AFFYMAX INC
Form 10-Q
August 18, 2008

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, 2008

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 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	Accelarated filter 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, 2008, 15,223,771 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, 2008 (Unaudited)	December 31, 2007
Assets		
Current assets		
Cash and cash equivalents	$ 70,243	$ 108,215
Restricted cash	11	11
Short-term investments	70,740	60,122
Receivable from Takeda	17,701	15,331
Deferred tax assets	1,810	1,810
Prepaid expenses and other current assets	6,849	9,323
Total current assets	167,354	194,812
Property and equipment, net	6,090	4,470
Restricted cash	1,135	1,135
Long-term investments	21,640	15,655
Deferred tax assets, net of current	8,272	8,272
Other assets	1,378	1,448
Total assets	$ 205,869	$ 225,792
Liabilities and Stockholders Equity		
Current liabilities		
Accounts payable	$ 3,191	$ 9,348
Accrued liabilities	10,193	3,517
Accrued clinical trial expenses	13,460	2,473
Income taxes payable		739
Deferred revenue	45,326	39,488
Capitalized lease obligations, current	52	133
Total current liabilities	72,222	55,698
Deferred revenue, net of current	68,162	75,911
Long-term income tax liability	9,434	9,434
Capitalized lease obligations, net of current		8
Other long-term liabilities	714	556
Total liabilities	150,532	141,607
Contingencies (Note 5)		
Stockholders equity		
Common stock	15	15
Additional paid-in capital	301,741	296,035
Deferred stock-based compensation	(16)	(28)
Accumulated deficit	(246,314)	(211,818)
Accumulated other comprehensive loss	(89)	(19)
Total stockholders equity	55,337	84,185
Total liabilities and stockholders equity	$ 205,869	$ 225,792

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

AFFYMAX, INC.

CONDENSED STATEMENTS OF OPERATIONS

(in thousands, except per share data)
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2008	2007	2008	2007
Collaboration revenue	$ 18,450	$ 9,654	$ 35,158	$ 16,972
License and royalty revenue	681	15	687	21
Total revenue	19,131	9,669	35,845	16,993
Operating expenses:				
Research and development	30,877	14,730	56,313	26,588
General and administrative	7,863	6,195	15,331	11,527
Total operating expenses	38,740	20,925	71,644	38,115
Loss from operations	(19,609)	(11,256)	(35,799)	(21,122)
Interest income	1,115	2,917	3,092	5,932
Interest expense	(172)	(4)	(201)	(9)
Other income (expense), net	(249)	20	(1,588)	35
Loss before provision for income taxes	(18,915)	(8,323)	(34,496)	(15,164)
Provision for income taxes		925		1,255
Net loss	$ (18,915)	$ (9,248)	$ (34,496)	$ (16,419)
Net loss per share:				
Basic and diluted	$ (1.24)	$ (0.62)	$ (2.27)	$ (1.10)
Weighted-average number of shares used in computing basic and diluted net loss per share	15,197	14,879	15,172	14,870

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

AFFYMAX, INC.

CONDENSED STATEMENTS OF CASH FLOWS
(in thousands)
(Unaudited)

	Six Months Ended June 30,	
	2008	2007
Cash flows from operating activities		
Net loss	$ (34,496)	$ (16,419)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	630	464
Amortization of discount/premium on investments	59	(179)
Stock-based compensation expense	5,112	3,269
Gain on disposal of property and equipment		(15)
Other-than-temporary impairment on investments	1,559	
Realized gain on investments	(4)	(27)
Changes in operating assets and liabilities:		
Receivable from Takeda	(2,370)	236
Prepaid expenses and other current assets	2,474	1,549
Deferred tax assets		(326)
Other assets	70	(885)
Accounts payable	(6,157)	611
Accrued liabilities	6,682	264
Accrued clinical trial expenses	10,987	147
Income taxes payable	(739)	924
Deferred revenue	(1,911)	(1,543)
Other long term liabilities	158	851
Net cash used in operating activities	(17,946)	(11,079)
Cash flows from investing activities		
Purchases of property and equipment	(2,256)	(1,875)
Purchases of investments	(98,796)	(143,512)
Proceeds from sales and maturities of investments	80,509	86,995
Proceeds from sale of property and equipment	6	15
Net cash used in investing activities	(20,537)	(58,377)
Cash flows from financing activities		
Repurchase of common stock		(15)
Proceeds from issuance of common stock upon exercise of stock options	145	1
Proceeds from issuance of common stock under employee stock purchase plan	454	427
Issuance costs related to IPO		(30)
Principal payments under capital lease obligations	(88)	(144)
Net cash provided by financing activities	511	239
Net decrease in cash and cash equivalents	(37,972)	(69,217)
Cash and cash equivalents at beginning of the period	108,215	147,541
Cash and cash equivalents at end of the period	$ 70,243	$ 78,324
Noncash investing and financing activities		
Change in unrealized gain (loss) on investments	(70)	(52)
Deferred stock-based compensation, net of cancellations	(227)	(208)

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

AFFYMAX, INC.
NOTES TO CONDENSED FINANCIAL STATEMENTS

(Unaudited)

1. The Company

Affymax, Inc. (the Company), a Delaware corporation, was incorporated on July 20, 2001. The Company is a biopharmaceutical company focused on developing novel peptide-based drug candidates to improve the treatment of serious and often life-threatening conditions. The Company s product candidate, Hematide , is designed to treat anemia associated with chronic renal failure and cancer. Hematide is a synthetic peptide-based erythropoiesis stimulating agent (ESA) designed to stimulate production of red blood cells. The Company is conducting Phase 3 clinical trials in patients suffering from chronic renal failure, on dialysis and not on dialysis (pre-dialysis).

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying condensed financial statements of the Company have been prepared following the requirements of the Securities and Exchange Commission (SEC) for interim reporting. As permitted under those rules, certain footnotes or other financial information that are normally required by U.S. generally accepted accounting principles have been condensed or omitted. The condensed financial statements are unaudited and reflect all adjustments which, in the opinion of management, are necessary to fairly state the financial position at, and the results of operations and cash flows for, the interim periods presented. The financial information included herein should be read in conjunction with the Company s Annual Report on Form 10-K for the year ended December 31, 2007, which includes the Company s 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.

Reclassifications and Adjustments

Certain amounts in prior period financial statements have been reclassified to conform to the current period presentation. These reclassifications did not change previously reported net loss, total assets or stockholders equity.

The Company identified an overstatement of clinical trial expense of $0.3 million and $1.6 million in the three months ended March 31, 2008 and December 31, 2007, respectively. As a result, clinical trial expense includes an out of period reduction of $1.9 million in the three and six months ended June 30, 2008 and collaboration revenue relating to reimbursement for these expenses by Takeda includes an out of period reduction of $0.5 million in the same three and six month periods. The overstatements were immaterial to the financial statements for the year ended December 31, 2007 and therefore were corrected in the second quarter of 2008.

Comprehensive Loss

Comprehensive loss consists of net loss plus the change in unrealized gains and losses on investments. At each balance sheet date presented, the Company s other comprehensive loss consists solely of unrealized gains and losses on investments. Comprehensive loss for the three and six months ended June 30, 2008 and 2007 are as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2008	2007	2008	2007
Net loss	$ (18,915)	$ (9,248)	$ (34,496)	$ (16,419)
Change in unrealized gains (losses) on investments	3	(80)	(70)	(52)
Comprehensive loss	$ (18,912)	$ (9,328)	$ (34,566)	$ (16,471)

Concentration of Risk and Uncertainties

Financial instruments that potentially subject the Company to a concentration of credit risk consist of cash, cash equivalents and investments. The Company deposits excess cash in accounts with major financial institutions in the United States. Deposits in these banks may exceed the amount of insurance provided on such deposits. The Company has not experienced any realized losses on its deposits of cash and cash equivalents. Although the Company s guidelines for investment of its excess cash are designed to maintain safety and liquidity through its policies on diversification and investment maturity, as of June 30, 2008, the Company held $21.6 million of investments in auction rate securities (ARS) that have failed in auctions.

The Company has experienced significant operating losses since inception. At June 30, 2008, the Company had an accumulated deficit of $246.3 million. The Company has generated no revenue from product sales to date. The Company has funded its operations to date principally from collaboration agreements and the sale of securities. The Company expects 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. There can be no assurance that such financing will be available or will be at terms acceptable to the Company.

The Company s accounts receivable balance contains billed and unbilled receivables in connection with our two separate collaboration agreements (the Arrangement) with Takeda Pharmaceutical Company Limited, or Takeda. The Company has not experienced any credit losses from its Arrangement with Takeda and none are expected.

The Company is currently developing its first product offering, Hematide, and has no products that have received regulatory approval. Hematide will require approval from the U.S. Food and Drug Administration (FDA) and/or foreign regulatory agencies prior to commercial sales. There can be no assurance that Hematide will receive the necessary approvals. If the Company is denied such approvals or such approvals are delayed, it would have a material adverse effect on the Company. To achieve profitable operations, the Company 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 the Company s future financial results.

Investments

Investments are classified as available-for-sale in accordance with SFAS No. 115, *Accounting for Certain Investments in Debt and Equity Securities,* and are carried at their fair market value at the balance sheet date. Realized gains and losses on sales of all such securities are reported in earnings and computed using the specific identification method. Unrealized gains and losses are reported as a separate component of stockholders equity until realized.

Effective January 1, 2008, the Company adopted SFAS No. 157, *Fair Value Measurements* (SFAS No. 157). In February 2008, the FASB issued Staff Position No. 157-2, *Effective Date of FASB Statement No. 157* (FSP No. 157-2), which delays the effective date of SFAS No. 157 for all nonfinancial assets and liabilities except for those recognized or disclosed at least annually. Therefore, the Company has adopted the provisions of SFAS No. 157 with respect to its financial assets and liabilities only. SFAS No. 157 defines fair value, establishes a framework for measuring fair value under generally accepted accounting principles, and expands disclosures about fair value measurements. SFAS No. 157 does not require any new fair value measurements, but provides guidance on how to measure fair value by providing a fair value hierarchy used to classify the source of the information. Effective January 1, 2008, the Company adopted SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities* (SFAS No. 159), which permits entities to choose to measure many financial instruments and certain other items at fair value that are not currently required to be measured at fair value. The Company did not elect to adopt the fair value option under SFAS No. 159.

Revenue Recognition

Collaboration Revenue

The Company recognizes revenue in accordance with the SEC s Staff Accounting Bulletin No. 104, *Revenue Recognition in Financial Statements* (SAB 104). When evaluating multiple element arrangements, the Company considers whether the components of the arrangement represent separate units of accounting as defined in Emerging

Issues Task Force Issue No. 00-21, *Revenue Arrangements with Multiple Deliverables* (EITF 00-21). Application of this standard 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.

The two collaboration agreements constituting the Arrangement with Takeda have been combined for accounting purposes due to their proximity of negotiation. The Company evaluated the multiple elements under the combined single arrangement in accordance with the provisions of EITF 00-21. As the Company was unable to determine the stand-alone value of the delivered elements and obtain verifiable objective evidence to determine the fair value of the undelivered elements, the Company concluded that there was a single unit of accounting.

Effective January 1, 2008, the Company entered into an amendment to the Arrangement with Takeda. The amendment modifies the ongoing commitments with respect to the Company s participation on the joint steering committee such that the contractual term of that obligation is no longer indefinite. As a result, the Company determined that it can separate the performance obligations which occur over the development period from the performance obligations that will occur during the commercialization period. As a result of the change in performance period from indefinite to approximately 4.5 years, beginning on January 1, 2008, the Company recognized revenue during the development period using the Contingency-Adjusted Performance Model. The cumulative effect adjustment of $1.4 million for the change of estimate, which resulted from now being able to estimate the period of performance, was recognized as additional revenue during the three months ended March 31, 2008. Upon commercialization, the Company will recognize revenue from the manufacture and supply of the API upon delivery, if all other SAB 104 criteria for revenue recognition are met. Royalty payments, profit share payments and sales milestone payments will be recognized as revenue when earned, if all other SAB 104 criteria for revenue recognition are met.

Prior to January 2008, the Company was unable to determine the period of its performance obligations under the Arrangement as the Company s required participation on the joint steering committee extends for as long as products subject to the collaboration with Takeda are being sold by either of the parties. Accordingly, the contractual term of the Company s joint steering committee obligations was considered indefinite. As a result, revenue for the single unit of accounting was recorded on a proportional performance basis as long as the overall Arrangement was determined to be profitable during the years ended December 31, 2007 and 2006. The Company accounted for the Arrangement using a zero profit proportional performance model (i.e., revenue was recognized equal to direct costs incurred, but not in excess of cash received or receivable assuming that the overall Arrangement was expected to be profitable). The Company used an input based measure, specifically direct costs, to determine proportional performance because the Company believed that the inputs were representative of the value being conveyed to Takeda through the research and development activities and delivery of the active pharmaceutical ingredients (API). The Company believed that using direct costs as the unit of measure of proportional performance also most closely reflected the level of effort related to the Company s performance under the Arrangement. Direct costs were those costs that directly resulted in the culmination of an earnings process for which Takeda received a direct benefit. The nature of these costs were third party and internal costs associated with conducting clinical trial activities for dialysis and pre-dialysis indications, costs associated with the manufacturing of API and API stability testing, allocated payroll related costs for representatives participating on the joint steering committee and sales and marketing costs during the co-commercialization period. Direct costs specifically excluded costs of a general and administrative nature, upfront payments to manufacturers unrelated to specific product manufactured such as reservation of capacity, cost for API not yet delivered to Takeda, travel and expense related costs, sales and marketing costs during the development period, any research and development costs not associated with Hematide, interest, depreciation and amortization expense. Revenue was recognized equal to direct costs incurred, but not in excess of cash received or receivable. Amounts resulting from payments received in advance of revenue recognized were recorded as deferred revenue until the earlier of (i) when the Company could meet the criteria for separate recognition of each element under the guidance of EITF 00-21 or (ii) after the Company had fulfilled all of its contractual obligations under the Arrangement.

The Company was required to assess the profitability of the overall Arrangement on a periodic basis throughout the life of the Arrangement when events or circumstances indicated a potential change in facts. Profitability was defined as a net cash inflow resulting from the Arrangement over its life. Such assessment was based on estimates to determine the most likely outcome based on available facts and circumstances at each assessment date. The

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estimates included the consideration of factors such as the progress and timing of clinical trials, competitive ESAs in the market, drug related serious adverse events and other safety issues in the clinical trials, pricing reimbursement in relevant markets and historical costs incurred compared to original estimates. When the periodic assessment or other events or circumstances indicated a loss would result from performance under the Arrangement, costs would continue to be recognized as they were incurred. However, revenue would be deferred until either: (i) the Arrangement became profitable, at which point revenue would continue to be recognized, or (ii) the end of the Arrangement.

License and Royalty Revenue

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

Clinical Trial Expense

The Company records expense for estimated clinical study external costs, which are a significant component of research and development (R&D) expenses. These clinical trial costs were $15.5 million and $4.4 million during the three months ended June 30, 2008 and 2007, respectively, and $28.2 million and $8.2 million during the six months ended June 30, 2008 and 2007, respectively. Clinical studies are administered by third-party contract research organizations (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 detailed reporting received from CROs and internal analyses. The Company accrues 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 based on monthly activities 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 the Company for appropriateness and adjustments are made as deemed necessary to ensure that the expenses reflect the actual effort incurred by the CROs. However, if the Company does not receive complete and accurate information from the vendors or underestimates activity levels associated with a study at a given point in time, the Company may have to record adjustments, including potentially significant additional R&D expenses in subsequent periods.

Based on additional reporting by one of the CROs, the Company recorded a change in estimate to decrease clinical trial expense by $0.7 million in the quarter ended June 30, 2008.

Net Loss Per Share

Basic and diluted net loss per share is computed using the weighted-average number of shares of common stock outstanding during the period. Stock options, common stock subject to repurchase, warrants, restricted stock units and common stock issuable pursuant to the 2006 Employee Stock Purchase Plan were not included in the diluted net loss per share calculation for the periods presented because the inclusion of such shares would have had an antidilutive effect.

	Three Months Ended June 30,		Six Months Ended June 30,	
	2008	2007	2008	2007
	(in thousands, except per share data)			
Numerator:				
Net loss	$ (18,915)	$ (9,248)	$ (34,496)	$ (16,419)
Denominator:				
Weighted-average shares outstanding	15,201	14,897	15,177	14,891
Less: Weighted-average unvested shares subject to repurchase	(4)	(18)	(5)	(21)
Weighted-average number of shares used in computing basic and diluted net loss per share	15,197	14,879	15,172	14,870
Basic and diluted net loss per share	$ (1.24)	$ (0.62)	$ (2.27)	$ (1.10)

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

	As of June 30,	
	2008	2007
Options to purchase common stock	2,164	1,765
Common stock subject to repurchase	3	16
Common stock issuable pursuant to the 2006 Employee Stock Purchase Plan	12	8
Restricted stock units	206	
Warrants to purchase common stock	2	2

Recent Accounting Pronouncements

In May 2008, the FASB issued SFAS No. 162, *The Hierarchy of Generally Accepted Accounting Principles* (SFAS No. 162). SFAS No. 162 identifies the sources of accounting principles and the framework for selecting the principles used in the preparation of financial statements of nongovernmental entities that are presented in conformity with generally accepted accounting principles. SFAS No. 162 will become effective 60 days following the SEC s approval of the Public Company Accounting Oversight Board amendments to AU Section 411, *The Meaning of Present Fairly in Conformity With Generally Accepted Accounting Principles*. The Company is currently assessing the potential impact that the adoption of SFAS No. 162 will have on its financial statements.

In March 2008, the FASB issued SFAS No. 161, *Disclosures about Derivative Instruments and Hedging Activities, an amendment of FASB Statement No. 133* (SFAS No. 161). SFAS No. 161 applies to all derivative instruments and related hedged items accounted for under SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities*. SFAS No. 161 requires entities to provide greater transparency about (a) how and why an entity uses derivative instruments, (b) how derivative instruments and related hedged items are accounted for under SFAS No. 133 and its related interpretations, and (c) how derivative instruments and related hedged items affect an entity s financial position, results of operations and cash flows. SFAS No. 161 is effective for financial statements issued for fiscal years beginning after November 15, 2008. The Company is currently assessing the potential impact that the adoption of SFAS No. 162 will have on its financial statements.

Effective January 1, 2008, the Company adopted the provisions of EITF Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities* (EITF No. 07-3). EITF No. 07-3 requires the Company to defer and capitalize nonrefundable advance payments for research and development activities. Such amounts will be recognized as expenses as the goods are delivered or the services are performed. If the Company does not expect the goods to be delivered or the services to be performed, the capitalized amounts should be expensed. The adoption of EITF No. 07-3 did not have a significant impact on the Company s financial statements.

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In December 2007, the FASB ratified EITF Issue No. 07-1, *Accounting for Collaborative Arrangements* (EITF No. 07-1), which defines collaborative arrangements and establishes reporting and disclosure requirements for transactions between participants in a collaborative arrangement and between participants in the arrangements and third parties. EITF No. 07-1 is effective retrospectively to all prior periods presented for all collaborative arrangements existing as of the effective date for fiscal years beginning after December 15, 2008. The Company is currently assessing the potential impact that the adoption of EITF No. 07-1 will have on its financial statements.

3. Stock-Based Compensation

The Company recognized stock-based compensation expense related to employee stock options, restricted stock units and stock purchase rights of $2.6 million and $1.5 million for the three months ended June 30, 2008 and 2007, respectively, and $4.7 million and $3.3 million for the six months ended June 30, 2008 and 2007, respectively, under SFAS No. 123(R). As of June 30, 2008, unrecognized compensation cost related to employee stock options and restricted stock units totaled $21.4 million. The cost is expected to be recognized over a weighted-average amortization period of 2.48 years.

Stock Option and Restricted Stock Unit Activity

The following table summarizes stock option activity for the six months ended June 30, 2008:

Stock Options Outstanding	Shares Available For Grant	Number of Shares	Weighted-Average Exercise Price Per Share
Balances at December 31, 2007	876,405	2,099,116	$ 17.37
Additional shares authorized	680,803		
Options granted	(164,900)	164,900	15.30
Options exercised		(53,478)	2.72
Options forfeited	38,969	(38,969)	24.75
Options cancelled	8,048	(8,048)	23.52
Restricted stock units forfeited	6,275		
Stock repurchased	110		
Balances at June 30, 2008	1,445,710	2,163,521	$ 17.42

The following table summarizes information about restricted stock unit activity for the six months ended June 30, 2008:

Restricted Stock Units Outstanding	Number of Shares	Weighted-Average Exercise Price Per Share
Nonvested shares at December 31, 2007	30,650	$ 21.74
Restricted stock units granted	181,625	14.20
Restricted stock units forfeited	(6,275)	16.00
Nonvested shares at June 30, 2008	206,000	$ 15.27

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4. Investments and Fair Value Measurements

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

	As of June 30, 2008			
	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Other-Than-Temporary Impairment	Fair Value
Short-term investments:					
Corporate securities	$ 16,156	$ 10	$ (22)	$	$ 16,144
Certificates of deposit	1,497		(6)		1,491
Government securities	53,150	7	(52)		53,105
Total short-term investments	$ 70,803	$ 17	$ (80)	$	$ 70,740
Long-term investments:					
Auction rate securities	$ 23,225	$	$ (26)	$ (1,559)	$ 21,640

	As of December 31, 2007			
	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Short-term investments:				
Corporate securities	$ 31,241	$ 10	$ (29)	$ 31,222
Foreign securities	1,497		(3)	1,494
Certificates of deposit	9,703	4	(1)	9,706
Auction rate securities	17,700			17,700
Total short-term investments	$ 60,141	$ 14	$ (33)	$ 60,122
Long-term investments:				
Auction rate securities	$ 15,655	$	$	$ 15,655

Fair Value Measurements

Effective January 1, 2008, the Company adopted the provisions of SFAS No. 157 with respect to its financial assets and liabilities only. Effective January 1, 2008, the Company also adopted SFAS No. 159, which permits entities to choose to measure many financial instruments and certain other items at fair value that are not currently required to be measured at fair value. The Company did not elect to adopt the fair value option under SFAS No. 159.

SFAS No. 157 established a three-tier hierarchy for fair value measurements, which prioritizes the inputs used in measuring fair value as follows:

- Level 1 observable inputs such as quoted prices in active markets.

- Level 2 inputs other than 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 the Company to develop its own assumptions.

The Company s 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 types of investments that are generally classified within Level 2 of the fair value hierarchy include corporate securities, certificates of deposits and U.S. government securities. The Company s investments in ARS are classified within Level 3 of the fair value hierarchy because of the lack of observable inputs. ARS are structured to provide liquidity via an auction process that resets the applicable interest rate at predetermined calendar intervals, usually every 28

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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 the Company was successful. In mid-February, overall market liquidity concerns resulted in the failure of a majority of the auctions in the ARS markets. In the following month, approximately one-fifth of the auctions for ARS held by the Company were successful. Based on the level of failed auctions through the filing date of the Company s Annual Report on Form 10-K, the Company classified $15.7 million of ARS held as long-term investments as of December 31, 2007. The $15.7 million represented all ARS held as of December 31, 2007 that had not been sold as of February 29, 2008.

Since the filing of the Company s Form 10-K for the year ended December 31, 2007, the overall ARS markets have continued to deteriorate and the ARS held by the Company have failed in all but a single auction. During the quarter ended June 30, 2008, the par value of the Company s ARS holdings decreased $5.1 million to $23.2 million as a result of redemptions by the issuers and one partially successful auction. The Company s sales or redemptions of ARS to date have not resulted in any loss of principal. The ARS held by the Company continue to pay interest, most recently in a range of 2-5%, though certain student loan issuances are temporarily at a zero coupon rate due to the particular interest provisions of the issuances. As of June 30, 2008, the Company s $23.2 million of par value of ARS were comprised of $17.5 million of municipal issuances that are collateralized by student loans guaranteed by the U.S. government under the Federal Family Education Loan Program, $3.5 million of closed end preferred issuances and $2.2 million of other municipal issuances. The ARS held by the Company are rated AAA by a major credit rating agency, except for one ARS that is rated AA by a major credit rating agency. The student loan and municipal issuances have final maturity dates from 2017 to 2046 while the closed end preferred issuances have no final maturity date.

As a result of the continued auction market failures, quoted prices in active markets are not available. Due to the lack of observable inputs, the Company determined the fair value of its ARS at June 30, 2008 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, the Company included in its 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 the Company s assumptions could lead to a significant change in determined value. The Company s analysis resulted in a decrease in fair value of ARS totaling $1.6 million as of June 30, 2008. Of the $1.6 million decrease, $26,000 was associated with the Company s ARS holdings for which issuers have announced or completed redemptions of some or all of such ARS. As a result, the Company deemed the decrease in the fair value of those ARS as temporary and recorded a $26,000 unrealized loss to accumulated other comprehensive loss. The remaining decrease in fair value was associated with ARS that the Company may be required to sell prior to the resumption of successful auctions or other liquidity events. As a result, the remaining decrease in fair value of $1.6 million was deemed to be other-than-temporary and recorded as an impairment charge to other expense in the six months ended June 30, 2008.

The following table presents the Company s investments measured at fair value on a recurring basis as of June 30, 2008 classified by the SFAS No. 157 valuation hierarchy (in thousands):

			Fair Value Measurements Using		
	Total	Level 1	Level 2	Level 3
Cash equivalents	$ 66,518	$ 64,523	$ 1,995	$
Short-term investments:				
Corporate securities	$ 16,144	$	$ 16,144	$
Certificates of deposit	1,491		1,491	
Government securities	53,105		53,105	
Total short-term investments	$ 70,740	$	$ 70,740	$
Long-term investments:				
Auction rate securities	$ 21,640	$	$	$ 21,640

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The following table presents changes in Level 3 investments measured at fair value on a recurring basis for the six months ended June 30, 2008 (in thousands):

	Auction Rate Securities
Balance at January 1, 2008	$
Transfers in and/or out of Level 3	36,405
Total unrealized losses	
Included in net loss	(1,559)
Included in other comprehensive loss	(26)
Settlements	(13,180)
Balance at June 30, 2008	$ 21,640

5. Contingencies

The Company has 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 erythropoietin receptor, or EPO-R, agonists (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 the Company and J&J, including a U.S. patent currently assigned to J&J, several U.S. patents currently assigned to the Company and a European patent application currently assigned to J&J. In this section, the Company refers to the patents and patent applications subject to the arbitration collectively as the intellectual property in dispute. The Company believes that it is the sole owner or co-owner of the intellectual property in dispute, including a European patent application currently naming J&J as sole owner that may issue in the near future and relates to specified ESA peptide compounds. 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 the Company is currently named as sole owner that relate to specified peptide compounds.

In June 2004, the Company filed a civil complaint in the Munich Regional Court in the Federal Republic of Germany against J&J alleging that it is an owner or co-owner of J&J s European patent application relating to agonist peptide dimers. In October 2005, J&J filed its response to the Company s complaint, denying its claims of inventorship and ownership. In April 2006, the Company 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, the Company 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 the Company is the sole or co-owner of them. The complaint also alleges that J&J breached the three-year Research and Development Agreement between Affymax N.V. and a division of Ortho Pharmaceutical Corporation, a subsidiary of J&J, or the R&D Agreement, by, among other things, engaging in a course of conduct designed to obtain patents for itself and to deny the Company patents on the Affymax scientists inventions. The complaint further alleges that the Company has 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 the Company s 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 the Company. J&J also brought related claims for breach of contract, breach of fiduciary duty, unjust enrichment and constructive trust.

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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 the Company 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 the Company 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 the Company to dismiss the German complaint, which the Company has done. The Illinois court further stated that it will retain jurisdiction over the subject matter during the arbitration in Illinois.

In April 2006, the Company filed a demand for arbitration with the AAA claiming that it is 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 has appointed a panel of arbitrators, and the arbitrators have established a schedule for the arbitration. The parties have commenced 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, the Company 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 can obtain limited discovery on Hematide, but that J&J cannot 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 currently scheduled to occur during the second half of 2008, but might be delayed. The outcome of the matter is uncertain and regardless of outcome, the matter may have an adverse impact on the Company because of legal costs, diversion of management resources and other factors.

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

6. Development and Commercialization Agreements with Takeda

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

In February 2006, the Company issued an exclusive license to Takeda for development and commercialization of Hematide in Japan. Pursuant to this agreement, Takeda paid the Company approximately $27 million, consisting of $17 million in upfront licensing fees and approximately $10 million for the purchase of 530,082 shares of the Company s Series E Redeemable Convertible Preferred Stock at a price of $18.86 per share. In addition, the Company is eligible to receive clinical and regulatory milestone payments of up to an aggregate of $75 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 the Company. Assuming Hematide is approved and launched in Japan, the Company 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. Beginning January 1, 2007, Takeda was responsible for the first $50 million of third party expenses related to development in pursuit of U.S. regulatory approval of Hematide. Of the first $50 million of third-party expenses related to the development in pursuit of U.S. regulatory approval of Hematide to be borne by Takeda, a total of $36.3 million was utilized by both parties through December 31, 2007 and the remainder was utilized during the first quarter of 2008. Thereafter, Takeda bears 70% of the third party U.S. development expenses, while the Company is responsible for 30% of the expenses. The Company retains responsibility for 100% of its internal development expenses. Under the June 2006 agreement, Takeda paid the Company an upfront license fee of $105 million, and the Company is eligible to receive from Takeda up to an aggregate of $280 million upon the successful achievement of clinical development and regulatory milestones across all indications, the majority of which relate to the renal program. Further, the Company may receive from Takeda up to an aggregate of $150 million upon the achievement of certain worldwide annual net sales milestones. The Company and Takeda will share equally in the net profits and losses of Hematide in the United States, which include expenses related to the marketing and launch of Hematide. Takeda will pay the Company a variable royalty based on annual net sales of Hematide outside the United States. The agreement establishes a joint steering committee to oversee the development, regulatory approval and commercialization of Hematide.

The Company will share responsibility with Takeda for clinical development activities required for U.S. regulatory approval of Hematide. Specifically, the Company has primary responsibility for Hematide s clinical development plan and clinical trials in the dialysis and pre-dialysis indications, while Takeda has primary responsibility in the chemotherapy induced anemia and anemia of cancer indications. The Company is responsible for United States regulatory filings in the dialysis, pre-dialysis, chemotherapy induced anemia and anemia of cancer indications, including holding the NDAs for those indications. Takeda is responsible for regulatory filings outside the United States and the creation of a global safety database.

The Company is 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 United States pursuant to which the Company and Takeda will divide Hematide promotional responsibilities in the U.S. The Company and Takeda will jointly decide on promotional responsibility for markets outside of these initial indications.

Under the February 2006 agreement, Takeda also obtained a right of first negotiation to any backup products for Hematide developed by the Company or its third-party partners. Specifically, during the first ten years of the agreement, if the Company or third-party partners develop a product that advances to Phase 2 clinical trials and competes with Hematide in the renal or oncology indications, the Company is 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.

The Company has recognized $18.5 million and $35.2 million of revenue under the Contingency-Adjusted Performance Model during the three and six months ended June 30, 2008, respectively, which includes a $1.4 million cumulative adjustment resulting from an amendment to the Arrangement with Takeda that was effective on January 1, 2008, and $9.7 million and $17.0 million of revenue under the zero profit proportional performance model during the three and six months ended June 30, 2007, respectively, under the Arrangement with Takeda. As of June 30, 2008, the amount receivable from Takeda was $17.7 million.

7. Income Taxes

The Company anticipates being in a net operating loss position for 2008. The Company recorded no combined federal and state tax liability for the six months ended June 30, 2008. The Company was in a taxable position for its year ended December 31, 2007. The Company recorded a provision for income taxes of $925,000 and $1.3 million

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for the three and six months ended June 30, 2007, respectively, after taking into consideration its net operating loss and research and development credit carryforwards as well as the relevant Section 382 and 383 limitation due to the ownership change in December 2006.

The Company adopted the provisions of FASB Interpretation No. 48*, Accounting for Uncertainty in Income Taxes*, effective January 1, 2007. At December 31, 2007, the Company had $10.7 million of unrecognized tax benefits, which because of the full valuation allowance position, will not affect the effective tax rate when recognized.

For the three and six months ended June 30, 2008, the Company recorded no additional unrecognized tax benefit. During the three months ended March 31, 2007, the Company recorded a $4.4 million liability related to its uncertain tax positions. A partial release of valuation allowance was also recorded to account for existing deferred tax assets for the three months ended March 31, 2007. Based on authority issued during the second quarter of 2007, the Company reevaluated and reduced its uncertain income tax position for the six months ended June 30, 2007 to $326,000, which was reflected as a long-term liability on its condensed balance sheet with a corresponding deferred tax asset.

As of June 30, 2008, the Company s federal returns for the years ended 2004 through the current period and state returns for the years ended 2003 through the current period are still open to examination. Net operating losses and research and development credit carryforwards used in 2007 will be open for examination until 2011 and 2012 for federal and state purposes, respectively. Any remaining net operating losses and research and development carryforwards that may be used in future years are still subject to inquiry given that the statute of limitation for these items would be from the year of the utilization. There are no tax years under examination by any jurisdiction at this time.

While the Company believes that it has identified all reasonably identifiable exposures and that the reserve it has established for identifiable exposures is appropriate under the circumstances, it is possible that additional exposures exist and that exposures may be settled at amounts different than the amounts reserved. It is also possible that changes in facts and circumstances could cause the Company to materially increase or reduce the carrying amount of its tax reserve, but it is not possible to quantify the amount that will change in the next 12 months.

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, 2007 and our unaudited condensed financial statements for the three and six month periods ended June 30, 2008.

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 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. For example, these forward-looking statements include statements regarding the timing, design and results of our clinical trials and drug development program, the success of our collaboration with Takeda, and the timing and likelihood of the commercialization of Hematide. We discuss in greater detail many of these risks, uncertainties and other factors in this Quarterly Report on Form 10-Q under Item 1A Risk Factors including information about the 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

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planned clinical studies, regulatory requirements and approvals, research and development efforts, industry and competitive environment, intellectual property rights and disputes 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 developing novel peptide-based drug candidates to improve the treatment of serious and often life-threatening conditions. Our product candidate, Hematide, is designed to treat anemia associated with chronic renal failure and cancer. 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 increase the risk of other diseases or death. 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.

We are conducting Phase 3 clinical trials in patients suffering from chronic renal failure, on dialysis and pre-dialysis. We are conducting four open-label, randomized controlled clinical trials. Of these trials, two trials are being conducted in pre-dialysis patients and are 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 are being conducted in dialysis patients and are 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 will be based on assessments of non-inferiority to the comparator drugs. The primary efficacy endpoint will be the mean change in hemoglobin from baseline. Each study is planned to continue until the last patient has been treated for 52 weeks. In addition, the assessment of safety will include a composite cardiovascular endpoint from a pooled safety database. The rate of accrual of these cardiovascular events could affect the duration of the studies if the events accrue at a higher or lower rate than estimated.

Hematide is at an earlier stage of development for chemotherapy induced anemia in comparison to our renal program and as part of our collaboration with Takeda Pharmaceutical Company Limited, or Takeda, Takeda has assumed primary responsibility for regulatory and clinical development activities related to the worldwide oncology program. In January 2008, Takeda initiated a Phase 1 clinical trial for the treatment of chemotherapy-induced anemia in prostate, breast and non-small cell lung cancer patients in the U.S.

To date, we have not generated any product revenue. We have funded our operations primarily through the sale of equity securities, expense reimbursements, 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. Since inception we have incurred net losses and 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, 2008, we had an accumulated deficit of $246.3 million.

Critical Accounting Policies and Significant Judgments and Estimates

Our management s discussion and analysis of our financial condition and results of operations is based on our condensed financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. 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

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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.

Except as noted herein, 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, 2007.

Clinical Trial Expense

We record expense for estimated clinical study costs, which are a significant component of R&D expenses. Clinical trial costs were $15.5 million and $4.4 million during the three months ended June 30, 2008 and 2007, respectively, and $28.2 million and $8.2 million during the six months ended June 30, 2008 and 2007, respectively. Our clinical studies are administered by third-party contract research organizations (CROs). CROs typically perform most of the total start-up activities for our trials, including document preparation, site identification, pre-study visits, training as well as on-going program management. For our Phase 3 studies, which represent the vast majority of our expense, our expense is based on detailed 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 our Phase 2 studies, our expense is based on monthly activities 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 and adjustments are made as deemed necessary to ensure that our expenses reflect the actual effort incurred by the CROs. However, if we do not receive complete and accurate information from our vendors or underestimates activity levels associated with a study at a given point in time, we would have to record additional and potentially significant R&D expenses in future periods.

We identified an overstatement of clinical trial expense of $0.3 million and $1.6 million in the three months ended March 31, 2008 and December 31, 2007, respectively. As a result, clinical trial expense includes an out of period reduction of $1.9 million in the three and six months ended June 30, 2008 and collaboration revenue, which includes reimbursement for these costs includes a $0.5 million out of period reduction in the same periods.

Investments

Effective January 1, 2008, we adopted SFAS No. 157, *Fair Value Measurements*, or SFAS No. 157. In February 2008, the FASB issued Staff Position No. 157-2, *Effective Date of FASB Statement No. 157*, or FSP No. 157-2, which delays the effective date of SFAS No. 157 for all nonfinancial assets and liabilities except for those recognized or disclosed at least annually. Therefore, we adopted the provisions of SFAS No. 157 with respect to our financial assets and liabilities only. SFAS No. 157 defines fair value, establishes a framework for measuring fair value under generally accepted accounting principles, and expands disclosures about fair value measurements. SFAS No. 157 does not require any new fair value measurements, but provides guidance on how to measure fair value by providing a fair value hierarchy used to classify the source of the information. Effective January 1, 2008, we adopted SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities*, or SFAS No. 159, which permits entities to choose to measure many financial instruments and certain other items at fair value that are not currently required to be measured at fair value. We did not elect to adopt the fair value option under SFAS No. 159.

Our investments, other than auction rate securities, or 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 quotations or dealer quotations, or alternative pricing sources with reasonable levels of price transparency. Our investments in ARS are classified within Level 3 of the fair value hierarchy because of the lack of observable inputs. As a result, we determined the value of these ARS at June 30, 2008 using a discounted cash flow analysis. The analysis considers, among other things, the amount and timing of coupon payments, contractual terms, underlying collateralization, credit risk and an illiquidity discount factor. 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.

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Results of Operations

Revenue

	Three Months Ended June 30,				Six Months Ended June 30,			
	2008	2007	Increase/ (Decrease)	% Increase/ (Decrease)	2008	2007	Increase/ (Decrease)	% Increase/ (Decrease)
	(in thousands, except percentages)							
Collaboration revenue	$ 18,450	$ 9,654	$ 8,796	91%	$ 35,158	$ 16,972	$ 18,186	107%
License and royalty revenue	$ 681	$ 15	$ 666	4,440%	$ 687	$ 21	$ 666	3,171%
Total revenue	$ 19,131	$ 9,669	$ 9,462	98%	$ 35,845	$ 16,993	$ 18,852	111%

We have recognized $18.5 million and $35.2 million of collaboration revenue under the Contingency-Adjusted Performance Model during the three and six months ended June 30, 2008, respectively, which included a $1.4 million cumulative adjustment resulting from an amendment to the collaboration agreements with Takeda and an out of period reduction of $0.5 million, as discussed in the notes to our unaudited condensed financial statements included in this Quarterly Report on Form 10-Q. We have recognized $9.7 million and $17.0 million of collaboration revenue using the zero profit proportional performance model during the three and six months ended June 30, 2007, respectively. The increase in collaboration revenue for the three and six months ended June 30, 2008 compared to the three and six months ended June 30, 2007 was primarily due to the growth in third-party development expenses reimbursed by Takeda related to our Phase 3 clinical trials which commenced enrollment in late 2007. 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.

The increase in license and royalty revenue in 2008 was due to payments received under a license agreement that we acquired in the 2001 spin out from GlaxoSmithKline (Glaxo), net of the 50% that we are required to remit to Glaxo.

Research and Development Expenses

	Three Months Ended June 30,				Six Months Ended June 30,			
	2008	2007	Increase/ (Decrease)	% Increase/ (Decrease)	2008	2007	Increase/ (Decrease)	% Increase/ (Decrease)
	(in thousands, except percentages)							
Research and development expenses	$ 30,877	$ 14,730	$ 16,147	110%	$ 56,313	$ 26,588	$ 29,725	112%

The increase in research and development expenses for the three and six months ended June 30, 2008 compared to the three and six months ended June 30, 2007 was primarily due to an increase of $13.7 million and $25.0 million, respectively, in clinical trial costs resulting principally from additional clinical trials and enrollment of higher number of patients and an increase of $1.9 million and $3.7 million, respectively, in personnel costs resulting from increased headcount and stock-based compensation expenses. We expect to incur substantially increasing research and development expenses in future periods, particularly expenses arising from clinical development activities including the enrollment of our Phase 3 clinical trials.

Based on additional reporting by one of the CROs, we recorded a change in estimate to decrease clinical trial expense by $0.7 million in the quarter ended June 30, 2008.

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General and Administrative Expenses

	Three Months Ended June 30,				Six Months Ended June 30,			
	2008	2007	Increase/ (Decrease)	% Increase/ (Decrease)	2008	2007	Increase/ (Decrease)	% Increase/ (Decrease)
	(in thousands, except percentages)							
General and administrative expenses	$ 7,863	$ 6,195	$ 1,668	27%	$ 15,331	$ 11,527	$ 3,804	33%

The increase in general and administrative expenses for the three and six months ended June 30, 2008 compared to the three and six months ended June 30, 2007 was primarily due to an increase of $0.9 million and $1.5 million, respectively, in personnel costs resulting from higher headcount and stock-based compensation expenses and an increase of $0.8 million and $2.6 million, respectively, in legal, Sarbanes-Oxley and other consulting fees. We expect to incur increasing general and administrative expense in future periods to support our research and development activities, preparation for the New Drug Application for Hematide, costs associated with our J&J litigation and development of commercial capabilities.

Interest Income (Expense), Net

	Three Months Ended June 30,				Six Months Ended June 30,			
	2008	2007	Increase/ (Decrease)	% Increase/ (Decrease)	2008	2007	Increase/ (Decrease)	% Increase/ (Decrease)
	(in thousands, except percentages)							
Interest income (expense), net	$ 943	$ 2,913	$ (1,970)	(68)%	$ 2,891	$ 5,923	$ (3,032)	(51)%

The decrease in interest income, net, was due primarily to lower level of cash, cash equivalents and investments and lower interest rates during the three and six months ended June 30, 2008 compared to the same periods in 2007.

Other Income (Expense), Net

	Three Months Ended June 30,				Six Months Ended June 30,			
	2008	2007	Increase/ (Decrease)	% Increase/ (Decrease)	2008	2007	Increase/ (Decrease)	% Increase/ (Decrease)
	(in thousands, except percentages)							
Other income (expense), net	$ (249)	$ 20	$ (269)	(1,345)%	$ (1,588)	$ 35	$ (1,623)	(4,637)%

Other income (expense), net, for the three and six months ended June 30, 2008 includes a $240,000 and $1.6 million other-than-temporary impairment charge related to the decrease in fair value of our investments in ARS, respectively. Based on projected cash usage, we may be required to sell the ARS prior to the resumption of successful auctions or other liquidity events and as a result, we deemed the impairment as other-than-temporary.

Provision for Income taxes

	Three Months Ended June 30,				Six Months Ended June 30,			
	2008	2007	Increase/ (Decrease)	% Increase/ (Decrease)	2008	2007	Increase/ (Decrease)	% Increase/ (Decrease)
	(in thousands, except percentages)							
Provision for income taxes	$	$ 925	$ (925)	(100)%	$	$ 1,255	$ (1,255)	(100)%

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We are subject to federal and California state income tax. We anticipate being in a net operating loss position for 2008. We recorded no tax provision for the three and six months ended June 30, 2008. For the three and six months ended June 30, 2007, we recorded a provision for income taxes of $925,000 and $1.3 million, respectively, based on our projected taxable income for 2007. The provision for income taxes was due to the limitation in utilization of net operating losses in 2007.

Liquidity and Capital Resources

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, 2008, we have received net proceeds of $258.2 million from the issuance of common stock and convertible preferred stock and $122 million of upfront license fees, a $10 million milestone payment and $54.9 million for the reimbursement of development and commercial expenses and purchase of API from our collaboration agreements with Takeda. Of the first $50 million of third-party expenses related to the development in pursuit of U.S. regulatory approval of Hematide to be borne by Takeda, a total of $36.3 million was utilized by both parties through December 31, 2007 and the remainder was utilized during the first quarter of 2008. Thereafter, Takeda bears 70% of the third-party U.S. development expenses, while we are responsible for 30% of the expenses.

As of June 30, 2008, we had $162.6 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, corporate bonds, commercial paper, ARS and money market funds. Cash in excess of immediate requirements is invested in accordance with our investment policy primarily with a view to liquidity and capital preservation.

As of June 30, 2008, we had $21.6 million invested in ARS 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, closed end preferred issuances and other municipal issuances. The ARS held by us are rated AAA by a major credit rating agency, except for one ARS that is rated AA by a major credit rating agency. ARS are structured to provide liquidity via 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 markets. In the following month, approximately one-fifth of the auctions for ARS we held were successful. However, the overall ARS market has continued to deteriorate and the ARS held by us have failed in all but a single auction since mid-March. During the quarter ended June 30, 2008, the par value of our ARS holdings decreased $5.1 million to $23.2 million as a result of redemptions by the issuers and one partial successful auction.

We determined the fair value of our ARS at June 30, 2008 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 decrease in fair value of ARS totaling $1.6 million as of June 30, 2008. Of the $1.6 million decrease, $26,000 is associated with our ARS holdings for which issuers have announced redemptions of their ARS or have completed a partial redemption on their ARS and is expected to redeem the remaining issuance. As a result, we deemed the decrease in the fair value of that ARS as temporary and recorded a $26,000 unrealized loss to accumulated other comprehensive loss. The remaining decrease in fair value was associated with ARS that we may be required to sell prior to the resumption of successful auctions or other liquidity events. As a result, the remaining decrease in fair value was deemed to be other-than-temporary and recorded as an impairment charge to other expense in the three and six months ended June 30, 2008. 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.

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Based on our expected cash usage and our balance of cash and other investments, we do not anticipate the current illiquidity of these investments will affect our ability to operate our business as usual for at least 12 months. However, there can be no assurance as to the timing of when, or if the market for ARS will recover in a manner that will allow us to receive a return of some or all of our principal or to meet our liquidity needs. If we are unable to liquidate our ARS to obtain funds when needed we may be unable to fund our operations.

	June 30, 2008	December 31. 2007
	(in thousands)	
Cash, cash equivalents, short-term investments	$ 140,983	$ 168,337
Working capital	$ 95,132	$ 139,114
Long-term investments	$ 21,640	$ 15,655

	Six Months Ended June 30,	
	2008	2007
	(in thousands)	
Cash provided by (used in):		
Operating activities	$ (17,946)	$ (11,079)
Investing activities	$ (20,537)	$ (58,377)
Financing activities	$ 511	$ 239
Capital expenditures (included in investing activities above)	$ (2,256)	$ (1,875)

Net cash used in operating activities for the six months ended June 30, 2008 primarily reflects the net loss for the period, which was reduced in part by non-cash activities including stock-based compensation, an other-than-temporary impairment charge related to our investments in ARS, depreciation and amortization, as well as a decrease in prepaid expenses and other current assets, and changes in operating assets and liabilities due to timing of payments made in connection with our Phase 3 clinical trials for Hematide. Net cash used in operating activities for the six months ended June 30, 2007 primarily reflects the net loss for the period and a $10 million milestone payment received from Takeda and $4.8 million for the reimbursement of third-party expenses received from Takeda under the Arrangement, which was reduced in part by depreciation and amortization, stock-based compensation and changes in operating assets and liabilities. Net cash used in investing activities for the six months ended June 30, 2008 and 2007 was primarily related to net purchases of investments and, to a lesser extent, purchase of property and equipment. Net cash provided by financing activities for the six months ended June 30, 2008 and 2007 was primarily attributable to the proceeds from issuance of common stock upon exercise of stock options and proceeds from the purchase of common stock under our Employee Stock Purchase Plan, which was offset by principal payments under the capital lease obligations.

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

- the initiation, progress, timing and completion of preclinical 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 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;

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- 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.

We believe that the existing cash, cash equivalents and investments together with the interest thereon, will enable us to maintain our currently planned operations through at least 12 months. However, we expect that we will need to raise additional funding to complete the development and commercialization of Hematide. There can be no assurance we can raise the additional funds to support our operations, and such funding may not be available to us on acceptable terms, or at all. We have elected to focus on Hematide, and as a result reduced our research capabilities and efforts, including the elimination of certain research programs. 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 may 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.

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, 2007.

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, fiduciary control of cash and investments and fulfillment of liquidity needs. However, as of June 30, 2008, we had $21.6 million invested in ARS 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, closed end preferred issuances and other municipal issuances. The ARS held by us are rated AAA by a major credit rating agency, except for one ARS that is rated AA by a major credit rating agency. Based on overall market liquidity concerns, we determined that there was a decrease in fair value of ARS totaling $1.6 million as of June 30, 2008.

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.

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 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 result.

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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, 2008. 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, 2008, our disclosure controls and procedures were not effective, at the reasonable assurance level, because of the material weakness in internal control over financial reporting described below.

Notwithstanding the material weakness described below, we believe the Company s financial statements included in this Quarterly Report on Form 10-Q present fairly, in all material respects, the Company s financial position, results of operations and cash flows for the periods presented. Our Chief Executive Officer and Chief Financial Officer have certified to their knowledge that this Quarterly Report on Form 10-Q does not contain any untrue statements of material fact or omit to state any material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered in this Quarterly Report.

Material weakness in internal control over financial reporting. A material weakness is a control deficiency, or a combination of control deficiencies, that results in more than a remote likelihood that a material misstatement of our interim or annual financial statements will not be prevented or detected. As of June 30, 2008, we did not maintain effective controls over the completeness and accuracy of our clinical trial expense. In connection with the preparation of the interim financial statements for the second quarter of 2008, we identified errors in the analysis and preparation of this clinical trial expense and related balance sheet accounts, including the incorrect application of information provided in reports from third party contract research organizations (CROs). These control deficiencies resulted in the recording of certain expenses twice and in turn, the overstatement of clinical trial expense of $0.3 million and $1.6 million in the three months ended March 31, 2008 and December 31, 2007, respectively, and related collaboration revenue in the same periods. The correction of these errors resulted in out of period adjustments in the interim financial statements for the three months and six months ended June 30, 2008 of a $1.9 million reduction to clinical trial expense and a $0.5 million reduction to collaboration revenue for reimbursed clinical trial expense. These errors arose from control deficiencies that, in the aggregate, could result in a misstatement to the aforementioned accounts that could result in a material misstatement of our annual or interim financial statements that would not be prevented or detected. Accordingly, management determined that these control deficiencies, in the aggregate, constitute a material weakness.

Plan for Remediation of Material Weakness. We have discussed this material weakness with our independent registered public accounting firm and our Audit Committee. We have taken significant actions and will take further actions to remediate the material weakness related to our internal controls over the completeness and accuracy of our clinical trial expense including the validation and reconciliation of clinical trial expense and accruals on a study by study basis using data provided by third parties and detailed budget versus actual expense by individual trial. We will continue to strengthen our internal controls over clinical trial expense during the remainder of the year.

We are in the process of performing our plan for testing and certification as provided under Section 404 of the Sarbanes-Oxley Act of 2002 (Section 404). If we are unable to correct the material weakness we have identified prior to the end of fiscal year 2008, or if we experience other problems that prevent the favorable assessment of the effectiveness of our internal control over financial reporting, we will be required to conclude and report that our internal control over financial reporting is not effective as of that date and investor confidence and our stock price could be adversely affected.

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, 2008, that have materially affected, or are reasonably likely to materially affect our ability to record, process, summarize and report financial information, except as discussed above.

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 erythropoietin receptor, or EPO-R, agonists (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 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. 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 a European patent application currently naming J&J as sole owner that may issue in the near future and relates to specified ESA peptide compounds. 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

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owner of one or more of the U.S. patents in the dispute that are assigned to us, 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.

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 discovered 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 discovered 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 and the rights to specified patents and patent applications that had previously been held by Affymax N.V. and Affymax Technologies, N.V. After the termination

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of the R&D Agreement in 1995, the Affymax Entities 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; and U.S. Patent Application No. 08/827,570.

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 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.

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 a patent being issued to J&J in the near future. In the J&J arbitration proceeding, we have claimed that we should be at least 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.

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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 relating to agonist peptide dimers (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 us patents on the Affymax scientists inventions. The complaint 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 (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, the Company 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 arbitrators have established a schedule for the arbitration. The parties have commenced 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, the Company 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 can obtain limited discovery on Hematide, but that J&J cannot 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 currently scheduled to occur during the second half of 2008, but might be delayed. The outcome of the matter is uncertain and regardless of outcome, the matter may have an adverse impact on the Company because of legal costs, diversion of management resources and other factors.

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

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, and we cannot give any assurance that it will receive regulatory approval or be successfully commercialized. Recent safety concerns surrounding the use of ESAs may limit the ability to develop or commercialize Hematide for use in oncology and potentially, other indications.

Hematide, an ESA, is a new chemical entity and currently our only product candidate. We are conducting Phase 3 clinical trials for the treatment of anemia associated with chronic renal failure. In order to commercialize Hematide, we will be required to conduct clinical trials to establish that Hematide is safe and effective which may not succeed and to obtain regulatory approvals which we may fail to do. We do not know, and are unable to predict, whether we will be able to successfully enroll patients or to otherwise execute the Phase 3 clinical trials in a timely or effective manner.

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:

- 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 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 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.

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

We cannot predict what further action, if any, the FDA may take in oncology and, potentially, in other indications, 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, 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 patient enrollment and the cost, scope, size, risk, or timing of our clinical trials, increase the risk of achieving regulatory approval, and significantly delay commercialization of Hematide. The market for ESAs has been significantly reduced and is likely to negatively impact the commercial potential 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 the clinical trial process. 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.

Some of the recent safety concerns surrounding commercially available ESAs relate to clinical trials conducted in certain cancer patients suggest higher mortality and serious side effects associated with ESA treatment. The safety concerns expressed by the ODAC recommendations and the FDA may significantly limit the ability to develop and pursue the Hematide oncology program. The current regulatory climate could result in the need to conduct significantly larger, longer, and more difficult clinical trials, including potentially involving survival data, in order to obtain approval for the use of Hematide for chemotherapy-induced anemia compared to the clinical trials that have been required to date of commercially available ESAs. In addition, the safety concerns, including the restrictions on labeling or use of ESAs, have significantly reduced the use of ESAs particularly in oncology and may limit the potential market opportunity. The decreased commercial potential for Hematide in oncology may not justify such expenditures by us or by our collaboration partner, Takeda Pharmaceutical Company Limited, or Takeda.

Hematide is at an earlier stage of development for chemotherapy-induced anemia in comparison to our renal program and as part of our collaboration with Takeda, Takeda has assumed primary responsibility for regulatory and clinical development activities related to the worldwide oncology program. Takeda has recently initiated a Phase 1 clinical trial for the treatment of chemotherapy-induced anemia in prostate, breast, and non-small cell lung cancer patients in the U.S. The safety concerns surrounding ESAs has had a significant negative impact on the timing, and development of the Hematide oncology program as well as the ultimate commercial potential of this indication. This in turn has adversely affected Takeda s or our ability and our interest in pursuing Hematide in the oncology setting, and depending upon the outcome of ongoing evaluation, could result in further delays, suspension or discontinuation of the oncology program altogether, which may have a material adverse effect on our business and stock price.

We have incurred significant operating losses since inception and anticipate that we will incur continued losses for the foreseeable future. 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, 2008, we had an accumulated deficit of $246.3 million. We have funded our operations to date principally from the sale of our securities and from payments by Takeda under our collaboration agreements. We expect to continue to incur substantial additional operating losses for the next several years as we pursue our clinical trials, prepare for commercialization of Hematide, potentially begin new research and development programs and add the necessary

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infrastructure to support operating as a public company. 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 at least several 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 they 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.

A portion of our investments consists of auction rate securities, or ARS, and the market for those securities has recently failed to provide liquidity, and if such illiquidity continues, may negatively impact our operations.

Since the filing of our Form 10-K for the year ended December 31, 2007, the overall ARS market has continued to deteriorate and our ARS have failed in all but a single auction. Although we do not currently need to liquidate these securities, we recorded a $1.6 million reduction of fair value of ARS which was recorded as an impairment charge in the first half of 2008. As of June 30, 2008, we have a remaining balance of $21.6 million invested in ARS. Our valuation 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 additional impairments in future periods. There can be no assurance as to the timing of when, or if the market for ARS will recover in a manner that will allow us to receive a return of some or all of our principal or to meet our liquidity needs. If we are unable to liquidate our ARS to obtain funds when needed we may be unable to fund 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 erythropoietin receptor, or EPO-R, agonists. An adverse result in this binding arbitration or litigation, together with adverse results in subsequent litigation J&J might 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 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 are 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 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

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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 the dispute that are assigned to us, J&J may seek to assert such patent against us in the U.S.

Although J&J s ownership of its European patent application relating to agonist peptide dimers 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 at least 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, and could necessitate prolonged discovery. Since we acquired assets from Affymax N.V. (a different company from us), discovery could uncover documents and other evidence of which we are not currently aware 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 expect we will continue to incur significant and increasing expenses for several more years, likely totaling in the millions of dollars as this matter progresses toward resolution. 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. The arbitration panel ruling permitting the scope of discovery to include certain information relating to Hematide could increase our legal expenses significantly and may further divert the efforts of our technical, legal and management personnel.

Our commercial success depends upon attaining significant market acceptance of Hematide among physicians, patients, health care payors and, in the renal market, acceptance by the 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 has been served by our competitors products for many years. These products may now be said to be the standard of care, and it may be difficult to encourage healthcare providers to switch from products with which they and their patients have become comfortable.

The dialysis market, which 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 prior to product launch, the revenue opportunity of Hematide could be significantly reduced. In October 2006, Amgen Inc., or Amgen, marketer of the

ESAs EPOGEN and Aranesp, and Fresenius Medical Care, or Fresenius, one of the two largest operators of dialysis clinics in the U.S., announced an agreement whereby Amgen would be the sole supplier of EPO products for Fresenius dialysis business effective immediately through the end of 2011. We are not aware of the specific terms of the Amgen-Fresenius agreement, and cannot project how it may impact the commercial opportunity for 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.

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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 reimbursements 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 pre-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 pre-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 pre-dialysis patients may be difficult, as these patients are spread thinly across a variety of treatment settings. Primary care physicians that treat pre-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;
- 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 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.

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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, currently marketed outside the U.S. by Roche. Aranesp is approved for once-monthly dosing for treatment of anemia in pre-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 pre-dialysis patients. If Amgen is successful in obtaining approval for once-monthly dosing, the market for Hematide may be decreased. In addition, Roche s Mircera has recently received approval in Europe. Mircera reportedly has greater plasma stability and is longer acting than any rEPO product that is currently on the market. Roche and Amgen are currently engaged in patent litigation. Mircera has recently been found to infringe several U.S. patents owned by Amgen. In February 2008, a preliminary injunction was issued enjoining Roche from selling Mircera in the U.S., but no permanent injunction was issued. Pending further proceedings, Roche is not yet permanently enjoined from launching Mircera in the U.S. and the court left open the possibility of a new order that would permit Roche to import and sell Mircera in the U.S. subject to certain conditions. If no permanent injunction is granted or if the court permits sales of Mircera by Roche, even under specified conditions, Mircera may enter the market before Hematide. Because of its ability to be longer acting than currently marketed ESAs, we believe that Mircera will be in direct competition with Hematide, and therefore could potentially limit the market for Hematide. If Roche successfully appeals the decision, or if Amgen is unsuccessful in maintaining an injunction or if Amgen is required to grant a license to Roche, Mircera may enter the market before Hematide. Because of its ability to be longer acting, we believe that Mircera will be in direct competition with Hematide, and therefore could potentially limit the market for Hematide. Another potential competitor, FibroGen, Inc., or FibroGen, is developing small molecules designed to promote the production of greater levels of naturally-occurring EPO in patients. The introduction of generics 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, preclinical 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 existing rEPO patents expire in the U.S. in 2013.

The last significant U.S. patent for epoetin alfa, a version of short-acting rEPO, expires in 2013. Patents related to epoetin alfa expired in the E.U. in 2004. Generic versions, or biosimilars, of short-acting rEPO are currently being developed or launched in and for various markets outside the U.S., including the E.U. Short-acting rEPO biosimilars are already being sold in various territories outside the U.S. and 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.

Any failure or delay in completing clinical trials for Hematide could severely harm our business.

Hematide, as well as any other product candidate we choose to pursue, must undergo extensive preclinical studies and clinical trials as a condition to regulatory approval. Preclinical studies and clinical trials are expensive and take many years to complete. We estimate that clinical

trials and related regulatory review for Hematide will continue for at least four years for the renal program, but could take significantly longer to complete. Hematide is at

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an earlier stage of development for chemotherapy-induced anemia in comparison to our renal program and would take many more years of development prior to commercialization, if ever. The completion of clinical trials for Hematide may be delayed or halted for many reasons, including:

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

- delays in initiating sites and patient enrollment, which is a function of many factors, including the variability in the number, types and eligibility of patients available for clinical trials, perceived risks and benefits of the drugs under study, and efforts and availability of resources to facilitate timely enrollment;

- longer duration of our Phase 3 clinical trials for Hematide than the currently planned 52 week treatment period of the last patient if the rates of cardiovascular events are lower than expected;

- difficulties of executing our clinical program, including the four Phase 3 clinical trials for Hematide, which is large and complex, involving numerous third parties, approximately 400 sites in the U.S. and Europe, compliance with a variety of government regulations, and a number of significant new initiatives and systems for which we do not have any prior experience implementing;

- delays or failure in reaching agreement on acceptable clinical trial contracts or clinical trial protocols with prospective sites;

- regulators or institutional review boards may not authorize us to commence a clinical trial;

- our inability, or the inability of our collaborators or licensees, to manufacture or obtain from third parties materials sufficient to complete our preclinical studies and clinical trials;

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

- difficulty in maintaining contact with patients after treatment, resulting in incomplete data;

- poor effectiveness or safety concerns during clinical trials;

- the failure of patients to complete clinical trials due to side effects, dissatisfaction with Hematide or other reasons;

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

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

Clinical trials may require the enrollment of large numbers of patients, and suitable patients may be difficult to identify and recruit. Our ability to enroll sufficient numbers of patients in our clinical trials depends on many factors, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical sites, the eligibility criteria for the trial and competing clinical trials. Patients participating in the trials may not live through completion of the trial or may suffer adverse medical effects unrelated to treatment with Hematide. The results from preclinical testing and prior clinical trials may not be predictive of results obtained in later and larger 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. Our failure to adequately demonstrate the safety and effectiveness of Hematide will prevent us from receiving regulatory approval and negatively impact our business.

It is possible that Hematide will not complete clinical trials in any markets. We also do not know and are unable to predict whether the data arising from the clinical trials for Hematide will be satisfactory to the FDA and, if not, whether the FDA will require us to conduct additional trials or alter the scope, size or design of such 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 clinical trials would delay commercialization of Hematide and severely harm our business and financial condition.

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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. We have elected to focus on Hematide, and as a result reduced our research capabilities and efforts, including the elimination of certain research programs. 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 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.

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.

Strategic collaborations for development of Hematide and any other future product candidates, if any, we decide to pursue are an important part of our business model. If we are not able to 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 after the second anniversary of the effective date of such agreement 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. Through the collaboration, Takeda currently provides development funding and services, 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.

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, President Bush signed into law new Medicare prescription drug coverage legislation that changes the methodology used to calculate reimbursement for certain drugs such as Hematide. In addition, the legislation directs the Secretary of Health and Human Services to contract with procurement organizations to purchase physician-administered drugs from the manufacturers and provides 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. 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.

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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 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 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. Although significant aspects of the bundled payment system have yet to be established, providers are expected to be reimbursed a fixed amount per patient. We cannot guarantee that Hematide will be reimbursed by CMS in a method that will support physician adoption and depending upon the details of the bundled payment system that are ultimately implemented, 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.

If we fail to obtain additional financing, we will be unable to complete the development and commercialization of Hematide.

Our operations have consumed substantial amounts of cash since our inception. We expect to continue to spend substantial amounts in order to:

- complete the Phase 3 clinical trials for the Hematide renal program and other clinical development of Hematide;
- prepare to launch and commercialize Hematide, including building our own commercial organization and sales force to address certain markets; and
- develop, license or acquire additional product candidates.

We believe that existing cash, cash equivalents and investments and the interest thereon, will enable us to maintain our currently planned operations through at least 12 months. However, we expect that additional capital will need to be raised to complete the development and commercialization of 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, our stockholders may experience significant dilution. Any debt financing, if available, may involve 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 significantly delay, scale back or discontinue the development and/or commercialization of Hematide.

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We rely on third parties to conduct preclinical 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 preclinical development activities or clinical trials may be extended, delayed, suspended or terminated. If any of these events occur, we may not be able to obtain regulatory approval of Hematide.

Our dependence upon third parties for the manufacture and supply may cause delays in, or prevent us from, successfully developing and commercializing Hematide.

We do not currently have the infrastructure or capability internally to manufacture the Hematide needed to conduct our clinical trials. We have entered into agreements with contract manufacturers to produce our clinical supplies of Hematide; however, we do not have all of our long-term supply arrangements established. 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 drug substance, which could include: cost overruns, process scale-up, process reproducibility, stability issues and timely availability of raw materials, as well as regulatory issues. Further, some of these 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 more susceptible to supply interruptions and potential delays. 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 Hematide manufacturing process. Any of these risks may prevent or delay us from successfully developing 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 use in our clinical trials. 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.

We, our third-party manufacturers and our partners are required to comply with applicable FDA manufacturing practice regulations. If one of our third-party manufacturers fails 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

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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 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.

The commercial success of Hematide depends in part on the development and marketing efforts of Takeda, over which we have limited control. If our collaboration 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, particularly for the chemotherapy-induced anemia indication, is dependent on the efforts of Takeda. 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 elect to 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, either developed by our collaboration partners 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 will not receive any future revenue from Hematide unless we are either able to find another partner or 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 preclinical 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.

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

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

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

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

- we or our licensors or collaborators might not have been the first to file patent applications for these inventions;

- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;

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

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

- we may not develop additional proprietary technologies that are patentable; or

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

We also may rely on trade secrets to protect our technology, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, outside scientific collaborators and other advisors may unintentionally or willfully disclose our information to competitors. Enforcing a claim that a third party illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the U.S. are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

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

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

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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 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;

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- 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 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 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 scientific staff, particularly Arlene Morris, our President and 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 planned clinical trials 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. 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.

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Risks Related to Our Industry

The regulatory approval process is expensive, time consuming and uncertain and may prevent us or our collaboration partners from obtaining approvals for the commercialization of 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 New Drug Application, or NDA, from the FDA. We have not received marketing approval for Hematide. Further, we have not 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 studies 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 preclinical studies and clinical trials. The number of preclinical 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 preclinical 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. 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.

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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 European Union and many other foreign jurisdictions, we must obtain separate regulatory approvals. We have had limited interactions with foreign regulatory authorities, and the approval procedures vary among countries and can involve additional testing, and the time required to obtain approval may differ from that required to obtain FDA approval. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. Foreign regulatory approvals may not be obtained on a timely basis, if at all. We or Takeda, as part of our 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 European Union, 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;

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- 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 develop. We currently carry product liability insurance covering our clinical studies 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, 2008, the price ranged between a high of $31.99 per share and a low of $13.14 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 actions taken by regulatory agencies with respect to ESAs generally or specifically as to Hematide;

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

- developments in the Amgen patent infringement litigation and Roche s potential to launch Mircera;

- issuance of patents to competitors, including the expected issuance of patents to J&J in Europe;

- developments in our litigation with J&J, including both substantive and procedural rulings by the arbitration panel;

- actual or anticipated results from, and any delays in, our clinical trials;

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

- 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;

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- 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;

- 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;

- trading volume of our common stock; and

- sales of our common stock by us or our stockholders.

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 has often been instituted against companies. Such litigation, 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, 2008, our executive officers, directors and principal stockholders, together with their respective affiliates, owned approximately 63% 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.

If we are unable to successfully assess the effectiveness of internal control over financial reporting, or if our independent registered public accounting firm is unable to provide an unqualified attestation report on our assessment, our stock price could be adversely affected.

The Sarbanes-Oxley Act of 2002 requires, among other things, that we maintain effective internal control over financial reporting and disclosure controls and procedures. In particular, for the year ending December 31, 2008, we must perform system and process evaluation and testing of our internal control over financial reporting to allow management and our independent registered public accounting firm to report on the effectiveness of our internal control over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. There can be no assurance that we will successfully and timely report on the effectiveness of our internal control over financial reporting as of the end of 2008. For example, during our review of the results of operations for the quarter ended June 30, 2008, we identified a material weakness in the operation of our internal controls over financial reporting, as defined in Public Company Accounting Oversight Board Standard No. 5, in connection with the completeness and accuracy of clinical trial expense. We have commenced efforts to remediate this material weakness through process and internal control improvements. However, if we cannot correct the material weakness we have identified prior to the end of fiscal year 2008, or if we experience other problems that prevent the favorable assessment of the effectiveness of our internal control over financial reporting, or if our independent registered public accounting firm is unable to provide an unqualified attestation report on our assessment in the future, investor confidence and our stock price could be adversely affected.

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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.

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 biotechnology and biopharmaceutical companies have experienced significant stock price volatility in recent years. If we were to face such litigation, it could result in substantial costs and a diversion of management s attention and resources, which could harm our business.

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

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

These provisions include:

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

- limiting the removal of directors by the stockholders;

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

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

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

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

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

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

Unregistered Sales of Equity Securities

None.

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, 2008, we had invested the aggregate net proceeds of approximately $96 million from our initial public offering in investment accounts.

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

Issuer Purchases of Equity Securities

The following table provides information relating to repurchases of our common stock in the three months ended June 30, 2008:

Period	Total Number of Shares Purchased (1)	Average Price Paid Per Share	Total Number of Shares Purchased as Part of a Publicly Announced Program	Approximate Dollar Value of Shares That May Yet Be Purchased Under the Program
April 1, 2008 - April 30, 2008	110	$ 4.36	N/A	N/A
May 1, 2008 - May 31, 2008			N/A	N/A
June 1, 2008 - June 30, 2008			N/A	N/A
Total	110	$ 4.36	N/A	N/A

(1) The 110 shares of our common stock were repurchased by us from an employee upon termination of services pursuant to the terms and conditions of our 2001 Stock Option/Stock Issuance Plan, which permits us to elect to purchase such shares at the original issuance price.

Item 3. Defaults Upon Senior Securities

Not applicable.

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

Our Annual Meeting of Stockholders was held on May 22, 2008 (the Meeting). Of the 15,153,033 shares of Common Stock entitled to be voted at the Meeting, 10,281,826 shares of Common Stock were voted in person or by proxy, constituting a quorum.

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The following matters were considered and voted at the Meeting:

(i) The stockholders voted to elect our three (3) Class II director nominees. Of the votes cast, Mr. R. Lee Douglas received 10,214,144 votes for election and 67,682 votes were withheld. Dr. Nicholas Galakatos received 10,269,465 votes for election and 12,361 votes were withheld. Mr. John P. Walker received 9,241,933 votes for election and 1,039,893 were withheld. Accordingly, the following persons were elected as directors for a three year period expiring in 2011:

R. Lee Douglas

Dr. Nicholas Galakatos

John P. Walker

Ted W. Love, Arlene M. Morris and Daniel K. Spiegelman will continue in office as directors in the class of directors to be elected at our 2009 annual meeting of stockholders. Kathleen LaPorte, Christi van Heek, and Keith R. Leonard will continue in office as directors in the class of directors to be elected at our 2010 annual meeting of stockholders

(ii) The stockholders voted to ratify the appointment of PricewaterhouseCoopers LLP as our independent registered public accounting firm for the fiscal year ending December 31, 2008. Of the votes cast, 10,270,034 shares were cast in favor of ratification, 11,173 votes against, 619 votes abstained and 0 broker non-votes. We recently announced the replacement of PricewaterhouseCoopers LLP with Ernst & Young LLP as our independent registered public accounting firm for the fiscal year ended December 31 2008 as reported in our Form 8-K as filed with the Securities and Exchange Commission on June 2, 2008.

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)
4.6	Form of Senior Debt Indenture, between Registrant and one or more trustees to be named(3)
4.7	Form of Subordinated Debt Indenture, between Registrant and one or more trustees to be named(3)
31.1	Certification required by Rule 13a-14(a) or Rule 15d-14(a)
31.2	Certification required by Rule 13a-14(a) or Rule 15d-14(a)
32.1	Certification required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. 1350)

(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 of our registration statement of Form S-3, as amended, registration no. 333-149773, filed with the Securities and Exchange Commission on March 18, 2008.

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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 18, 2008	By:	/s/ ARLENE M. MORRIS Arlene M. Morris *President, Chief Executive Officer and Member of the Board of Directors*
Dated: August 18, 2008	By:	/s/ PAUL B. CLEVELAND Paul B. Cleveland *Executive Vice President, Corporate Development and Chief Financial Officer (Principal Financial Officer)*

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EXHIBIT INDEX

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