selling and marketing of drug candidates are subject to extensive regulation by the FDA and other regulatory authorities in the U.S. and other countries, and regulations may differ from country to country. Neither we nor Takeda is permitted to market peginesatide in the U.S. until we receive approval of our NDA from the FDA which we may never obtain. We have not received marketing approval for peginesatide or for any product approval. Obtaining approval of an NDA can be a lengthy, expensive and uncertain process. In addition, failure to comply with FDA and other applicable U.S. and foreign regulatory requirements may subject our company to administrative or judicially imposed sanctions, including warning letters, civil and criminal penalties, injunctions, product seizure or detention, product recalls, total or partial suspension of production and refusal to approve pending NDAs or supplements to approved NDAs.

Regulatory approval of an NDA or NDA supplement is not guaranteed, and the approval process is expensive and may take several years. The FDA also has substantial discretion in the drug approval process. We initiated our Phase 3 clinical trials for peginesatide following extensive discussion with the FDA on the design of the program. Based on the nature of these discussions and guidance from the FDA in light of the current regulatory environment, we did not enter into a special protocol assessment, or SPA, with the FDA for our Phase 3 clinical trials for peginesatide. Nonetheless, in some instances a SPA could provide more assurance that the design, clinical endpoints, and statistical end analyses resulting from these trials would be acceptable to the FDA to support regulatory approval. Despite the time and expense exerted, failure can occur at any stage, and we could encounter problems that cause us to abandon clinical trials or to repeat or perform additional pre-clinical studies and clinical trials. The number of pre-clinical studies and clinical trials that will be required for FDA approval varies depending on the drug candidate, the disease or condition that the drug candidate is designed to address, and the regulations applicable to any particular drug candidate. The FDA can delay, limit or deny approval of a drug candidate for many reasons, including:

- a drug candidate may not be deemed safe or effective;
- FDA officials may not find the data from pre-clinical studies and clinical trials sufficient;
- the FDA might not approve our or our third party manufacturer s processes or facilities; or
- the FDA may change its approval policies or adopt new regulations.

Even if we receive regulatory approval for peginesatide, we will be subject to ongoing FDA obligations and continued regulatory review, which may result in significant additional expense and limit our ability to commercialize peginesatide.

Any regulatory approvals that we or Takeda receive for peginesatide may also be subject to limitations on the indicated uses for which the product may be marketed, or contain requirements for potentially costly post-marketing follow-up studies. In addition, if the FDA approves peginesatide, the labeling, packaging, adverse event reporting, storage, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. Our Phase 3 results may increase the risk of significant additional requirements to maintain any regulatory approval that we might receive. The subsequent discovery of previously unknown problems with the drug, including adverse events of unanticipated severity or frequency, may result in restrictions on the marketing of the drug, and could include withdrawal of the drug from the market.

The FDA s policies may change and additional government regulations may be enacted that could prevent or delay regulatory approval of peginesatide. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the U.S. or abroad. If we are not able to maintain regulatory compliance, we might not be permitted to market our future products and we may not achieve or sustain profitability.

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Failure to obtain regulatory approval in foreign jurisdictions will prevent us from marketing our products abroad through our Takeda collaboration.

We intend to co-market peginesatide in the U.S., and have exclusively licensed Takeda to develop peginesatide in international markets. In order to market peginesatide in the E.U. and many other foreign jurisdictions, we must obtain separate regulatory approvals. We have had limited interactions with foreign regulatory authorities, and the approval procedures vary among countries and can involve additional testing, and the time required to obtain approval may differ from that required to obtain FDA approval. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. Foreign regulatory approvals may not be obtained on a timely basis, if at all. We or Takeda, as part of our peginesatide collaboration, may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in any market.

Foreign governments often impose strict price controls, which may adversely affect our future profitability.

We intend to seek approval to market peginesatide in the U.S. and, through our Takeda collaboration, in foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions, we will be subject to rules and regulations in those jurisdictions relating to our product. In some foreign countries, particularly in the E.U., prescription drug pricing is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a drug candidate. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of peginesatide to other available therapies or a clinical trial that studies pharmacoeconomic benefits. If reimbursement of peginesatide is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, we may be unable to achieve or sustain profitability.

We may incur significant costs complying with environmental laws and regulations, and failure to comply with these laws and regulations could expose us to significant liabilities.

We use hazardous chemicals and radioactive and biological materials in our business and are subject to a variety of federal, state and local laws and regulations governing the use, generation, manufacture, storage, handling and disposal of these materials. Although we believe our safety procedures for handling and disposing of these materials and waste products comply with these laws and regulations, we cannot eliminate the risk of accidental injury or contamination from the use, storage, handling or disposal of hazardous materials. In the event of contamination or injury, we could be held liable for any resulting damages. We are uninsured for third party contamination injury.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of peginesatide.

We face an inherent risk of product liability as a result of conducting clinical trials and will face an even greater risk if we commercialize peginesatide. We may be held liable if any product we develop causes injury or is found otherwise unsuitable during product testing, manufacturing, marketing or sale. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of peginesatide. Even successful defense would require significant financial and management resources. Regardless of the merit or eventual outcome, liability claims may result in:

- decreased demand for peginesatide;
- injury to our reputation;
- withdrawal of clinical trial participants;
- costs of related litigation;
- diversion of management s attention and resources;
- substantial monetary awards to patients;

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- product recalls;

- loss of revenue; and

- the inability to commercialize peginesatide.

Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of pharmaceutical products we develop. We currently carry product liability insurance covering our clinical trials in the amount of $11 million in the aggregate. However, our insurance may not reimburse us or may not be sufficient to reimburse us for the expenses or losses we may suffer. In addition, insurance coverage is becoming increasingly expensive, and in the future we may not be able to maintain insurance coverage at a reasonable cost or obtain insurance coverage that will be adequate to satisfy any liability that may arise.

Risks Related to the Ownership of Our Common Stock

The market price of our common stock has been highly volatile and is likely to remain highly volatile, and you may not be able to resell your shares at or above your purchase price.

The trading price of our common stock has been highly volatile. For the 52 weeks ended September 30, 2011, the closing price of our common stock ranged between a high of $7.99 per share and a low of $4.04 per share. Our stock is expected to be subject to wide fluctuations in price in response to various factors, many of which are beyond our control, including:

- actual or anticipated results from, and any delays in, our development program, regulatory review and commercialization of peginesatide;

- actual or anticipated regulatory approvals of peginesatide or competing products;

- actual or anticipated changes in our funding requirements, capital resources and our ability to obtain financing and the terms thereof;

- actual or anticipated actions taken by regulatory agencies with respect to ESAs generally or specifically as to peginesatide;

- new products or services introduced or announced by us or our collaboration partners, or our competitors, including Roche s Mircera or biosimilars, and the timing of these introductions or announcements;

- actions taken by regulatory agencies with respect to clinical trials, manufacturing process or sales and marketing activities;

- changes in laws or regulations applicable to peginesatide, including but not limited to clinical trial requirements for approvals;

- the success of our development efforts and clinical trials;

- the success of our efforts to discover, acquire or in-license additional products or product candidates;

- developments concerning our collaborations, including but not limited to those with our sources of manufacturing supply and our commercialization partners;

- actual or anticipated variations in our quarterly operating results;

- announcements of technological innovations by us, our collaborators or our competitors;

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- actual or anticipated changes in earnings estimates or recommendations by securities analysts;

- conditions or trends in the biotechnology and biopharmaceutical industries;

- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;

- general economic and market conditions and other factors that may be unrelated to our operating performance or the operating performance of our competitors;

- changes in the market valuations of similar companies;

- sales of common stock or other securities by us or our stockholders in the future;

- additions or departures of key scientific or management personnel;

- developments relating to proprietary rights held by us or our competitors;

- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies; and

- trading volume of our common stock.

In addition, the stock market in general and the market for biotechnology and biopharmaceutical companies in particular have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance. In the past, following periods of volatility in the market, securities class-action litigation or regulatory investigations have often been instituted against companies. Such litigation or investigations, if instituted against us, could result in substantial costs and diversion of management s attention and resources, which could materially and adversely affect our business and financial condition.

Failure to maintain effective internal controls in accordance with Section 404 of the Sarbanes-Oxley Act of 2002 could have a material adverse effect on our stock price.

The Sarbanes-Oxley Act of 2002 requires, among other things, that we maintain effective internal control over financial reporting and disclosure controls and procedures. We currently have not had any material weaknesses for the years ended December 31, 2010 or 2009. We did identify a material weakness in the operation of our internal controls over financial reporting that occurred during the second quarter of 2008 which has been fully remediated. We cannot assure you that material weaknesses will not be identified in future periods. There can be no assurance that we will successfully and timely report on the effectiveness of our internal control over financial reporting in future periods. If we do experience a material weakness in future periods, then investor confidence, our stock price and our ability to obtain additional financing on favorable terms could be adversely affected.

A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues, if any, within an organization have been detected. We continue to implement, improve and refine our disclosure controls and procedures and our internal control over financial reporting.

Future sales of our common stock in the public market could cause our stock price to fall.

Sales of a substantial number of shares of our common stock in the public market that were previously restricted from sale, or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. In the event that we do raise capital through the sale of additional equity securities, the dilution represented by the additional shares of our equity securities in the public market could cause our stock price to fall, in which case investors may not be able to sell their shares of our equity securities at a price equal to or above the price they paid to acquire them.

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Our ability to use net operating loss carryforwards and tax credit carryforwards to offset future taxable income may be limited as a result of recent sale of shares of our common stock or other transactions involving our common stock.

In general, under Section 382 of the Internal Revenue Code of 1986, as amended, a corporation that undergoes an ownership change is subject to limitations on its ability to utilize its pre-change net operating losses, or NOLs, and certain other tax assets to offset future taxable income. In general, an ownership change occurs if the aggregate stock ownership of certain stockholders increases by more than 50 percentage points over such stockholders lowest percentage ownership during the testing period (generally three years). An ownership change could limit our ability to utilize our NOL and tax credit carryforwards for taxable years including or following such ownership change . The issuance of shares of our common stock in our March 2011 public offering resulted in an ownership change and further ownership changes may occur in the future, including as a result of transactions outside of our control, such as sales by existing stockholders, and as a consequence, our ability to utilize our NOL and tax credit carryforwards could be limited. Limitations imposed on the ability to use NOLs and tax credits to offset future taxable income could require us to pay U.S. federal income taxes earlier than would otherwise be required if such limitations were not in effect and could cause such NOLs and tax credits to expire unused, in each case reducing or eliminating the benefit of such NOLs and tax credits. Similar rules and limitations may apply for state income tax purposes.

We are at risk of securities class action litigation.

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 of the significant decrease in our stock price as a result of the announcement of our Phase 3 data and the decision from the arbitration panel relating to the dispute with J&J. Further, our stock price may continue to experience extreme price volatility as has been experienced by biotechnology and biopharmaceutical companies in recent years. If we were to face such litigation, it could result in substantial costs and a diversion of management s attention and resources, which could harm our business.

Some provisions of our charter documents and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders.

Provisions in our certificate of incorporation and bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us, even if doing so would benefit our stockholders.

These provisions include:

- authorizing the issuance of blank check preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval;

- limiting the removal of directors by the stockholders;

- prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders;

- eliminating the ability of stockholders to call a special meeting of stockholders;

- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings; and

- our board of directors is classified, consisting of three classes of directors with staggered three-year terms, with each class consisting as nearly as possible of one third of the total number of directors.

In addition, we are subject to Section 203 of the Delaware General Corporation Law, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with an interested stockholder for a period of three years following the date on which the stockholder became an interested stockholder. This provision could have the effect of delaying or preventing a change of control, whether or not it is desired by or beneficial to our stockholders.

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Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

Unregistered Sales of Equity Securities

Not applicable.

Use of Proceeds

Not applicable.

Issuer Purchases of Equity Securities

We did not repurchase any of our equity securities during the three or nine months ended September 30, 2011.

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. (Removed and Reserved)

Item 5. Other Information

Not applicable.

Item 6. Exhibits

The following documents are being filed as part of this report:

3.3	Amended and Restated Certificate of Incorporation (1)
3.5	Amended and Restated Bylaws (2)
4.1	Reference is made to exhibits 3.3 and 3.5
4.2	Specimen Common Stock Certificate (1)
4.3	Warrant to purchase shares of Series C Preferred Stock (1)
4.4	Amended and Restated Investor Rights Agreement, dated September 7, 2006, by and between the Registrant and certain of its stockholders (1)
4.5	Form of Warrant to Purchase shares of Common Stock (3)
31.1	Certification required by Rule 13a-14(a) or Rule 15d-14(a)
31.2	Certification required by Rule 13a-14(a) or Rule 15d-14(a)
32.1	Certification required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. 1350)
101.INS*	XBRL Instance
101.SCH*	XBRL Taxonomy Extension Schema
101.CAL*	XBRL Taxonomy Extension Calculation
101.LAB*	XBRL Taxonomy Extension Labels
101.PRE*	XBRL Taxonomy Extension Presentation
101.DEF*	XBRL Taxonomy Extension Definition

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(1) Incorporated by reference to the indicated exhibit of our registration statement on Form S-1, as amended, registration no. 333-136125, declared effective by the Securities and Exchange Commission on December 14, 2006.

(2) Incorporated by reference to the indicated exhibit of our Form 8-K as filed with the Securities and Exchange Commission on September 10, 2007.

(3) Incorporated by reference to the indicated exhibit in our Form 8-K as filed with the Securities and Exchange Commission on February 19, 2009.

* In accordance with Rule 406T of Regulation S-T, the information in these exhibits is furnished and deemed not filed or a part of registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, is deemed not filed for purposes of Section 18 of the Exchange Act of 1934, as amended, and otherwise is not subject to liability under these sections and shall not be incorporated by reference into any registration statement or document filed under the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such filing

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SIGNATURES

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

AFFYMAX, INC.

Dated: November 9, 2011	By:	/s/ JOHN A. ORWIN *Chief Executive Officer and Member of the Board of Directors*
Dated: November 9, 2011	By:	/s/ HERB CROSS *Chief Financial Officer (Principal Financial Officer)*

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