AFFYMAX INC
Form 10-Q
August 05, 2010
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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 June 30, 2010

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 o 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 July 31, 2010, 24,369,977 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)

	June 30, 2010 (Unaudited)	December 31, 2009
Assets		
Current assets		
Cash and cash equivalents	$ 64,178	$ 125,296
Short-term investments	77,651	35,292
Receivable from Takeda	10,275	18,561
Income taxes receivable	125	1,443
Deferred tax assets	1,443	1,443
Prepaid expenses and other current assets	8,465	8,704
Total current assets	162,137	190,739
Property and equipment, net	4,682	5,469
Restricted cash	1,135	1,135
Long-term investments	15,132	7,978
Deferred tax assets, net of current	5,797	5,797
Other assets	253	392
Total assets	$ 189,136	$ 211,510
Liabilities and Stockholders Equity		
Current liabilities		
Accounts payable	$ 2,467	$ 464
Accrued liabilities	11,528	12,594
Accrued clinical trial expenses	30,690	39,499
Deferred revenue	44,054	71,972
UBS loan	5,378	9,192
Total current liabilities	94,117	133,721
Long-term income tax liability	9,425	9,425
Other long-term liabilities	1,454	1,459
Total liabilities	104,996	144,605
Contingencies (Note 6)		
Stockholders equity		
Common stock	24	24
Additional paid-in capital	449,483	441,795
Accumulated deficit	(365,413)	(374,859)

Accumulated other comprehensive income (loss)		46		(55)
Total stockholders equity		84,140		66,905
Total liabilities and stockholders equity	$	189,136	$	211,510

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 June 30,		Six Months Ended June 30,	
	2010	2009	2010	2009
Collaboration revenue	$ 54,341	$ 26,918	$ 88,987	$ 52,767
License and royalty revenue	5	5	9	9
Total revenue	54,346	26,923	88,996	52,776
Operating expenses:				
Research and development	28,909	40,778	62,002	81,225
General and administrative	8,172	8,689	17,591	16,106
Total operating expenses	37,081	49,467	79,593	97,331
Income (loss) from operations	17,265	(22,544)	9,403	(44,555)
Interest income	83	261	180	662
Interest expense	(35)	(1)	(69)	(1)
Other income (expense), net	(1)	161	(68)	
Net income (loss) before benefit for income taxes	17,312	(22,123)	9,446	(43,894)
Benefit for income taxes		(31)		(62)
Net income (loss)	$ 17,312	$ (22,092)	$ 9,446	$ (43,832)
Net income (loss) per share:				
Basic	$ 0.71	$ (1.17)	$ 0.39	$ (2.48)
Weighted-average number of shares used in computing basic net income (loss) per share	24,219	18,894	24,076	17,698
Diluted	$ 0.70	$ (1.17)	$ 0.38	$ (2.48)
Weighted-average number of shares used in computing diluted net income (loss) per share	24,736	18,894	24,676	17,698

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)

	Six Months Ended June 30,	
	2010	**2009**
Cash flows from operating activities		
Net income (loss)	$ 9,446	$ (43,832)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Depreciation and amortization	1,110	999
Amortization of discount/premium on investments	380	38
Stock-based compensation expense	4,827	5,625
Gain on disposal of property and equipment		14
Other-than-temporary impairment on investments		133
Realized gain on investments	(695)	
Unrealized (gain) loss on auction rate securities rights	604	(49)
Changes in operating assets and liabilities:		
Receivable from Takeda	8,286	3,522
Income taxes receivable	1,318	355
Prepaid expenses and other current assets	239	23
Other assets	139	832
Accounts payable	2,003	4,527
Accrued liabilities	(1,066)	767
Accrued clinical trial expenses	(8,809)	5,787
Income taxes payable		(163)
Deferred revenue	(27,918)	(14,487)
Long-term income tax liability		13
Other long term liabilities	(5)	(59)
Net cash used in operating activities	(10,141)	(35,955)
Cash flows from investing activities		
Purchases of property and equipment	(323)	(518)
Purchases of investments	(80,479)	(4,337)
Proceeds from sales of investments	3,817	150
Proceeds from maturities of investments	26,961	50,050
Proceeds from sale of property and equipment		15
Net cash provided by (used in) investing activities	(50,024)	45,360
Cash flows from financing activities		
Repurchase of common stock		(1)
Proceeds from issuance of common stock upon exercise of stock options	2,233	461
Proceeds from issuance of common stock under employee stock purchase plan	628	107
Proceeds from common stock and warrants issued upon private placement, net of issuance costs		41,567
Repayment of UBS loan	(3,814)	
Net cash provided by (used in) financing activities	(953)	42,134

Net increase (decrease) in cash and cash equivalents		(61,118)		51,539
Cash and cash equivalents at beginning of the period		125,296		24,046
Cash and cash equivalents at end of the period	$	64,178	$	75,585

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. Our product candidate, Hematide TM/peginesatide (USAN or nonproprietary name), is a synthetic peptide-based erythropoiesis stimulating agent, or ESA, designed to stimulate production of red blood cells. As previously reported in our Current Report on Form 8-K dated June 21, 2010, we recently announced preliminary top-line results from the Hematide Phase 3 clinical program for the treatment of patients with anemia associated with chronic renal failure.

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 United States or 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. In February 2010, the Financial Accounting Standards Board, or FASB, amended certain recognition and disclosure requirements for events that occur after the balance sheet date but before financial statements are issued. We have evaluated subsequent events through the date the financial statements were issued and filed with the SEC. The financial information included herein should be read in conjunction with our Annual Report on Form 10-K for the year ended December 31, 2009, 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 Income (Loss)

Comprehensive income (loss) consists of net income (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 income (loss) for the three and six months ended June 30, 2010 and 2009 are as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2010	2009	2010	2009
Net income (loss)	$ 17,312	$ (22,092)	$ 9,446	$ (43,832)
Decrease (increase) in unrealized gains (losses) on investments	155	(65)	193	(436)
Reclassification adjustment for (gains) losses on investments recognized in earnings	(71)	(41)	(91)	83
Comprehensive income (loss)	$ 17,396	$ (22,198)	$ 9,548	$ (44,185)

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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 three 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. Although our guideline for investment of excess cash is designed to maintain safety and liquidity through our policies on diversification and investment maturity, as of June 30, 2010, we held fair value of investments in auction rate securities, or ARS, totaling $12.3 million that have failed in auctions and all were subsequently sold in July 2010.

At June 30, 2010, we had an accumulated deficit of $365.4 million. Due to the recognition of revenues from milestone payments from our collaboration with Takeda Pharmaceutical Company Limited, or Takeda, we were profitable in the three and six months ended June 30, 2010. Prior to the three and six month periods ended June 30, 2010, we had incurred net losses since our inception. We continue to expect to incur substantial additional operating losses for the next several years and will need to obtain additional financing in order to complete the development and commercialization of Hematide. In addition, we have generated no revenue from product sales to date and we have funded our operations to date principally from our collaboration agreements with Takeda and the sale of equity securities. There can be no assurance that such financing will be available or will be at terms acceptable to us.

Our accounts receivable balance contains receivables in connection with our two separate collaboration agreements, or the Arrangement, with Takeda. We have not experienced any credit losses from our Arrangement with Takeda and none are expected. We do not require collateral on our receivable.

We are currently developing our first product offering, Hematide, and have no products that have received regulatory approval. Hematide will require approval from the U.S. Food and Drug Administration, or FDA, and/or foreign regulatory agencies prior to commercial sales. There can be no assurance that Hematide 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 Hematide. There can be no assurance that Hematide can be developed successfully or manufactured at an acceptable cost and with appropriate performance characteristics, or that Hematide 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 Hematide from Nektar Therapeutics AL, Corporation are currently single-sourced, leaving us at greater risk of supply interruptions and potential delays.

Recent Accounting Pronouncements

In October 2009, the FASB issued Accounting Standards Update, or ASU, No. 2009-13, multiple deliverable revenue arrangements. This update provides amendments to the criteria in ASC Topic 605, *Revenue Recognition,* for separating consideration in multiple-deliverable arrangements by establishing a selling price hierarchy. The selling price used for each deliverable will be based on vendor-specific objective evidence, or VSOE, if available, third party evidence if VSOE is not available, or estimated selling price if neither VSOE nor third party evidence is

available. ASU No. 2009-13 also eliminates the residual method of allocation and requires that arrangement consideration be allocated at the inception of the arrangement to all deliverables using the relative selling price method. ASU No. 2009-13 is effective prospectively for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010. We are currently assessing the potential impact that the adoption of ASU No. 2009-13 will have on our financial statements.

In April 2010, the FASB issued ASU No. 2010-17, revenue recognition milestone method (Topic 605), which provides guidance on defining a milestone and determining when it may be appropriate to apply the milestone method of revenue recognition for research or development transactions. However, the FASB clarified that, even if the requirements in ASU No. 2010-17 are met, entities would not be precluded from making an accounting policy election to apply another appropriate accounting policy that results in the deferral of some portion of the arrangement consideration. ASU No. 2010-17 is effective on a prospective basis for milestones achieved in fiscal years, and interim periods within those years, beginning on or after June 15, 2010. Early adoption is permitted.

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We are currently assessing the potential impact that the adoption of ASU No. 2010-17 will have on our financial statements.

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 accretions 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 value has been below our cost basis and the current financial condition of the investee. We do not intend to sell an impaired security and it is not more likely than not that we will be required to sell the security before the recovery of its amortized cost basis. 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.

Revenue Recognition

We recognize revenue in accordance with the authoritative guidance, revenue recognition in financial statements. 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.

We evaluated the multiple elements under the combined single arrangement in accordance with the provisions of the guidance for revenue arrangements with multiple deliverables. We recognize revenue using the 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 include amounts due for upfront license fees, milestone payments earned, purchases of active pharmaceutical ingredient, or API, and reimbursement of development and commercial expenses. We had previously estimated the development period to end on January 1, 2011. Based on the announcement on June 21, 2010 of our top-line results from our Phase 3 clinical program, we re-evaluated our development period and determined that the development period is now estimated to end in the first half of 2011. The extension of the development period will result in the remaining deferred collaboration revenue to be recognized over a longer period. The change in estimate resulted in a decrease to revenue recognized by $961,000 or $0.04 per share for the three and six months ended June 30, 2010. During the development period, 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. Included in the reimbursable expense is the cost of API that we manufacture and supply to Takeda during the development period, which we will also supply during the commercialization period. Further changes in the estimated term of the development period could materially affect the amount of collaboration revenue recognized in future periods.

We have recognized $54.3 million and $26.9 million of collaboration revenue during the three months ended June 30, 2010 and 2009, respectively, and $89.0 million and $52.8 million for the six months ended June 30, 2010 and 2009, respectively. As of June 30, 2010, the amount receivable from Takeda was $10.3 million.

Clinical Trial Expense and Accruals

We record expense for estimated clinical study external costs, which are a significant component of research and development, or R&D, expense. These clinical trial costs were $10.1 million and $23.8 million during the three months ended June 30, 2010 and 2009, respectively, and $23.1 million and $48.2 million during the six months

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ended June 30, 2010 and 2009, respectively. Clinical studies are administered by third-party contract 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 represent 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.

There is a significant degree of estimation involved in quantifying the expense associated with the clinical trial activity. The complexity and magnitude of the activities and, as such, the expense can be significant and subject to frequent change, especially for our Phase 3 trials, which may require negotiation or amendment of our CRO contracts from time to time. The activities in our trials are performed globally, in many sites and countries, involving numerous CROs and third parties. If we do not receive complete and accurate information from the CRO or third parties on a timely basis or correctly estimate the outcome of negotiations or activity levels, we may have to record adjustments, which could potentially impact R&D expense in subsequent periods. During the three months ended March 31, 2010, we concluded negotiations and finalized amendments for activities completed in 2009 resulting in adjustments to estimates recorded in our expense for the year ended December 31, 2009. These changes in estimate decreased expense by $553,000 or $0.02 per share in the three months ended March 31, 2010. Additional changes in estimate may result as the reconciliation activities are completed on our clinical trials.

Net Income (Loss) Per Share

Basic net income (loss) per share is computed by dividing net income (loss) by the weighted-average number of shares of common stock outstanding during the period less the weighted-average unvested shares subject to repurchase, without consideration for potential common shares.

Diluted net income (loss) per share is computed similarly to basic net income (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 income (loss) per share when their effect is dilutive. The computations for basic and diluted net income (loss) per share were as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2010	2009	2010	2009
	(in thousands, except per share data)			
Numerator:				
Net income (loss) used in basic and diluted	$ 17,312	$ (22,092)	$ 9,446	$ (43,832)
Denominator:				
Weighted-average shares outstanding used in basic	24,219	18,895	24,076	17,699
Less: Weighted-average unvested shares subject to repurchase		(1)		(1)
Weighted-average number of shares used in computing basic net income (loss) per share	24,219	18,894	24,076	17,698
Dilutive effect of:				

Options to purchase common stock	388		455	
Common stock issuable pursuant to the 2006 Employee Stock Purchase Plan			2	
Restricted stock units	41		53	
Warrants to purchase common stock	88		90	
Weighted-average number of shares used in computing diluted net income (loss) per share	24,736	18,894	24,676	17,698
Basic net income (loss) per share	$ 0.71	$ (1.17)	$ 0.39	$ (2.48)
Diluted net income (loss) per share	$ 0.70	$ (1.17)	$ 0.38	$ (2.48)

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2010	2009	2010	2009
Options to purchase common stock	1,791	2,582	1,711	2,582
Common stock subject to repurchase		1		1
Common stock issuable pursuant to the 2006 Employee Stock Purchase Plan	1	13		13
Restricted stock units		107		107
Warrants to purchase common stock		426		426

3. Stock-Based Compensation

We recognized stock-based compensation expense related to employee and director stock options, restricted stock units and stock purchase rights of $2.9 million and $2.3 million for the three months ended June 30, 2010 and 2009, respectively, and $5.5 million and $4.8 million for the six months ended June 30, 2010 and 2009, respectively, under the authoritative guidance for share-based payments. As of June 30, 2010, unrecognized compensation costs related to employee and director stock options and restricted stock units totaled $21.2 million. The cost is expected to be recognized over a weighted-average amortization period of 1.87 years.

4. Investments and Fair Value Measurements

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

	As of June 30, 2010			
	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Other-Than-Temporary Impairment	Fair Value
Short-term investments:					
Certificates of deposit	$ 3,487	$	$	$	$ 3,487
Government securities	65,664	12	(14)		65,662
Auction rate securities	10,400			(1,898)	8,502
Total short-term investments	$ 79,551	$ 12	$ (14)	$ (1,898)	$ 77,651
Long-term investments:					
Government securities	$ 11,270	$ 49	$ (1)	$	$ 11,318
Auction rate securities	4,600			(786)	3,814
Total long-term investments	$ 15,870	$ 49	$ (1)	$ (786)	$ 15,132

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	As of December 31, 2009				
	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Other-Than-Temporary Impairment	Fair Value
Short-term investments:					
Certificates of deposit	$ 3,714	$	$	$	$ 3,714
Government securities	20,006	3			20,009
Auction rate securities	14,125			(2,556)	11,569
Total short-term investments	$ 37,845	$ 3	$	$ (2,556)	$ 35,292
Long-term investments:					
Government securities	$ 4,059	$	$ (58)	$	$ 4,001
Auction rate securities	4,800			(823)	3,977
Total long-term investments	$ 8,859	$	$ (58)	$ (823)	$ 7,978

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.

Effective January 2010, we adopted the provisions of the authoritative guidance for improving fair value disclosures. Our cash equivalents and investments, other than ARS, 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 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 represent quoted prices for similar investments in active markets or these inputs have been derived from observable market data. Our investments in ARS and ARS Rights are 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 UBS AG of Series C-2 ARS Rights, or ARS Rights, is an income approach, which we used a discounted cash flow analysis. As of June 30, 2010, there were no transfers in and out between the fair value hierarchy Level 1, Level 2 and Level 3 and there were no changes in our valuation technique. Our policy is to recognize transfers into or out of Level 3 classifications as of the actual date of the event or change in circumstances that caused the transfer.

ARS are structured to provide liquidity by an auction process that resets the applicable interest rate at predetermined calendar intervals, usually every 28 days but have stated or contractual maturities that are generally greater than one year. Through mid-February 2008, every auction reset date of the ARS held by us was successful. In mid-February, overall market liquidity concerns resulted in the failure of a majority of the auctions in the ARS

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markets, which continued until the current date. The majority of the ARS held by us continue to pay interest, most recently in a range of 1-3%, though certain student loan issuances are temporarily at a zero coupon rate due to the particular interest provisions of the issuances. The ARS held by us are rated A through AAA by a major credit rating agency. Our sales or redemptions of ARS through June 30, 2010 have not resulted in any loss of principal, except for a $62,000 loss of par value upon acceptance of a tender offer below market.

As of June 30, 2010, our $15.0 million of par value of ARS were comprised of $12.4 million of municipal issuances that are collateralized by student loans guaranteed by the U.S. government under the Federal Family Education Loan Program and a $2.6 million closed end preferred issuance, all of which were subsequently sold in July 2010. We exercised our ARS Rights on June 30, 2010 which resulted in repurchase by UBS of the ARS at par of $10.4 million on July 1, 2010. In July, we also sold our long-term ARS securities with a par value of $4.6 million for $3.7 million which resulted in a loss of $158,000 of fair value upon acceptance of a tender offer below market. We currently do not maintain any ARS in our investment portfolio.

As a result of the continued auction market failures, quoted prices in active markets are not available. Due to the lack of observable inputs, we determined the fair value of our ARS at June 30, 2010 using a discounted cash flow analysis. The analysis considers, among other things, the amount and timing of coupon payments, contractual terms, underlying collateralization and credit risk. In addition, we included in our analysis an illiquidity factor to estimate the discount necessary to sell a security for which there is no active market. The analysis considers that issuers have continued to meet interest payment obligations and are expected to continue to do so at levels consistent with issuer s credit risk. The analysis is based on dynamic market conditions and changes in our assumptions could lead to a significant change in determined value. Our analysis resulted in no net decrease in fair value of ARS for the six months ended June 30, 2010. For the six months ended June 30, 2009, our analysis resulted in a net decrease in fair value of ARS totaling $160,000 that was deemed to be other-than-temporary and was recorded as impairment charges to other income (expense) net. Upon sale or redemption, the other-than-impairment charges were reversed to the extent that the proceeds from the sale or redemption exceeded the fair value of the ARS. We reversed other-than-temporary impairment charges of $695,000 and $27,000 for the six months ended June 30, 2010 and 2009, respectively.

As a result of a settlement between various regulatory agencies, including the SEC, and UBS entities relating to sales and marketing practices of ARS, in October 2008, we received an offer from ARS Rights in connection with the $10.4 million of par value of ARS as of June 30, 2010 that were purchased through UBS. In November 2008, we accepted the terms of the ARS Rights and delivered the required legal release of claims against the UBS entities. These ARS Rights give us the option to require UBS to repurchase, at par, the ARS beginning on June 30, 2010, which we exercised on June 30, 2010 as described above. In connection with the ARS Rights, UBS also offered, through UBS Financial Services, Inc., an affiliate of UBS AG, a loan facility that allows draws of up to 75% of the stated value of our ARS portfolio, as determined by UBS Financial Services, Inc. In December 2009, we obtained a loan of approximately $9.2 million, which was secured by the ARS and ARS Rights as collateral. See Note 5 to our Condensed Financial Statements UBS Loan. As of June 30, 2010, the balance of the loan was $5.4 million and classified as short-term debt, which we repaid as part of our ARS Rights cash settlement on July 1, 2010.

We determined that the ARS Rights do not meet the definition of a derivative security as described in the authoritative guidance for accounting for derivative instruments and hedging activities because the ARS Rights are non-transferrable, and we must tender the related ARS to receive the cash settlement. Therefore, we elected to measure the ARS Rights separately under the authoritative guidance pertaining to the fair value option for financial assets and financial liabilities in order to partially offset the changes in the fair value of the ARS to the ARS Rights. We did not elect to adopt the guidance for the fair value option for financial assets and financial liabilities to measure financial instruments, except for the ARS Rights. We determined the fair value of our ARS Rights using a discounted cash flow analysis based on, among other things, the timing and likelihood of the recovery of the par value of the ARS from UBS. Our analysis resulted in no net increase in the fair value of our ARS Rights for the six months ended June 30, 2010. For the six months ended June 30, 2009, our analysis resulted in a net increase in the fair value of our ARS Rights of $57,000 and was recorded as an other current asset with a corresponding credit to other income (expense), net. Upon sale or redemption of the related ARS, the fair value of our ARS Rights was decreased by $604,000 and $8,000 for the six months ended June 30, 2010 and 2009, respectively, and was recorded as a charge to other income (expense), net.

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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 June 30, 2010			
		Fair Value Measurements Using		
	Total	Level 1	Level 2	Level 3
Cash equivalents	$ 58,165	$ 34,673	$ 23,492	$
Short-term investments:				
Certificates of deposit	$ 3,487	$	$ 3,487	$
Government securities	65,662		65,662	
Auction rate securities	8,502			8,502
Total short-term investments	$ 77,651	$	$ 69,149	$ 8,502
Long-term investments:				
Government securities	$ 11,318	$	$ 11,318	$
Auction rate securities	3,814			3,814
Total long-term investments	$ 15,132	$	$ 11,318	$ 3,814
ARS Rights	$ 1,733	$	$	$ 1,733

	As of December 31, 2009			
		Fair Value Measurements Using		
	Total	Level 1	Level 2	Level 3
Cash equivalents	$ 112,510	$ 102,216	$ 10,294	$
Short-term investments:				
Certificates of deposit	$ 3,714	$	$ 3,714	$
Government securities	20,009		20,009	
Auction rate securities	11,569			11,569
Total short-term investments	$ 35,292	$	$ 23,723	$ 11,569
Long-term investments:				
Government securities	$ 4,001	$	$ 4,001	$
Auction rate securities	3,977			3,977
Total long-term investments	$ 7,978	$	$ 4,001	$ 3,977
ARS Rights	$ 2,337	$	$	$ 2,337

The following table presents changes in Level 3 investments measured at fair value on a recurring basis for the six months ended June 30, 2010 and 2009 (in thousands):

	Six Months Ended June 30,	
	2010	2009
Balance at beginning of the period	$ 17,883	$ 20,026
Transfers in and/or out of Level 3		
Total unrealized losses related to ARS Included in net income (loss)		(160)
Total realized gains related to ARS Included in net income (loss)	695	27
Total unrealized losses related to ARS Rights Included in net income (loss)	(604)	(8)
Total unrealized gains related to ARS Rights Included in net income (loss)		57
Settlements	(3,925)	(150)
Balance at end of the period	$ 14,049	$ 19,792

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5. 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. In December 2009, we obtained a loan of approximately $9.2 million, the full available amount, which was secured by the ARS. The loan amount was based on 75% of the fair value of the ARS as assessed by UBS at the time of the loan. This no net cost loan bears interest at a rate that will not exceed the average rate of interest paid on the pledged ARS such that the net interest cost to us will be zero As of June 30, 2010, the balance of the loan was $5.4 million and classified as short-term debt. As described above, we repaid the loan on July 1, 2010 as part of our ARS Rights cash settlement on July 1, 2010.

As required by UBS, we applied the net interest received in and the proceeds from the sales and redemptions of ARS to the principal of the loan. For the three months ended June 30, 2010, we paid $29,000 of interest expense associated with the loan and received $42,000 in interest income from the collateralized ARS. For the three months ended June 30, 2010, the net interest earned of $13,000 and $3.7 million from sales and redemptions was applied to the principal of the loan. For the six months ended June 30, 2010, we paid $54,000 of interest expense associated with the loan and received $143,000 in interest income from the collateralized ARS. For the six months ended June 30, 2010, the net interest earned of $89,000 and $3.7 million from sales and redemptions was applied to the principal of the loan. The carrying amount of the loan with UBS approximates its fair value due to the loan s short-term nature.

6. Contingencies

We have initiated binding arbitration and related litigation with Johnson & Johnson, Ortho-McNeil Pharmaceutical, Inc., Ortho Pharmaceutical Corporation, The R.W. Johnson Pharmaceutical Research Institute and Johnson & Johnson Pharmaceutical Research and Development, L.L.C., or, collectively, J&J, over ownership of intellectual property related to certain erythropoietin receptor, or EPO-R, agonists (ESA compounds capable of binding to and activating the EPO-R). This intellectual property is the subject of a number of U.S. and international patents and patent applications assigned to us and/or J&J, including a U.S. patent currently assigned to J&J, several U.S. patents currently assigned to us and a European patent application currently assigned to J&J that may issue in the near future and relates to specified ESA peptide compounds (J&J s European Patent Application). In this section, we refer to the patents and patent applications subject to the arbitration collectively as the intellectual property in dispute. We believe that we are the sole owner or co-owner of the intellectual property in dispute, including J&J s European Patent Application. J&J, on the other hand, alleges that they are the sole owner or co-owner of the intellectual property in dispute, including several U.S. patents on which we are currently named as sole owner that relate to specified ESA peptide compounds.

In June 2004, we filed a civil complaint in the Munich Regional Court in the Federal Republic of Germany against J&J alleging that we are an owner or co-owner of J&J s European Patent Application and other related technology. In October 2005, J&J filed its response to our complaint, denying our claims of inventorship and ownership. In April 2006, we requested the court to dismiss the complaint so that the issues it raised could be resolved pursuant to the arbitration proceeding described below. The court has done so.

In September 2004, we filed a civil complaint in the U.S. District Court for the Northern District of Illinois, or the Illinois case, against J&J alleging claims for correction of inventorship and ownership of the above-referenced patents and patent applications assigned to J&J, for corresponding declaratory and injunctive relief, for breach of contract, and for unjust enrichment and constructive trust. The complaint alleges that the Affymax Research Institute scientists are sole or co-inventors of the intellectual property in dispute, including the above-referenced J&J patents and patent applications, and that we are the sole or co-owner of them. The complaint also alleges that J&J breached the three-year Research and Development Agreement or the R&D Agreement between Affymax N.V. and a division of Ortho Pharmaceutical Corporation, a

subsidiary of J&J, by, among other things, engaging in a course of conduct designed to obtain patents for itself and to deny Affymax N.V. patents on its scientists inventions. The complaint

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further alleges that we have suffered damages as a result of J&J s breaches and that J&J has been unjustly enriched through its misconduct and should be subject to the imposition of a constructive trust.

J&J denied all material claims in our complaint and, among other things, counterclaimed that its employees are the true inventors of the intellectual property in dispute and that it is therefore entitled to sole or co-ownership of the above-referenced patents and patent applications assigned solely or jointly to us. J&J also brought related claims for breach of contract, breach of fiduciary duty, unjust enrichment and constructive trust. J&J alleges, among other things, that Affymax N.V., Affymax Technologies, N.V. and Affymax Research Institute, or the Affymax Entities, filed in their own name certain patent applications allegedly claiming inventions of J&J employees without notifying or consulting with J&J, that during patent prosecution the Affymax Entities improperly removed the names of J&J employees from certain patent applications on which those employees had been identified as inventors, and that these and other alleged breaches entitle J&J to damages and waive all rights we may have had to the intellectual property in dispute.

J&J requested that the Illinois case be dismissed and the matter decided under the R&D Agreement s arbitration provisions. In February 2006, the Illinois court entered an order that the appropriate forum for us and J&J to resolve the inventorship, ownership, breach of contract and related claims was binding arbitration under the American Arbitration Association, or AAA, rules in Illinois. The Illinois court held that the claims pending in the German court were also subject to arbitration and required us to dismiss the German complaint, which we have done. The Illinois court further stated that it will retain jurisdiction over the subject matter during the arbitration in Illinois.

In April 2006, we filed a demand for arbitration with the AAA claiming that we are the owner or co-owner of the intellectual property in dispute and alleging claims for correction of inventorship and ownership of the above-referenced patents and patent applications assigned to J&J, for corresponding declaratory and injunctive relief, for breach of contract, for unjust enrichment and constructive trust, and for breach of fiduciary duty. In May 2006, J&J filed its answer and counterclaims, substantially restating their allegations made in the U.S. and German courts. The AAA appointed a panel of arbitrators, and the arbitration has commenced.

In June 2007, J&J filed a motion to compel discovery of information relating to Hematide and then filed a substitute motion to compel. In July 2007, we filed an opposition to J&J s motion to compel and a motion for protective order. In September 2007, the arbitrators ruled that J&J could obtain limited discovery on Hematide, but that J&J could not obtain discovery on Hematide product formulas, sequences, laboratory notebooks containing such information, experimental results, clinical trial results and strategies, or internal business planning. The arbitration hearing is near completion and the decision is expected in second half of 2010. The outcome of the matter is uncertain and regardless of outcome, the matter may have an adverse impact on us because of legal costs, diversion of management resources and other factors.

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.

7. Development and Commercialization Agreements with Takeda

In February 2006, we granted an exclusive license to Takeda for development and commercialization of Hematide in Japan. Pursuant to this agreement, Takeda paid us approximately $27 million, consisting of $17 million in upfront licensing fees and approximately $10 million for the purchase of equity. In January 2007, Takeda paid us a $10 million cash milestone payment for the completion of the first Phase 1 trial of

Hematide in Japan. In March 2010, Takeda paid us a $5 million cash milestone payment for the initiation of Japan s Phase 3 renal indication. In addition, we are eligible to receive clinical and regulatory milestone payments of up to an aggregate of $60 million upon Takeda s successful achievement of clinical development and regulatory milestones in Japan. Takeda is responsible for all development and commercialization costs in Japan and will purchase the API for Hematide from us. Assuming Hematide is approved and launched in Japan, we will receive a royalty from Takeda on Hematide sales in Japan.

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In June 2006, the parties expanded their collaboration to develop and commercialize Hematide worldwide, which includes the co-development and co-commercialization of Hematide in the U.S. Takeda received an exclusive license to develop and commercialize Hematide outside of the U.S. Takeda bears 70% of the third party U.S. development expenses while we are responsible for 30% of the expenses. We retain responsibility for 100% of our internal development expenses. In addition, third party expenses related to the commercialization of Hematide in the U.S. are equally shared by both parties. Certain employee expenses related to commercialization will also be equally shared, which we expect to occur in the first half of 2011. Takeda will have primary responsibility and bear all costs for Hematide clinical development in support of regulatory approval for all territories outside the U.S. Under the June 2006 agreement, Takeda paid us an upfront license fee of $105 million. In May 2010, Takeda paid us a $15 million milestone payment for database lock of the non-dialysis Phase 3 clinical trials and in June 2010, Takeda paid us an additional $15 million milestone payment for database lock of the dialysis Phase 3 clinical trials. We are eligible to receive from Takeda a $10 million milestone payment upon FDA acceptance of the submission of the New Drug Application, or NDA, for the dialysis indication and an additional $50 million milestone payment upon approval by the FDA for dialysis as the first renal indication as well as $25 million milestone payments for clinical development and regulatory milestones for the dialysis indication for territories outside the U.S. In addition to milestone payments for dialysis as the first renal indication, to the extent we pursue other indications, an aggregate of approximately $165 million of milestone payments may be payable to us by Takeda upon the successful achievement of clinical development and regulatory milestones of which $75 million relate to the non-dialysis indication as a second renal indication (including $10 million milestone payments upon FDA acceptance of the submission of NDA and $45 million of milestone payments upon approval by the FDA) and the remainder of milestones relate to oncology indications. Further, we may receive from Takeda up to an aggregate of $150 million upon the achievement of certain worldwide annual net sales milestones. We and Takeda will share equally in the net profits and losses of Hematide in the U.S., which include expenses related to the marketing and launch of Hematide. Takeda will pay us a variable royalty based on annual net sales of Hematide outside the U.S. The arrangement establishes a joint steering committee to oversee the development, regulatory approval and commercialization of Hematide.

We share responsibility with Takeda for clinical development activities required for U.S. regulatory approval of Hematide. Specifically, we have primary responsibility for Hematide s clinical development plan and clinical trials in the dialysis and non-dialysis indications, 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 Hematide to treat chemotherapy-induced anemia and to focus all development efforts for Hematide on the treatment of chronic renal failure anemia. We are responsible for U.S. regulatory filings in the dialysis, non-dialysis, chemotherapy induced anemia and anemia of cancer indications, 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.

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

The parties have agreed to jointly develop the initial commercial marketing plan for Hematide in the U.S. pursuant to which we and Takeda will divide Hematide 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 any backup products for Hematide developed by us or our third-party partners. Specifically, during the first ten years of the agreement, if we or third-party partners develop a product that advances to Phase 2 clinical trials and competes with Hematide 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.

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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, 2009 and our unaudited condensed financial statements for the three and six month periods ended June 30, 2010.

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, plan, anticipate, believe, estimate, project, predict, potential and similar expressions intended to identify forward-looking statements. These forward-looking statements include statements regarding the timing, design and results of our clinical trials, drug development program and registration strategy, the continuation and success of our collaboration with Takeda, and the timing and likelihood of the commercialization of Hematide. 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 timing of and regulatory requirements for approvals, including the FDA s interpretation of the data from the Phase 3 studies, in particular with respect to the secondary analyses in the non-dialysis patients, risks relating to the continued safety and efficacy of Hematide 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 Hematide, industry and competitive environment, controversy surrounding the class of erythropoiesis stimulating agents, reimbursement coverage, intellectual property rights and disputes, 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. Our product candidate, Hematide TM/peginesatide, is designed to treat anemia associated with chronic renal failure. Anemia is a serious condition in which blood is deficient in red blood cells and hemoglobin. It is common in patients with chronic renal failure, 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 cancer patients. According to IMS Health Incorporated, rEPO generated $6.3 billion in the United States or U.S. revenues for 2009, of which we estimate that over one-half is attributable to use of rEPO in patients with chronic renal failure, and the remainder is attributable to other indications, primarily cancer patients. Hematide is a synthetic peptide-based erythropoiesis stimulating agent, or ESA, designed to stimulate production of red blood cells. Hematide is designed to be longer acting than currently marketed ESAs in the U.S. and therefore has the potential to offer both better care for patients and reduced cost and complexity for healthcare providers.

In late June 2010, we announced preliminary top-line results from the Hematide Phase 3 clinical program for the treatment of patients with anemia associated with chronic renal failure. Our Phase 3 clinical program included four open-label, randomized controlled clinical trials. Of these trials, two trials, called PEARL 1 and PEARL 2,

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were conducted in non-dialysis patients and designed to evaluate the safety and efficacy of Hematide 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 Hematide and its ability to maintain hemoglobin levels in a corrected range compared to epoetin alpha or epoetin beta when switched to Hematide. Analysis of efficacy and safety for all of the Phase 3 studies were based 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, Hematide met the statistical criterion for non-inferiority for the assessment of safety for the cardiovascular composite safety endpoint (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.

We are continuing to conduct further analysis of the PEARL and EMERALD studies which evaluated the efficacy and safety of Hematide in chronic renal failure patients with anemia. Before year end, we plan to discuss with the U.S. Food and Drug Administration, or FDA, the U.S. registration strategy for Hematide. Subject to feedback from the FDA, the plan is to pursue a New Drug Application, NDA, for treatment of anemia in dialysis patients, while continuing to evaluate the non-dialysis indication. The timeline for possible submission of the NDA will be aimed for first half of 2011, but will be finalized after the FDA meeting.

Despite meeting the primary efficacy endpoints and the CSE for Hematide, the differences observed in the Phase 3 secondary analyses present risks to our ability to obtain regulatory approval for Hematide particularly in the non-dialysis setting due to the heightened concerns surrounding safety of ESAs. Further, any negative perception of Hematide s safety relative to other ESAs would significantly limit the likelihood of obtaining regulatory approval for Hematide. 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 Hematide.

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. Prior to the three and six month periods ended June 30, 2010, we had incurred net losses since our inception. However, due to the recognition of revenues from milestone payments from our collaboration with Takeda Pharmaceutical Company Limited, or Takeda, we were profitable in the three and six months ended June 30, 2010 and may have profitable quarters from time to time. We continue to expect to incur substantial and increasing losses for the next several years in order to complete the development and commercialization of Hematide. As of June 30, 2010, we had an accumulated deficit of $365.4 million.

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 12 months. However, we expect that we will need to raise additional funding to complete the development and commercialization of Hematide. Since the announcement in late June 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 need to raise funding has only increased as the Hematide development program has suffered delays and due to the reduction of potential milestone payments from Takeda associated with the non-dialysis indication. As we continue to analyze the data, we may experience further challenges or delays to approval of Hematide if issues arise or additional requirements are imposed based on our discussions with the FDA.

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 and the issues arising from our Phase 3 results 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

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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 Hematide. 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, which could negatively impact our ability to complete development or commercialize Hematide. We may seek to raise additional funds through public or private financing, strategic partnerships or other arrangements. Any additional equity financing, particularly at our recent stock trading levels, would be difficult to obtain, if accessible at all, and our current stockholders may be significantly diluted. Further, our equity facility with Azimuth Opportunity Ltd., or Azimuth, is subject to a number of conditions that limit our ability to draw against such facility as our stock price has fallen below the minimum price established under the facility. Any debt financing, if available, may involve restrictive covenants or security interests in our assets. 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.

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 United States or U.S. generally accepted accounting principles, or GAAP. The preparation of these condensed financial statements requires us to make estimates and assumptions 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, 2009.

Results of Operations

Revenue

	Three Months Ended June 30,			Six Months Ended June 30,		
	2010	2009	% Increase/ (Decrease)	2010	2009	% Increase/ (Decrease)
	(in thousands, except percentages)					
Collaboration revenue	$ 54,341	$ 26,918	102%	$ 88,987	$ 52,767	69%
License and royalty revenue	5	5	%	9	9	%
Total revenue	$ 54,346	$ 26,923	102%	$ 88,996	$ 52,776	69%

We have recognized $54.3 million and $26.9 million of collaboration revenue during the three months ended June 30, 2010 and 2009, respectively, and $89.0 million and $52.8 million for the six months ended June 30 2010 and 2009, respectively. The increase in collaboration revenue for the three and six months ended June 30, 2010 compared to the three and six months ended June 30, 2009 was due to the continued

amortization of collaboration revenue under the Contingency-Adjusted Performance Model, or CAPM, from expense reimbursements and milestones received from Takeda in prior periods and increased recognition of payments received or due from Takeda in the current period as the estimated remaining development period continued to decrease prior to the changes in the estimated development period described below. In March 2010, we received a $5 million cash milestone payment from Takeda for the initiation of Japan s Phase 3 renal indication. In May 2010, Takeda paid us a $15 million milestone payment for database lock of the Phase 3 non-dialysis clinical trials and in June 2010, Takeda paid us an additional $15 million milestone payment for database lock of the dialysis Phase 3 clinical trials.

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We had previously estimated the development period to end on January 1, 2011. Based on the announcement on June 21, 2010 of our top-line results from our Phase 3 clinical program, we re-evaluated our development period and determined that the development period is now estimated to end in the first half of 2011. The change in estimate resulted in a decrease to revenue recognized by $961,000 or $0.04 per share for the three and six months ended June 30, 2010. The extension of the development period will result in the remaining deferred collaboration revenue to be recognized over a longer period. Further changes in the estimated term of the development period could materially affect the amount of collaboration revenue recognized in future periods. 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 June 30,			Six Months Ended June 30,		
	2010	2009	% Increase/ (Decrease)	2010	2009	% Increase/ (Decrease)
	(in thousands, except percentages)					
Research and development expenses	$ 28,909	$ 40,778	(29)%	$ 62,002	$ 81,225	(24)%

The decrease in research and development expenses for the three and six months ended June 30, 2010 compared to the three and six months ended June 30, 2009 was primarily due to the completion of the treatment and follow up of our Phase 3 clinical trials at the start of 2010 and we expect such expenses in 2010 to continue to remain below 2009 levels.

General and Administrative Expenses

	Three Months Ended June 30,			Six Months Ended June 30,		
	2010	2009	% Increase/ (Decrease)	2010	2009	% Increase/ (Decrease)
	(in thousands, except percentages)					
General and administrative expenses	$ 8,172	$ 8,689	(6)%	$ 17,591	$ 16,106	9%

The decrease in general and administrative expenses for the three months ended June 30, 2010 compared to the three months ended June 30, 2009 was primarily due to lower legal fees. The increase in general and administrative expenses for the six months ended June 30, 2010 compared to the six months ended June 30, 2009 was due to higher external commercial expenses. We expect to incur increasing general and administrative expenses in future periods to support our preparation for the NDA for Hematide and expansion of commercial capabilities.

Interest Income (Expense), Net

	Three Months Ended June 30,			Six Months Ended June 30,		
	2010	2009	% Increase/ (Decrease)	2010	2009	% Increase/ (Decrease)

	(in thousands, except percentages)					
Interest income (expense), net	$ 48	$ 260	(82)%	$ 111	$ 661	(83)%

The decrease in interest income, net, was due primarily to lower interest rates during the three and six months ended June 30, 2010 compared to the same periods in 2009.

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Other Income (Expense), Net

	Three Months Ended June 30,			Six Months Ended June 30,		
	2010	2009	% Increase/ (Decrease)	2010	2009	% Increase/ (Decrease)
	(in thousands, except percentages)					
Other income (expense), net	$ (1)	$ 161	(101)%	$ (68)	$	(100)%

Other income (expense), net, for the three and six months ended June 30, 2009 primarily includes the other-than-temporary impairment charge related to the decrease in fair value of our investments in auction rate securities, or ARS, in comparison to the three and six months ended June 30, 2010 which only reflects the subsequent adjustment to fair value. We do not intend to sell an impaired security and it is not more likely than not that we will be required to sell the security before the recovery of its amortized cost basis. 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.

Benefit for Income Taxes

	Three Months Ended June 30,			Six Months Ended June 30,		
	2010	2009	% Increase/ (Decrease)	2010	2009	% Increase/ (Decrease)
	(in thousands, except percentages)					
Benefit for income taxes	$	$ (31)	100%	$	$ (62)	100%

We are subject to federal and California state income taxes. We anticipate being in a net operating loss position for 2010 and therefore have not recorded any federal or California tax liability for the three and six months ended June 30, 2010. We were also in a taxable loss position for the year ended December 31, 2009 and therefore did not record any federal and state tax liability for the three and six months ended June 30, 2009. We recorded $31,000 and $62,000 of federal tax benefit for the three and six months ended June 30, 2009, respectively, due to a research and development credit refund available to us pursuant to a provision within the American Recovery and Reinvestment Tax Act of 2009.

Liquidity and Capital Resources

	June 30, 2010	December 31, 2009
	(in thousands)	
Cash, cash equivalents, short-term investments	$ 141,829	$ 160,588
Working capital	$ 68,020	$ 57,018
Long-term investments	$ 15,132	$ 7,978

	Six Months Ended June 30,	
	2010	2009
	(in thousands)	

Cash provided by (used in):				
Operating activities	$	(10,141)	$	(35,955)
Investing activities	$	(50,024)	$	45,360
Financing activities	$	(953)	$	42,134
Capital expenditures (included in investing activities above)	$	(323)	$	(518)

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 June 30, 2010, we have received net

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proceeds of $261.6 million from the issuance of equity securities, $122 million of upfront license fees, $45 million in milestone payments and $209.0 million for the reimbursement of development and commercial expenses and purchase of API from our collaboration agreements with Takeda. Takeda bears 70% of the third party U.S. development expenses, while we are responsible for 30% of the expenses. We retain responsibility for 100% of our internal development expenses. Certain employee expenses related to commercialization will also be equally shared, which we expect to occur in the first half of 2011.

Net cash used in operating activities for the six months ended June 30, 2010 and 2009 reflects net income (loss) for the periods generated primarily by the development of Hematide. The net income (loss) for the six months ended June 30, 2010 and 2009 were reduced in part by non-cash activities including stock-based compensation, depreciation and amortization. The six months ended June 30, 2009 reflects the benefit of increasing liabilities due to the lag in payments relative to expense of our Phase 3 clinical trials for Hematide in comparison to the six months ended June 30, 2010, which includes the payment of a portion of our accrued clinical trial expenses. In addition to the reimbursement received from Takeda, we received a $5 million cash milestone payment for the initiation of Japan s Phase 3 renal indication during the first six months of 2010 and $30 million milestone payments for database lock of the non-dialysis and dialysis Phase 3 clinical trials. Due to the recognition of revenue from these milestone payments, we were profitable in the six months ended June 30, 2010, but we expect to incur substantial additional operating losses for the next several years. We are eligible to receive additional clinical development and regulatory milestones from Takeda of approximately $85 million relating to dialysis as the first renal indication, including $10 million milestone payments upon FDA acceptance of the submission of the NDA and $50 million of milestone payments upon approval by the FDA. Further, we may receive from Takeda up to an aggregate of $150 million upon the achievement of certain worldwide annual net sales milestones.

Net cash used in investing activities for the six months ended June 30, 2010 and provided by for the six months ended June 30, 2009 was a result of maturities and sales of investments offset by the net purchase of investments using the proceeds from our financings and purchases of capital expenditures.

Net cash used in financing activities for the six months ended June 30, 2010 was primarily attributable to the proceeds from issuance of common stock upon exercise of stock options and the purchase of common stock under our Employee Stock Purchase Plan offset by repayment of $3.8 million towards the UBS loan. Net cash provided by financing activities for the six months ended June 30, 2009 was primarily attributable to the $41.6 million of net proceeds from the private placement, proceeds from issuance of common stock upon exercise of stock options and the purchase of common stock under our Employee Stock Purchase Plan offset by principal payments under the capital lease obligations. The private placement also included warrants to purchase 423,971 shares of common stock at $16.78 that are exercisable and expire in March 2014.

In September 2009, we entered into a common stock purchase agreement, sometimes referred to as an equity line of credit arrangement, with Azimuth that provides that, upon the terms and subject to the conditions set forth in the purchase agreement, Azimuth is committed to purchase up to $60.0 million worth of shares of our common stock over the 24-month term of the purchase agreement which ends October 1, 2011. The per share purchase price for these shares equals the daily volume weighted average price of our common stock on each date during the Azimuth draw down period on which shares are purchased, less a discount ranging from 3.75% to 5.75%, based on a minimum price of $8.00 as specified in the agreement. In addition, we are required to pay Reedland Capital Partners a placement fee equal to 1% of the aggregate dollar amount of common stock purchased by Azimuth. Our equity facility is subject to a number of conditions that limit our ability to draw against such facility. For example, 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 or 2,411,638 shares as of June 30, 2010. Azimuth is not required to purchase our common stock when the price of our common stock is below $8.00 per share. Even if such $8.00 per share minimum was inapplicable or waived and assuming that all 2,411,638 shares were sold at the $5.98 closing price of our common stock at June 30, 2010 at the largest possible discount, the maximum aggregate net proceeds we could receive under the agreement with Azimuth would be approximately $13.4 million. There have been no purchases by Azimuth under the facility to date.

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As of June 30, 2010, we had $157.0 million in unrestricted cash, cash equivalents and short-term and long-term 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, money market funds and ARS. Cash in excess of immediate requirements is invested in accordance with our investment policy primarily with a view to liquidity and capital preservation.

Included in our investments as of June 30, 2010 were ARS with a fair value totaling $12.3 million that were comprised of municipal issuances that are collateralized by student loans guaranteed by the U.S. government under the Federal Family Education Loan Program and a closed end preferred issuance, all of which were sold in July 2010. We exercised our UBS AG of Series C-2 ARS Rights, or ARS Rights, on June 30, 2010 which resulted in repurchase by UBS of the ARS at par of $10.4 million on July 1, 2010. In July also, we sold our long-term ARS securities with a par value of $4.6 million for $3.7 million which resulted in a loss of $158,000 of fair value upon acceptance of a tender offer below market. We currently do not maintain any ARS in our investment portfolio.

The ARS held by us are rated A through AAA by a major credit rating agency. ARS are structured to provide liquidity by an auction process that resets the applicable interest rate at predetermined calendar intervals, usually every 28 days but have stated or contractual maturities that are significantly greater than one year. The overall ARS market deteriorated in early 2008, and the ARS held by us have failed in all but a single auction since mid-March 2008.

We determined the fair value of our ARS at June 30, 2010 using a discounted cash flow analysis. The analysis considers, among other things, the amount and timing of coupon payments, contractual terms, underlying collateralization and credit risk. In addition, we included in our analysis an illiquidity factor to estimate the discount necessary to sell a security for which there is no active market. The analysis considers that issuers have continued to meet interest payment obligations and are expected to continue to do so at levels consistent with issuer s credit risk. Our analysis resulted in a net decrease in fair value of ARS totaling $2.7 million through June 30, 2010. The decrease in fair value was deemed to be other-than-temporary and was recorded as an impairment charge to other income (expense), net. We do not intend to sell an impaired security and it is not more likely than not that we will be required to sell the security before the recovery of its amortized cost basis. Our analysis is based on dynamic market conditions and further deterioration in the ARS markets or changes in our assumptions could lead to significant reductions in determined value thus resulting in impairments in future periods.

In November 2008, UBS AG issued us ARS Rights in connection with the $10.4 million of par value of ARS we own as of June 30, 2010. The ARS Rights are not transferable and give us the option to require UBS to repurchase, at par, our ARS beginning on June 30, 2010 which we exercised on June 30, 2010 as described above. We determined the value of the ARS Rights was $1.7 million as of June 30, 2010 using a discounted cash flow analysis based on, among other things, the timing and likelihood of the recovery of the par value of the ARS from UBS. We recorded the fair value of the ARS Rights as an other current asset with a corresponding credit to other income (expense), net, partially offsetting the unrecognized losses incurred to date on the related ARS. We anticipate that future changes in the fair value of the ARS Rights will be offset by the changes in the fair value of related ARS with no material net impact to net income (loss). In connection with ARS rights, UBS made available loans to eligible borrowers. In December 2009, we obtained a loan from UBS Financial Services, Inc., an affiliate of UBS AG, of approximately $9.2 million, which was secured by the ARS and ARS Rights as collateral. See Note 5 to our Condensed Financial Statements UBS Loan. As of June 30, 2010, the balance of the loan was $5.4 million and classified as short-term debt, which we repaid as part of our ARS Rights cash settlement on July 1, 2010.

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 12 months. However, we expect that we will need to raise additional funding to complete the development and commercialization of Hematide. Since the announcement in late June 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 need to raise funding has only increased as the Hematide development program has suffered delays and due to the reduction of potential milestone payments from Takeda associated with the non-dialysis

indication. As we continue to analyze the data, we may experience further challenges or delays to approval of Hematide if issues arise or additional requirements are imposed based on our discussions with the FDA. Our current view of the worldwide capital markets is that they are extremely volatile

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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 Hematide. 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 development activities including pre-clinical studies and clinical trials for Hematide;
- our ability to maintain and achieve milestones under our collaboration agreements with Takeda;
- costs of litigation;
- outcome, timing and cost of obtaining 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 sales, marketing and distribution capabilities;

- cost of procuring clinical and commercial supplies of Hematide 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.

Contractual Obligations and Significant Commitments

Our future contractual obligations at June 30, 2010 were as follows:

		Payments Due by Period			
Contractual Obligations	**Total**	**Less Than 1 Year**	**1-3 Years**	**3-5 Years**	**More than 5 Years**
			(in thousands)		
Operating lease obligations (1)	$ 15,954	$ 1,485	$ 7,462	$ 7,007	$
Long-term income tax liability (2)	9,425				
UBS loan (3)	5,378	5,378			
Total fixed contractual obligations	$ 30,757	$ 6,863	$ 7,462	$ 7,007	$

(1) In May 2010, we entered into an amendment of our lease agreement for additional office space in Palo Alto, California. The total square footage covered by the lease amendment is approximately 28,709 square feet, of which we lease 10,794 square

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feet starting in the third quarter of 2010, 1,570 square feet starting in January 2011 and the remaining 16,345 square feet starting in May 2011 until the end of the lease term in September 2014.

(2) With respect to our long-term income tax liability as of June 30, 2010, we were unable to make a reasonably reliable estimate of the period of cash settlement, if any, with the respective taxing authorities.

(3) The loan with UBS is classified as short-term debt, which we repaid as part of our ARS Rights cash settlement on July 1, 2010. See Note 5 to our Condensed Financial Statements UBS Loan.

Recent Accounting Pronouncements

For additional information on our recent accounting pronouncements, please refer to the discussion in Recent Accounting Pronouncements under Note 2 of the Notes to Condensed Financial Statements in this Quarterly Report on Form 10-Q and Item 7 of our Annual Report on Form 10-K for the year ended December 31, 2009.

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.

As of June 30, 2010, we had fair value of ARS totaling $12.3 million that were comprised of municipal issuances that are collateralized by student loans guaranteed by the U.S. government under the Federal Family Education Loan Program and a closed end preferred issuance, all of which were subsequently sold in July 2010. The ARS held by us are rated A through AAA by a major credit rating agency. Based on overall market liquidity concerns, we determined that there was a net decrease in fair value of ARS totaling $2.7 million through June 30, 2010.

In December 2009, we obtained a loan of approximately $9.2 million, which was secured by the ARS and ARS Rights as collateral. See Note 5 to our Condensed Financial Statements UBS Loan. As of June 30, 2010, the balance of the loan was $5.4 million and classified as short-term debt, which we repaid as part of our ARS Rights cash settlement on July 1, 2010.

The loan bears interest at a rate that will not exceed the average rate of interest paid on the collateralized ARS such that the net interest cost to us will be zero. The weighted-average interest rate on the loan was 1.32% as of June 30, 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 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.

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Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures. Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act) as of June 30, 2010. 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 June 30, 2010, our disclosure controls and procedures were effective.

Limitations on the effectiveness of controls. 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.

Changes in Internal Control over Financial Reporting. There were no changes in our internal control over financial reporting during our fiscal quarter ended June 30, 2010, that have materially affected, or are reasonably likely to materially affect our ability to record, process, summarize and report financial information.

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PART II OTHER INFORMATION

Item 1. Legal Proceedings

J&J Intellectual Property Dispute

We have initiated binding arbitration and related litigation with certain subsidiaries of Johnson & Johnson, or J&J, over ownership of intellectual property related to certain erythropoietin receptor, or EPO-R, agonists (ESA compounds capable of binding to and activating the EPO-R). This intellectual property is the subject of a number of U.S. and international patents and patent applications assigned to Affymax and/or J&J, including a U.S. patent currently assigned to J&J, several U.S. patents currently assigned to us and a European patent application currently assigned to J&J that may issue in the near future and relates to specified ESA peptide compounds (J&J s European Patent Application). See Risk Factors Risk Related to Our Business. In this section, we refer to the patents and patent applications subject to the arbitration collectively as the intellectual property in dispute. We believe that we are the sole owner or co-owner of the intellectual property in dispute, including J&J s European Patent Application. J&J, on the other hand, alleges that they are the sole owner or co-owner of the intellectual property in dispute, including several U.S. patents on which we are currently named as sole owner that relate to specified peptide compounds.

We believe the U.S. intellectual property in dispute does not encompass Hematide and that we can manufacture, commercialize and sell Hematide in the U.S. regardless of the outcome of this arbitration. However, if, through the ongoing arbitration or otherwise, J&J or another potential competitor obtains or possesses patents or patent rights that are determined by an arbitration panel or a court to encompass one or more elements of Hematide, that party could initiate proceedings, an adverse result in which could prevent us from manufacturing or commercializing Hematide, either for ourselves or with Takeda, in the U.S.

If the intellectual property in dispute is determined by the arbitration panel or a court to be broad enough to cover Hematide, then under the laws applicable to most relevant jurisdictions outside the U.S., a finding of joint ownership would permit us to manufacture and sell Hematide, but may not allow us to license third parties to do so. We have entered into a collaboration agreement with Takeda to commercialize Hematide worldwide, so a finding of joint ownership of the patents and applications in question could materially affect our business plans outside the U.S. In the U.S., joint ownership of a patent gives each joint owner the right to license third parties, so even if the patents in question are held to be jointly owned by us and J&J, we do not believe we would be prevented from pursuing our partnership strategy for Hematide in the U.S. If the arbitration panel determines that J&J is the sole owner of one or more of the U.S. patents in dispute, J&J may seek to assert such patent against us in the U.S.; however, we believe that we have strong defenses to any assertion that Hematide infringes any claims of these U.S. patents.

The Research and Development Agreement with J&J

In April 1992, Affymax N.V. (a different company from us) entered into a three-year Research and Development Agreement, which we refer to as the R&D Agreement, with a division of Ortho Pharmaceutical Corporation, a subsidiary of J&J. In 2001, we assumed the rights and obligations of Affymax N.V. under the R&D Agreement and acquired rights to patents and patent applications that comprise much of the intellectual property in dispute.

Under the R&D Agreement, J&J provided Affymax N.V. research funding and Affymax N.V. sought to discover compounds directed at the EPO receptor. The R&D Agreement provided for us to retain rights to our existing technology and identified as our technology our methodologies for creating peptide sequence libraries, each of which contained billions of different peptide sequences, and methodologies that could be used to determine which if any of the peptide sequences contained in a library would bind to an identified receptor. The R&D Agreement further provided for any invention made by either party to be the property of the party making the invention and that joint inventions would be jointly owned.

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Our position is based on the following chronology: From 1992 through 1995, a group of scientists working for Affymax N.V., performed extensive research under the R&D Agreement and discovered numerous peptides and peptide dimers that bind to and activate the EPO-R. These Affymax N.V. scientists started with the Affymax N.V. peptide sequence libraries, conducted numerous tests, experiments and analyses and discovered and identified a set of active peptides that bind to and activate the EPO-R. The Affymax scientists disclosed the inventions and the results of their research to J&J. In November 1993, Affymax N.V., through Affymax Technologies, N.V., a related entity, filed U.S. Patent Application No. 08/155,940, or the 940 application, claiming various of the Affymax N.V. scientists inventions and identifying four Affymax scientists, and no J&J scientists, as the inventors. Affymax N.V. provided J&J with a draft copy of the 940 application before filing it. The Affymax scientists research gave rise to numerous other patent applications, including continuation-in-part applications based on and claiming priority from the 940 application, a continuation of one of those applications, and numerous foreign and international patent applications based on one or more of these applications. Ultimately, the 940 application was abandoned in favor of these other applications. In 2001, we acquired the rights, previously held by Affymax N.V. and Affymax Technologies, N.V., to these patents and patent applications. Some of the applications have issued as patents, and these patents and patent applications comprise much of the intellectual property in dispute. Based on the inventions of the Affymax N.V. scientists, we believe we are the sole owner or a co-owner of the intellectual property in dispute.

J&J, however, alleges that it invented the idea of searching peptide sequence libraries, such as Affymax N.V. s libraries, to find peptides that bind to and activate the EPO-R, and that the Affymax N.V. scientists did not make inventive contributions when they discovered and identified the specific peptides that bind to and activate the EPO-R. J&J also alleges that it invented the idea of, and methodology for, dimerizing these peptides to make them more biologically active, and that it provided Affymax with reagents and control substances for use in research under the R&D Agreement, as well as instructions on how to use them. J&J further alleges that Affymax N.V. improperly removed the names of the J&J employees who had been identified as inventors on the parties joint applications pending before the U.S. Patent and Trademark Office without notifying or consulting J&J. For these reasons, J&J claims that it should be granted sole ownership or joint ownership of the intellectual property in dispute.

Post-R&D Agreement Development Activities

In March 1995, Affymax N.V., Affymax Technologies, N.V. and Affymax Research Institute, or the Affymax Entities, were acquired by Glaxo Wellcome plc. In July 2001, we acquired specified assets from Glaxo Wellcome plc and related entities, including the rights to the R&D Agreement (which had been finally terminated in 2000) and the rights to specified patents and patent applications that had previously been held by Affymax N.V. and Affymax Technologies, N.V. After our company was founded in 2001, we pursued efforts to create a synthetic compound that activated the EPO-R and had the biological and physical properties needed to be a commercially viable pharmaceutical product. Our efforts culminated in the first chemical synthesis of Hematide in 2003.

Patent Applications Filed During and After the R&D Agreement

The intellectual property in dispute relates primarily to the following patents and patent applications: U.S. Patent No. 5,767,078; U.S. Patent Application No. 08/484,135; PCT Application No. PCT/US96/09469 (International Publication No. WO96/40772); European Patent Office application EP96/918,317; Canadian Patent Application No. CA 2228277; Japanese Patent Application No. JP 09-(1997) 501781; Australian Patent No. 732,294; Australian Patent Application AU01/054,337; Australian Patent Application AU04/203,690; U.S. Patent No. 5,773,569; U.S. Patent No. 5,830,851; U.S. Patent No. 5,986,047; European Patent No. EP 0 886,648; PCT Application No. PCT/US96/09810 (International Publication No. WO96/40749); U.S. Patent Application No. 08/155/940; U.S. Patent Application No. 08/484,631; U.S. Patent Application No. 08/484,635; U.S. Patent Application No. 08/827,570; U.S. Patent Application No. 08/451,550, U.S. Patent Application No. 08/479,992, U.S. Patent Application No. 08/827,573, U.S. Patent Application No. 09/155,158, U.S. Patent Application No. 10/156,934, U.S. Patent Application No. 10/465,167, and U.S. Patent Application No. 11/855,948.

In November 1993, the Affymax Entities filed a U.S. patent application (U.S.S.N. 08/155,940), or the 940 application, identifying four of their scientists as inventors. In June 1995, the Affymax Entities filed U.S. Patent Application Nos. 08/484,631 and 08/484,635, or the 631 and 635 applications. These applications were

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continuation-in-part applications based on and claiming priority from the 940 application. They also included certain subject matter that J&J specifically requested be added. At the time of filing, the 631 and 635 applications listed certain J&J employees as inventors in addition to the Affymax scientists. Prior to filing the 940, 631, and 635 applications, the Affymax Entities provided J&J with drafts and/or copies of the applications or informed them of their intent to file them. On or about June 7, 1996, the Affymax Entities filed PCT Application No. PCT/US96/09810, which was based on and clamed priority from the 631 and 635 applications and has given rise to a European patent (EP 0 866 648), which has been assigned jointly to us and J&J. Beginning in 1995, the Affymax Entities and later we filed a series of other continuation and continuation-in-part applications (U.S. Patent Application Nos. 08/451,550, 08/479,992, 08/827,573, 09/155,158, 10/156,934, 10/465,167, and 11/855,948) claiming priority from earlier applications; these have been abandoned, except for U.S. Patent Application No. 11/855,948, which remains pending.

On the same day in June 1995 that the Affymax Entities filed the 631 and 635 applications, J&J separately filed U.S. Patent Application No. 08/484,135, or the 135 application, which identified J&J employees as the sole inventors of the described subject matter and J&J as the sole assignee. J&J later filed a PCT application (PCT Application No. PCT/US96/09810) based on and claiming priority from the 135 application, and various foreign patent applications (including in Europe, Canada, Japan and Australia) based on the PCT application. The parties dispute whether J&J informed the Affymax Entities prior to filing these applications. U.S. Patent No. 5,767,078 and Australian Patent No. 732,294 issued to J&J based on these applications, and other applications are pending, including European patent application EP96/918,317. We claim in the arbitration that we are the sole or joint owner of these patents and applications and any U.S., foreign or international patents or applications based on, claiming priority from or relating to them.

On March 28, 1997, the Affymax Entities filed U.S. Patent Application No. 08/827,570, or the 570 application, a continuation of the 635 application. That day, the Affymax Entities also filed a preliminary amendment and a petition for correction of inventorship in connection with the 570 application, as well as supplemental responses and petitions for correction of inventorship in connection with the 631 and 635 applications. The 631, 635, and 570 applications have now issued to Affymax as U.S. Patents Nos. 5,773,569; 5,830,851; and 5,986,047. J&J alleges that the Affymax Entities filed the 570 application and the above-referenced petitions, preliminary amendment and supplemental responses without notifying or consulting with J&J. J&J claims in the arbitration that it is the sole or joint owner of these patents and applications and any U.S., foreign, or international patents or applications based on, claiming priority from, or relating to them.

J&J s European patent application EP96/918,317, which relates to agonist peptide dimers, could result in European patents being issued to J&J in the near future. In the J&J arbitration proceeding, we have claimed that we should be a sole owner or at least a joint owner of this European application. If the patent issues, J&J could seek to enforce this patent against us in Europe. In many European countries, a patent cannot be asserted to stop clinical trials, but in some, a patent holder can seek to enjoin clinical trials.

Litigation and Arbitration Chronology

On June 9, 2004, we filed a civil complaint in the Munich Regional Court in the Federal Republic of Germany against J&J alleging that we are an owner or co-owner of J&J s European Patent Application (European Patent Application EP96/918,317). In October 2005, J&J filed its response to our complaint, denying our claims of inventorship and ownership. In April 2006, we requested the court to dismiss the complaint so that the issues it raised could be resolved pursuant to the arbitration proceeding described below. The court has done so.

On September 23, 2004, we filed a civil complaint in the U.S. District Court for the Northern District of Illinois, or the Illinois case, against J&J alleging claims for correction of inventorship and ownership of the above-referenced patents and patent applications assigned to J&J, for corresponding declaratory and injunctive relief, for breach of contract, and for unjust enrichment and constructive trust. The complaint alleges

that the Affymax N.V. scientists are sole or co-inventors of the intellectual property in dispute, including the above-referenced J&J patents and patent applications, and that we are the sole or co-owner of them. The complaint also alleges that J&J breached the R&D Agreement by, among other things, engaging in a course of conduct designed to obtain patents for itself and to deny the Affymax Entities patents on the Affymax scientists inventions. The complaint further alleges that

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we have suffered damages as a result of J&J s breaches and that J&J has been unjustly enriched through its misconduct and should be subject to the imposition of a constructive trust.

J&J denied all material claims in our complaint and, among other things, counterclaimed that its employees are the true inventors of the intellectual property in dispute and that it is therefore entitled to sole or co-ownership of the above-referenced patents and patent applications assigned solely or jointly to us (including U.S. Patent Nos. 5,986,047, 5,773,569, and 5,830,851, which are solely assigned to us, and European Patent No. EP 0 866 648, which is assigned jointly to us and J&J). J&J also brought related claims for breach of contract, breach of fiduciary duty, unjust enrichment and constructive trust. J&J alleges, among other things, that the Affymax Entities filed in their own name certain patent applications allegedly claiming inventions of J&J employees without notifying or consulting with J&J, that during patent prosecution the Affymax Entities improperly removed the names of J&J employees from certain patent applications on which those employees had been identified as inventors, and that these and other alleged breaches entitle J&J to damages and waive all rights we may have had to the intellectual property in dispute.

J&J requested that the Illinois case be dismissed and the matter decided under the R&D Agreement s arbitration provisions. On February 28, 2006, the Illinois court entered an order that the appropriate forum for us and J&J to resolve the inventorship, ownership, breach of contract and related claims was binding arbitration under the American Arbitration Association, or AAA, rules in Illinois. The Illinois court held that the claims pending in the German court were also subject to arbitration and required us to dismiss the German complaint, which we have done. The Illinois court further stated that it will retain jurisdiction over the subject matter during the arbitration in Illinois.

On April 12, 2006, we filed a demand for arbitration with the AAA claiming that we are the owner or co-owner of the intellectual property in dispute and alleging claims for correction of inventorship and ownership of the above-referenced patents and patent applications assigned to J&J, for corresponding declaratory and injunctive relief, for breach of contract, for unjust enrichment and constructive trust, and for breach of fiduciary duty. On May 8, 2006, J&J filed its answer and counterclaims, substantially restating their allegations made in the U.S. and German courts. In April 2007, we filed an amended demand for arbitration. In June 2007, J&J filed an amended counterdemand. The AAA has appointed a panel of arbitrators, and the arbitration has commenced. The parties have conducted discovery. In June 2007, J&J filed a motion to compel discovery of information relating to Hematide and then filed a substitute motion to compel. In July 2007, we filed an opposition to J&J s motion to compel and a motion for protective order. In September 2007, the arbitrators ruled that J&J could obtain limited discovery on Hematide, but that J&J could not obtain discovery on Hematide product formulas, sequences, laboratory notebooks containing such information, experimental results, clinical trial results and strategies, or internal business planning. The arbitration hearing is near completion and the decision is expected in second half of 2010. The outcome of the matter is uncertain and regardless of outcome, the matter may have an adverse impact on us because of legal costs, diversion of management resources and other factors.

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. Our business could be harmed by any of these risks. The trading price of our common stock could decline due to any of these risks, and you may lose 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.

Risks Related to Our Business

We are dependent on the success of Hematide. Hematide is a new chemical entity and currently our only product candidate. We cannot give any assurance that the development program for Hematide will be successful or completed in a timely or effective manner. Our recently announced Phase 3 results present challenges to our ability to obtain regulatory approval for Hematide in particular due to the heightened concerns surrounding safety of erythropoiesis stimulating agent, or ESAs. Our failure to adequately demonstrate the safety and effectiveness of Hematide will prevent us from receiving regulatory approval and would have a material and adverse impact on our business. Any failure of our Hematide clinical program or the timely and complete submission of our New Drug Application, or NDA, would severely harm our business.

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

In late June 2010, we announced preliminary top-line results from the Hematide Phase 3 clinical program for the treatment of patients with anemia associated with chronic renal failure. 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 Hematide 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 Hematide and its ability to maintain hemoglobin levels in a corrected range compared to epoetin alpha or epoetin beta when switched to Hematide. Analysis of efficacy and safety for all of the Phase 3 studies were based 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, Hematide met the statistical criterion for non-inferiority for the assessment of safety for the cardiovascular composite safety endpoint (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.

We are continuing to conduct further analysis of the PEARL and EMERALD studies which evaluated the efficacy and safety of Hematide in chronic renal failure patients with anemia. Before year end, we plan to discuss with the U.S. Food and Drug Administration, or FDA, the U.S. registration strategy for Hematide. Subject to feedback from the FDA, the plan is to pursue a NDA for treatment of anemia in dialysis patients, while continuing to evaluate the non-dialysis indication. The timeline for possible submission of the NDA will be aimed for first half of 2011, but will be finalized after the FDA meeting.

Despite meeting the primary efficacy endpoints and the CSE for Hematide, the differences observed in the Phase 3 secondary analyses present risks to our ability to obtain regulatory approval for Hematide particularly in the non-dialysis setting due to the heightened concerns surrounding safety of ESAs. Further, any negative perception of Hematide s safety relative to other ESAs would significantly limit the likelihood of obtaining regulatory approval for Hematide. 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 Hematide.

Regardless of whether Hematide met the statistical criteria for non-inferiority to the comparator drugs, Hematide could still fail to establish that it is sufficiently safe for regulatory approval for any indication. In addition to clinical trials, Hematide must undergo extensive pre-clinical studies, including carcinogenicity studies, as a condition to submission of an NDA and regulatory approval. As Hematide 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. In addition, the submission of our NDA may be delayed or fail for many reasons, including:

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

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- difficulties arising from administration, data gathering and analysis of our large and complex Phase 3 clinical program for Hematide, which involved numerous third parties, approximately 2,600 patients and 400 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;

- regulators or institutional review boards may not authorize continuation of clinical trials or require suspension or termination such trials for various reasons, including exposure of the participating patients to unacceptable health risks or noncompliance with regulatory requirements;

- our inability, or the inability of our collaborators or licensees, to manufacture or obtain from third parties materials of sufficient quality;

- risks associated with non-inferiority trials, which are studies devised and statistically powered to show that the test drug is not inferior to the control 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, delays or failures to establish adequate procedures or corrective actions, problems maintaining contact with patients after treatment or as a consequence of the open-label, non-inferiority design of the Phase 3 trials;

- 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 Hematide or other reasons including adverse medical effects unrelated to treatment with Hematide;

- our lack of experience as an organization in preparing a complete and acceptable large NDA submission for Hematide that is expected to be submitted in electronic Common Technical Document (e-CTD) format, which will involve significant complexity and coordination with a number of third party contractors and our collaboration partner, Takeda;

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

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

The results from earlier pre-clinical testing and prior clinical trials may not be predictive of results obtained in other pre-clinical models or later clinical trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in clinical trials, even in advanced clinical trials after showing promising results in earlier clinical trials. 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 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. Our failure to adequately demonstrate the safety and effectiveness of Hematide will prevent us from receiving regulatory approval and will have a material adverse impact our business.

We also do not know and are unable to predict whether the data arising from the clinical trials, including the Phase 3 results, or the development program for Hematide will be satisfactory to the FDA and, if not, whether the

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FDA will require us to conduct additional studies or trials or alter the scope, size or design of such studies or trials, which could result in additional delays in bringing Hematide to market, if ever. Accordingly, we may not receive the regulatory approvals needed to market Hematide. Any failure or delay in completing any portion of the development program or submitting our NDA to the FDA would delay or foreclose commercialization of Hematide and severely harm our business and financial condition.

The Trial to Reduce Cardiovascular Endpoints with Aranesp Therapy, or TREAT, results heightens concerns surrounding safety of ESAs and increases the regulatory risk for Hematide as the class faces greater scrutiny. These concerns may limit the ability to develop and obtain regulatory approval for Hematide. The FDA announced that it anticipates convening an advisory committee meeting later in 2010 to re-evaluate the use of ESAs in the treatment of anemia in chronic kidney disease.

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 is higher than the 10 g/dL - 12 g/dL range approved by the FDA in the current label, reportedly failed to show benefit compared to placebo 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 placebo 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 announced that it anticipates convening a public advisory committee meeting later this year 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 article indicates that more conservative hemoglobin targets (well below 12 g per deciliter), 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 risk evaluation and mitigation strategy (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.

The TREAT results and the FDA s recent actions, including plans to convene another advisory committee, represent additional challenges to the ESAs as a class and increases the uncertainty associated with Hematide 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 particularly in oncology, 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 (ODAC) in May 2007 to consider recent information on risks associated with ESAs for use in the treatment of anemia in cancer patients. The

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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 2008.

- 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.

- 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 Hematide to treat chemotherapy-induced anemia, which 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 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.

The controversy surrounding ESAs and FDA concerns has, and may, further negatively affect Hematide, including the completion of the development program. These safety concerns may increase the risk of 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 Hematide. Even a small imbalance in safety events or unfavorable signal or trend against Hematide 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 Hematide.

Our clinical development program for Hematide may not lead to a commercial drug either because we fail to demonstrate that it is safe and effective in clinical trials 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 Hematide through development commercialization. Our analyses of the Phase 3 results remains preliminary and no conclusions as to the safety and efficacy can be drawn as only the FDA can ultimately make such determination. Any failure to obtain approval of Hematide 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 Hematide receives approval by the FDA for treatment of chronic renal failure, the market opportunity for Hematide, may be significantly reduced as a result of the increasing controversy surrounding ESAs, TREAT 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

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likely to further negatively impact the use of ESAs and the commercial potential of Hematide. The FDA has announced plans to convene an advisory committee to re-evaluate the use of ESAs in the treatment of anemia in chronic kidney disease. The FDA may further lower target hemoglobin levels and other actions that may limit the use of ESAs in chronic kidney disease potentially beyond non-dialysis patients to dialysis as well. In additional to potential FDA action to limit use of ESAs, CMS convened a meeting of the Medicare Evidence Development & Coverage Advisory Committee (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. Any action by FDA to further restrict ESA use or decrease reimbursement coverage by CMS could have a materially negative impact on the size of the ESA market in the United States and reduce the overall size of the market Hematide 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 Hematide increase FDA approval risk or the risk of Hematide obtaining reimbursement, but any negative perception of Hematide s safety relative to other ESAs could keep us from successfully commercializing Hematide.

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 fail to obtain additional financing, we will be unable to complete the development and commercialization of Hematide and may need to cease operations. Even if we obtain additional financing, 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 June 30, 2010, we had an accumulated deficit of $365.4 million. Due to the recognition of revenues from milestone payments from our collaboration with Takeda, we were profitable in the three and six months ended June 30, 2010 and may have profitable quarters from time to time. We continue to expect to incur substantial and increasing losses for the next several years. 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 Hematide;
- prepare the submission of the NDA for Hematide;
- validate the manufacturing process for Hematide at our contract manufacturers; and
- prepare to launch and commercialize Hematide, 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 12 months. However, we expect that we will need to raise additional funding to complete the development and commercialization of Hematide. Since the announcement in late June 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 need to raise funding has only increased as the Hematide development program has suffered delays and due to the reduction of potential milestone payments from Takeda associated with the non-dialysis indication. As we continue to analyze the data, we may experience further challenges or delays to approval of Hematide if issues arise or

additional requirements are imposed based on our discussions with the FDA.

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 to support our continuing operations and maintain current development and commercialization timelines for Hematide.

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

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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 as our stock price has fallen below the minimum $8.00 per share limit established under the facility. Any debt financing, if available, may involve security interests on our assets or restrictive 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 Hematide;

- relinquish greater rights to Hematide;

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

- pursue merger and acquisition alternatives.

We expect to continue to incur substantial additional operating losses for the next several years as we pursue our clinical trials, prepare for the NDA and add infrastructure and operations to support commercialization of Hematide, 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, Hematide. If due to lengthy and complicated development, clinical and regulatory requirements or any other reason, we are unable to commercialize Hematide, it will be a long time before we will be able to commercialize any future product candidates, if ever.

Even if we receive regulatory approval of Hematide, we must successfully commercialize Hematide before we can become profitable. We anticipate that it will be years before we can commercialize Hematide 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 Hematide 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.

Hematide will require extensive additional clinical evaluation, 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 Hematide or even if we receive marketing approval for Hematide, sales revenue therefrom may be insufficient, and we may not achieve or sustain profitability, and we may be unable to continue our operations.

We have initiated binding arbitration and related litigation with Johnson & Johnson Pharmaceutical Research & Development, L.L.C., and Ortho-McNeil Pharmaceutical, Inc., or collectively, J&J, over ownership of intellectual property related to certain erythropoietin receptor, or EPO-R, agonists. An adverse result in this binding arbitration or litigation, together with adverse results in subsequent litigation J&J may then bring, could prevent us from manufacturing or commercializing Hematide in a number of countries in accordance with our current plans or could limit our ability to license third parties to do so.

We have initiated binding arbitration and related litigation with J&J over the ownership of a number of U.S. and international patents and patent applications related to certain EPO-R agonists, or the intellectual property in dispute. We believe that we are the sole owner or co-owner of the intellectual property in dispute. J&J, on the other hand, alleges that it is the sole owner or co-owner of the intellectual property in dispute, including several U.S. patents on which we are currently named as sole owner that relate to specified peptide compounds. Although we believe our position in this dispute is meritorious and that we have substantial defenses to J&J s counterclaims, litigation is time consuming and expensive and the outcome is inherently uncertain. A number of outcomes in the dispute is possible, including, without limitation, the possibility that we lose or do not acquire specific patents and patent rights in the ESA field, J&J obtains or retains specific patents and patent rights in the ESA field or we become liable for damages, attorneys fees and costs. Moreover, if the arbitration panel were to determine that J&J is

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the sole owner of one or more of the disputed patents, J&J may seek to assert such patents against us in the U.S., Europe and elsewhere.

We believe the U.S. intellectual property in dispute does not encompass Hematide and that we can manufacture, commercialize and sell Hematide in the U.S. regardless of the outcome of this arbitration. However, if, through the ongoing arbitration or otherwise, J&J or another potential competitor obtains or possesses patents or patent rights that are deemed to encompass one or more elements of Hematide, that party could initiate proceedings, an adverse result in which could prevent us from manufacturing or commercializing Hematide, either for ourselves or with Takeda, in the U.S.

If the intellectual property in dispute is deemed broad enough to cover Hematide, then under the laws applicable to most relevant jurisdictions outside the U.S., a finding of joint ownership would permit us to manufacture and sell Hematide, but may not allow us to license third parties to do so. Because our strategy is to commercialize Hematide worldwide through our partnership with Takeda, a finding of joint ownership of the patents and applications in question could materially affect our business plans outside the U.S. Within the U.S., joint ownership of a patent gives each joint owner the right to license third parties, so even if the patents in question are held to be jointly owned by us and J&J, we do not believe we would be prevented from pursuing our partnership strategy for Hematide in the U.S. If the arbitration panel determines that J&J is the sole owner of one or more of the U.S. patents in dispute, J&J may seek to assert such patents against us in the U.S.

Although J&J s ownership of J&J s European Patent Application is subject to the pending arbitration, a patent could be issued from this application to J&J by the European Patent Office in the near future. In the J&J arbitration proceeding, we have claimed that we should be a sole owner or at least a joint owner of this European application. If this patent issues, J&J could seek to enforce this patent against us in Europe. In many European countries, a patent cannot be asserted to stop clinical trials, but in some, a patent holder can seek to enjoin clinical trials. We are seeking to minimize the effect this might have on our development plans, but there can be no assurance that our clinical trial and manufacturing plans would not be delayed if a European patent issues to J&J.

The outcome of any arbitration or litigation proceeding is inherently unpredictable. The claims and underlying facts at issue in this dispute are complex. Since we acquired assets from Affymax N.V. (a different company from us), documents and other evidence of which we are not currently aware may be uncovered that are adverse to our position. We have incurred significant expense in pursuing this matter to date, and because a final decision on the arbitration and related litigation may not be reached for years, we may continue to incur significant expenses for years. In addition, the efforts of our technical, legal and management personnel have been and will continue to be diverted as a result of this dispute.

Our commercial success depends upon attaining significant market acceptance of Hematide 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.

Hematide has not been approved or commercialized for any indication. Even if approved for sale by the appropriate regulatory authorities, physicians may not prescribe Hematide, in which case we would not generate revenue or become profitable. In particular, the therapeutic indications targeted by Hematide have 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 is one of the largest and most established markets that Hematide will attempt to penetrate, is highly concentrated, with two companies 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 Hematide. The concentration of customers for ESAs within the dialysis market may pose a risk to our ability to obtain revenues or favorable margins on Hematide, 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, we cannot do so on favorable terms or on a timely basis, the revenue opportunity of Hematide 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

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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 Hematide 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 Hematide, and adversely impact our ability to generate revenues.

Currently, CMS reimburses healthcare providers for use of ESAs at a rate of average sales price plus a 6% margin to the provider, or ASP plus 6%. These reimbursement rates have been declining and have been subject to concerns over the uses that will be subject to future reimbursement. In addition, Congress has recently enacted legislation entitled Medicare Improvements for Patients and Providers Act of 2008, or 2008 Medicare Legislation, that adopts a bundled payment system covering the cost of drugs, including ESAs, as well as dialysis services effective January 2011. Significant aspects of the 2008 Medicare Legislation and the details of the bundled payment system will be determined through additional rulemaking. We cannot be certain what reimbursement policies will be in effect at the time we seek to enter the chronic renal failure market or any other indication in the U.S., or the effect these policies may have on our ability to compete effectively, if we are ever successful in reaching the market.

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 Hematide.

In the non-dialysis market, one challenge is that patients suffering from anemia may not access health care resources to treat their condition for some time following its onset. As a result, the available non-dialysis market may be limited by the overall proportion of patients who are diagnosed with the condition, how early these patients are diagnosed, and at what point they begin treatment. Additionally, reaching and educating the doctors who treat non-dialysis patients may be difficult, as these patients are spread thinly across a variety of treatment settings. Primary care physicians that treat non-dialysis patients may not be comfortable with reimbursement procedures for injectible products and thus delay or restrict treatment with ESAs.

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

- the clinical indications for which Hematide is approved;
- acceptance by physicians and patients of Hematide as a safe and effective treatment alternative;
- perceived advantages over alternative treatments;
- the cost of treatment in relation to alternative treatments;

- 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 Hematide, 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 Hematide or any other future products that we may develop and commercialize. In addition, significant delays in the development of Hematide could allow our competitors to bring new products to market before we do and impair our ability to commercialize Hematide. Competitors may also reduce the price of their ESAs in order to gain market share. These price reductions could

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force us to lower the price of Hematide in order to compete effectively, resulting in lower revenues and reduced margins on the sales of Hematide.

We anticipate that, if approved, Hematide would compete with EPOGEN and Aranesp, which are both marketed by Amgen, PROCRIT, which is marketed by Ortho Biotech Products, L.P. (a subsidiary of J&J), NeoRecormon and Mircera, which are currently marketed outside the U.S. by Roche. 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 Hematide 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 Hematide or upon its entry, we believe that Mircera will be in direct competition with Hematide, and therefore could potentially limit the market for Hematide, 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 Hematide, 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 Hematide, 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 Hematide 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.

The U.S. market opportunity for Hematide 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. and the E.U. The introduction of biosimilars into the ESA market could prove to be a significant threat to Hematide if they are able to demonstrate bioequivalence to existing ESAs. Biosimilars will constitute additional competition for Hematide and could drive its price and sales volume down, which may adversely affect our revenues.

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

Hematide 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 Hematide, 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 Hematide. We have limited ability and resources to pursue internal research 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

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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 Hematide;
- 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 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 Hematide is dependent upon the strength and performance of our collaboration with Takeda. 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 Hematide and our business. If we fail to enter into new, strategic collaborations with other future product candidates we pursue, we may have to reduce or delay our product candidate development efforts or increase our expenditures.

The maintenance and successful performance of our strategic collaboration with Takeda for development of Hematide is an important part of our business model. Our collaboration with Takeda is extremely complex particularly with respect to financial provisions, allocations of responsibilities, and the respective rights of the parties with respect to decision making. Accordingly, significant aspects of the development and commercialization of Hematide require Takeda s agreement or approval prior to implementation, which can cause delays. Further, if we are not able to reach agreement with Takeda or maintain our existing collaboration with Takeda to develop and commercialize Hematide, our business could be severely 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 provide us notice of termination of either or both of our collaboration agreements, which would likely have a material adverse effect on the advancement of our Hematide program and our business. The suspension of the Hematide oncology program and the impact of the Phase 3 results particularly on the non-dialysis indication may increase the likelihood that Takeda terminates the collaboration or affect the resources Takeda is willing to commit to Hematide. Through the collaboration, Takeda currently provides development 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, Takeda s failure to provide funding or perform its obligations on a timely basis may have a material adverse effect on our business and the success of Hematide.

In addition, 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 Hematide 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.

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

Market acceptance and sales of Hematide 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 Hematide. Also, we cannot be sure that reimbursement amounts will not reduce the demand for, or the price of, Hematide. We have not commenced efforts to have our Hematide 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 Hematide.

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 Hematide profitably. These proposals include prescription drug benefit proposals for Medicare beneficiaries and measures that would limit or prohibit payments for certain medical treatments or subject the pricing of drugs to government control. Legislation creating a prescription drug benefit and making certain changes in Medicaid reimbursement has recently been enacted. In particular, in December 2003, then President Bush signed into law new Medicare prescription drug coverage legislation that changed the methodology used to calculate reimbursement for certain drugs such as Hematide. In addition, the legislation directed the Secretary of Health and Human Services to contract with procurement organizations to purchase physician-administered drugs from the manufacturers and provided physicians with the option to obtain drugs through these organizations as an alternative to purchasing from the manufacturers, which some physicians may find advantageous.

In addition, in response to the FDA s recent black box warning and public health advisories, CMS has recently 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. Independent of any additional action the FDA may take as to ESAs, CMS may further decrease coverage which could have a materially negative impact on the size of the ESA market in the United States and reduce the overall size of the market Hematide 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 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 Hematide 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 Hematide 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

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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 Hematide for any therapeutic indication we may pursue. 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 Hematide) 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.

CMS currently reimburses healthcare providers for use of ESAs at average selling price or ASP, plus 6%. However, the 2008 Medicare Legislation replaces ASP plus 6% reimbursement with a new bundled payment system to be implemented commencing in January 2011. Under the new bundled payment system, providers are expected to be reimbursed a fixed amount per patient. We cannot guarantee that Hematide 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 Hematide. In fact, a capitated reimbursement payment methodology may create incentives for significantly lower utilization or dosing of ESAs, including Hematide, and reduce the commercial potential for Hematide.

We rely on third parties to conduct pre-clinical studies and clinical trials for Hematide, and if they do not properly and successfully perform their obligations to us, we may not be able to obtain the necessary regulatory approvals.

We rely on contract research organizations, contractors and other third parties to assist us in managing, monitoring and otherwise conducting clinical trials. We compete with larger companies for the resources of these third parties.

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.

We may not be able to maintain our relationships with these contract research organizations or contractors on acceptable terms. These third parties generally may terminate their engagements with us at any time and having to enter into alternative arrangements would delay development and commercialization of Hematide. As a result, we can control their activities only within certain limits, and they will devote only a certain amount of their time to Hematide.

If these third parties do not successfully carry out their duties under their agreements with us, if the quality or accuracy of the data they obtain is compromised due to failure to adhere to our clinical protocols or regulatory requirements, or if they otherwise fail to comply with clinical trial

protocols or meet expected deadlines, our clinical trials may not meet regulatory requirements. If our clinical trials do not meet regulatory requirements or if these third parties need to be replaced, our pre-clinical development activities or clinical trials may be extended, delayed, suspended, terminated or negatively impact the quality and acceptability of the data. If any of these events occur, we may not be able to obtain regulatory approval of Hematide.

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Significant challenges remain with us and Takeda to manufacture Hematide on a commercial scale. Our dependence upon third parties for the manufacture and supply may cause delays in, or prevent us from, successfully developing and commercializing Hematide. 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 Hematide manufacturing process is a complicated, time-consuming process. Manufacture of Hematide active pharmaceutical ingredient, or API, involves long lead times. We do not currently have the infrastructure or capability internally to manufacture the Hematide needed to conduct our clinical trials or to commercialize Hematide. We are and will continue to rely upon contract manufacturers to produce our clinical trial materials and in the future commercial supplies of Hematide. For the foreseeable future, we expect to continue to rely on contract manufacturers, partners and other third parties to produce sufficient quantities of Hematide 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 Hematide or Hematide 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 capabilities, we may be required to delay or suspend clinical trials or our planned NDA filing or otherwise discontinue development and production.

Hematide is a new chemical entity and the manufacturing process for commercial scale production remains to be validated at any manufacturer in accordance with applicable regulatory guidelines and as such, there are risks associated with the full 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 Hematide, 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 Hematide 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 Hematide from Nektar Therapeutics AL, Corporation, or Nektar, are currently single-sourced, leaving us at greater risk of supply interruptions and potential delays.

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 Hematide 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 Hematide. 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 Hematide. Any inability to acquire sufficient quantities of Hematide 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 Hematide 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 Hematide from our competitors products.

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The commercial success of Hematide depends in part on the development and marketing efforts of Takeda, over which we have limited control. 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 Hematide and our other collaboration arrangements, subjects us to a number of risks. Our ability to develop and commercialize drugs that we develop with our collaboration partners depends on our collaboration partners abilities to establish the safety and efficacy of Hematide, obtain and maintain regulatory approvals and achieve market acceptance of Hematide once commercialized. Under our collaboration with Takeda, we co-develop and co-commercialize Hematide in the U.S. Because we share responsibility with Takeda for clinical development activities in the U.S., the progress of the Hematide program is dependent on the efforts of Takeda of which we have no control. In fact, Takeda has taken responsibility for conducting several clinical trials and is expected to produce substantial portions of the NDA so that any failure of Takeda to act in a timely manner may delay our ability to develop Hematide in accordance with our timelines. Takeda holds an exclusive license to develop and commercialize Hematide outside of the U.S. and 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 Hematide, independently develop products that compete with Hematide, or fail to commit sufficient resources to the marketing and distribution of Hematide. 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 Hematide.

In the event that Takeda fails to diligently develop or commercialize Hematide, we may have the right to terminate our partner s rights but we may choose not to as we will not receive any future revenue from Hematide or even if we do, we may not be able to find another partner requiring us to commercialize Hematide on our own, which is likely to result in significant additional expense and delay. Business combinations, significant changes in business strategy, litigation and/or financial difficulties may also adversely affect the willingness or ability of Takeda to complete its obligations under our collaboration agreements. If Takeda fails to perform in the manner we expect, our potential to develop and commercialize products Hematide and to generate future revenue would be significantly reduced. If a conflict of interest arises between us and Takeda, it may act in its own self-interest and not in the interest of our company or our stockholders. If Takeda were to breach or terminate the collaboration agreements with us or otherwise fail to perform its obligations thereunder in a timely manner, the pre-clinical or clinical development or commercialization of Hematide could be delayed or terminated.

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 Hematide 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 Hematide 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 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.

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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.

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 Hematide 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

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any product. There can also be no assurance that patents owned by us will not be challenged by others. We are currently involved in binding arbitration with J&J, which could result in one or more patents being issued to these parties for technology that we jointly or solely own. 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 Hematide 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.

Our ongoing litigation is described in the section entitled Legal Proceedings. We have incurred substantial expense as a result of our litigation and arbitration proceedings and we expect to incur even greater expense in the future. In addition, 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 Hematide 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 Hematide successfully.

We currently have no sales, marketing or distribution capabilities. To commercialize Hematide, 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 Hematide directly, we must commit significant financial and managerial resources to develop a marketing and sales force with technical expertise and with supporting distribution capabilities. Factors that may inhibit our efforts to commercialize Hematide 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 Hematide, which would adversely affect our business and financial condition. To the extent we rely on other pharmaceutical or

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biotechnology companies with established sales, marketing and distribution systems to market Hematide, 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 Hematide 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 Arlene Morris, our Chief Executive Officer, and Dr. Anne-Marie Duliege, our Chief Medical Officer. The loss of services of Ms. Morris, 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 Hematide.

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. 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 Hematide through clinical trials, we will need to expand our development, regulatory, manufacturing, 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 Hematide 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, manage our clinical trials effectively and hire, train and integrate additional management, administrative and sales and marketing personnel. We may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successfully growing our company.

Our operations may be adversely impacted by our exposure to risks related to foreign currency exchange rates.

Some of our costs and expenses associated with our clinical trials are denominated in foreign currencies. We are primarily exposed to changes in exchange rates with Europe due to agreements with third party vendors and clinical sites located in Europe. When the United States dollar weakens against these currencies, the dollar value of the foreign-currency denominated expense increases, and when the dollar strengthens against these currencies, the dollar value of the foreign-currency denominated expense decreases. Accordingly, changes in exchange rates, and in particular a weakening of the United States dollar, may adversely affect our results of operations. We currently do not hedge against our foreign currency risks.

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 Hematide.

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 Hematide in the U.S. until we receive approval of a NDA, from the FDA. We have not received marketing approval for Hematide. Further, we have not

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previously prepared an NDA submission, which involves compliance with governmental regulations and successful completion of a number of significant and complicated undertakings for which we do not have any prior experience implementing. 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 Hematide 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 Hematide. 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 Hematide, 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 Hematide.

Any regulatory approvals that we or Takeda receive for Hematide 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 Hematide, the labeling, packaging, adverse event reporting, storage, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. Our recent 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 Hematide. 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.

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 Hematide in the U.S, and have exclusively licensed Takeda to develop Hematide in international markets. In order to market Hematide 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

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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 Hematide 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 Hematide 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 Hematide to other available therapies or a clinical trial that studies pharmacoeconomic benefits. If reimbursement of Hematide 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 Hematide.

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 Hematide. 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 Hematide. 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 Hematide;

- 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;

- product recalls;

- loss of revenue; and

- the inability to commercialize Hematide.

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

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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 July 31, 2010, the price ranged between a high of $26.20 per share and a low of $5.12 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 and commercialization of Hematide;
- 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 Hematide;
- actual or anticipated regulatory approvals of Hematide or competing products
- 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;
- issuance of patents to competitors, including the expected issuance of patents to J&J in Europe;
- developments in and the outcome of our litigation with J&J, including both substantive and procedural rulings by the arbitration panel;

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

- changes in laws or regulations applicable to Hematide, 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;

- 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;

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- 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.

Our principal stockholders and management own a significant percentage of our stock and will be able to exercise significant influence over matters subject to stockholder approval.

As of February 15, 2010, our executive officers, directors and principal stockholders, together with their respective affiliates, owned approximately 34% of our voting stock. Accordingly, these stockholders will be able to exert a significant degree of influence over our management and affairs and over matters requiring stockholder approval, including the election of our board of directors and approval of significant corporate transactions. This concentration of ownership could have the effect of delaying or preventing a change in our control or otherwise discouraging a potential acquirer from attempting to obtain control of us, which in turn could have a material and adverse effect on the fair market value of our common stock.

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 have in the past identified material weaknesses in the operation of our internal controls over financial reporting, as

defined in Public Company Accounting Oversight Board Standard No. 5. Although we believe these material weaknesses have been fully remediated and none were identified as of December 31, 2009, 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 you may not be able to sell your shares of our equity securities at a price equal to or above the price you 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 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. It is possible that transactions involving our common stock, even those outside our control, such as purchases or sales by investors, within the testing period could result in an ownership change. 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 results. 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.

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

Unregistered Sales of Equity Securities

Not applicable.

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Use of Proceeds from the Sale of Registered Securities

Our initial public offering of common stock was effected through a Registration Statement on Form S-1, as amended (File No. 333-136125) and a Registration Statement on Form S-1 filed pursuant to Rule 462(b) (File No. 333-139363) that were declared effective by the Securities and Exchange Commission on December 14, 2006. We registered 4,255,000 shares of our common stock for an aggregate offering price of $106,375,000, all of which were sold. After deducting expenses, we received net offering proceeds of approximately $96 million from our initial public offering. As of June 30, 2010, approximately $30.7 million of aggregate net proceeds from our initial public offering are maintained in investment accounts and we have used the remaining proceeds of approximately $65.4 million to fund our development of Hematide and other working capital and general corporate purposes, including the expansion of commercial capabilities.

The foregoing represents our best estimate of our use of proceeds for the period indicated.

Issuer Purchases of Equity Securities

We did not repurchase any of our equity securities during the three months ended June 30, 2010.

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. Submission of Matters to a Vote of Security Holders

Not applicable.

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)
10.35	Fifth Amendment dated May 20, 2010 by and between Registrant and EOP-Foothill Research Center, L.L.C.
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)

(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 in 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.

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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: August 4, 2010	By:	/s/ ARLENE M. MORRIS Arlene M. Morris *Chief Executive Officer and Member of the Board of Directors*
Dated: August 4, 2010	By:	/s/ PAUL B. CLEVELAND Paul B. Cleveland *Executive Vice President, Corporate Development and Chief Financial Officer (Principal Financial Officer)*

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