

AFFYMAX INC  
Form 10-Q  
August 13, 2007

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 10-Q**

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

**For the quarterly period ended June 30, 2007**

**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**

(State or other jurisdiction of  
incorporation or organization)

**77-0579396**

(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)

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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  No

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

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

As of July 15, 2007, 14,894,210 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.**  
**(A development stage company)**  
**CONDENSED BALANCE SHEETS**  
**(in thousands)**  
**(Unaudited)**

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	June 30, 2007	December 31, 2006
<b>Assets</b>		
Current assets		
Cash and cash equivalents	\$ 78,324	\$ 147,541
Restricted cash	1,051	1,051
Short-term investments	139,555	76,751
Related party receivable	9,955	10,191
Prepaid expenses and other current assets	3,027	4,576
Total current assets	231,912	240,110
Property and equipment, net	3,425	2,014
Restricted cash	1,135	1,135
Long-term investments		6,133
Deferred tax assets	326	
Other assets	1,481	596
Total assets	\$ 238,279	\$ 249,988
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities		
Accounts payable	\$ 9,724	\$ 9,113
Accrued liabilities	2,948	2,566
Income taxes payable	924	
Capitalized lease obligations, current	236	293
Total current liabilities	13,832	11,972
Deferred revenue	119,278	120,821
Other long term liabilities	1,007	156
Capitalized lease obligations, net of current	53	140
Total liabilities	134,170	133,089
Commitments and contingencies (Note 5)		
Stockholders' equity		
Common stock	15	15
Additional paid-in capital	289,423	285,771
Deferred stock-based compensation	(65)	(94)
Deficit accumulated during the development stage	(185,168)	(168,749)
Other comprehensive loss	(96)	(44)
Total stockholders' equity	104,109	116,899
Total liabilities and stockholders' equity	\$ 238,279	\$ 249,988

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



**AFFYMAX, INC.**

**(A development stage company)**

**CONDENSED STATEMENTS OF OPERATIONS**

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

**(Unaudited)**

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	Three Months Ended		Six Months Ended		Cumulative Period From July 20, 2001 (Date of Inception) to June 30, 2007
	June 30, 2007	2006	June 30, 2007	2006	
Collaboration revenue	\$ 9,654	\$ 127	\$ 16,972	\$ 127	\$ 28,660
License and royalty revenue	15	14	21	22	612
Total revenue	9,669	141	16,993	149	29,272
Operating expenses					
Research and development	14,730	25,525	26,588	31,978	158,758
General and administrative	6,195	3,314	11,527	4,201	50,587
Amortization of intangible assets					14,471
Impairment of assets					4,224
Total operating expenses	20,925	28,839	38,115	36,179	228,040
Loss from operations	(11,256 )	(28,698 )	(21,122 )	(36,030 )	(198,768 )
Interest income	2,917	877	5,932	1,567	14,856
Interest expense	(4 )	(14 )	(9 )	(47 )	(179 )
Other income (expense), net	20	(2 )	35	1	178
Net loss before provision for income taxes	(8,323 )	(27,837 )	(15,164 )	(34,509 )	(183,913 )
Provision for income taxes	925		1,255		1,255
Net loss	(9,248 )	(27,837 )	(16,419 )	(34,509 )	(185,168 )
Accretion of mandatorily redeemable convertible preferred stock		(216 )		(409 )	(1,899 )
Net loss attributable to common stockholders	\$ (9,248 )	\$ (28,053 )	\$ (16,419 )	\$ (34,918 )	\$ (187,067 )
Net loss per common share:					
Basic and diluted	\$ (0.62 )	\$ (23.49 )	\$ (1.10 )	\$ (45.44 )	
Weighted-average number of common shares used in computing basic and diluted net loss per common share calculations	14,879	1,194	14,870	768	

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





**AFFYMAX, INC.**  
**(A development stage company)**  
**CONDENSED STATEMENTS OF CASH FLOWS**  
**(in thousands)**  
**(Unaudited)**

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	Six Months Ended June 30, 2007		2006	Cumulative Period From July 20, 2001 (Date of Inception) to June 30, 2007
<b>Cash flows from operating activities</b>				
Net loss	\$	(16,419 )	\$ (34,509 )	\$ (185,168 )
Adjustments to reconcile net loss to net cash provided by (used in) operating activities				
Depreciation and amortization		464	317	21,494
Stock-based compensation expense		3,269	(3 )	9,735
Interest expense related to common stock warrants				56
Loss on termination of capital lease				156
(Gain) loss on disposal of fixed assets		(15 )		160
Impairment of assets				4,224
Realized gain on investments		(27 )		(120 )
Lease deposit write off				23
Changes in operating assets and liabilities :				
Related party receivable		236	(105,071 )	(9,955 )
Prepaid expenses and other current assets		1,549	(1,062 )	(2,755 )
Deferred tax assets		(326 )		(326 )
Other assets		(885 )		(46 )
Accounts payable		611	18,675	9,118
Accrued liabilities		411	258	2,379
Income taxes payable		924		924
Deferred revenue		(1,543 )	122,000	119,278
Other long term liabilities		851	(86 )	1,007
Net cash provided by (used in) operating activities		(10,900 )	519	(29,816 )
<b>Cash flows from investing activities</b>				
Purchases of property and equipment		(1,875 )	(588 )	(5,136 )
Purchases of marketable securities		(143,691 )	(54,245 )	(667,836 )
Proceeds from sales and maturities of marketable securities		86,995	39,296	528,305
Proceeds from sale of property and equipment		15		548
Acquisition of net assets, net of cash acquired				(1,086 )
Change in restricted cash				(2,186 )
Net cash used in investing activities		(58,556 )	(15,537 )	(147,391 )
<b>Cash flows from financing activities</b>				
Repurchases of common stock		(15 )		(479 )
Proceeds from issuance of common stock upon exercise of stock options, including early exercise of stock options		1	170	745
Proceeds from issuance of common stock under employee stock purchase plan		427		427
Proceeds from issuance of common stock upon exercise of common stock warrant				1,824
Proceeds from issuance of common stock				1,000
Proceeds from issuance of preferred stock, net of issuance costs			9,982	157,035
Proceeds from IPO, net of issuance costs		(30 )	(64 )	96,055
Principal payments under capital lease obligations		(144 )	(130 )	(1,076 )
Net cash provided by financing activities		239	9,958	255,531
Net increase (decrease) in cash and cash equivalents		(69,217 )	(5,060 )	78,324
Cash and cash equivalents at beginning of the period		147,541	14,399	
Cash and cash equivalents at end of the period	\$	78,324	\$ 9,339	\$ 78,324
<b>Noncash investing and financing activities</b>				
Change in unrealized loss on marketable securities		(52 )	(23 )	(96 )

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



**AFFYMAX, INC.**  
**(A development stage company)**

**NOTES TO CONDENSED FINANCIAL STATEMENTS**

**(Unaudited)**

1. The Company

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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 lead product candidate, Hematide, is designed to treat anemia associated with chronic renal failure and cancer. Hematide is a synthetic peptide-based erythropoiesis stimulating agent, or ESA, designed to stimulate production of red blood cells. The Company is planning to commence its Phase 3 clinical trials in patients suffering from chronic renal failure patients, on dialysis and not on dialysis, in the fourth quarter of 2007.

In December 2006, the Company completed its initial public offering of 4,255,000 shares of its common stock at a public offering price of \$25.00 per share, including the underwriters' exercise of their option to purchase an additional 555,000 shares to cover over-allotments. The aggregate net cash proceeds from the offering, including the shares issued upon exercise of the over-allotment option, were approximately \$96 million, after deducting the underwriting discount and commissions and other offering expenses. In connection with the closing of the initial public offering, all of the Company's shares of convertible preferred stock outstanding at the time of the offering were automatically converted into 8,993,572 shares of common stock. In addition, the Company issued 240,561 shares of its common stock in December 2006 upon the net and cash exercise of outstanding warrants that would have terminated if not exercised prior to the closing of the Company's initial public offering. As of June 30, 2007, a warrant to purchase 1,987 shares of common stock remains outstanding.

The Company is in the development stage and since inception has devoted substantially all of its efforts to research and development, raising capital and recruiting personnel.

### 2. Summary of Significant Accounting Policies



**Basis of Presentation**

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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 ( GAAP ) have been condensed or omitted. The condensed financial statements are unaudited and reflect all adjustments which are, in the opinion of management, necessary to state fairly the financial position at, and the results of operations 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, 2006, 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.

### **Concentration of Risk and Uncertainties**

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Financial instruments that potentially subject the Company to a concentration of credit risk consist of cash, cash equivalents and marketable securities. The Company deposits excess cash in accounts with three major financial institutions in the United States. Deposits in these financial institutions may exceed the amount of insurance provided on such deposits. The Company has not experienced any significant losses on its deposits of cash and cash equivalents. The Company has adopted guidelines for investment of its excess cash with the objective of maintaining safety and liquidity through its policies on diversification and investment maturity.

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The Company has experienced significant operating losses since inception. At June 30, 2007, the Company had a deficit accumulated during the development stage of approximately \$185.2 million. The Company has generated no revenue from product sales to date. The Company has funded its operations to date principally from the sale of securities and collaboration agreements with a single collaboration partner. The Company expects to incur substantial additional operating losses for the next several years and may need to obtain additional financing in order to complete the clinical development of Hematide and other product candidates, launch and commercialize its product candidates for which it receives regulatory approval, continue research and development programs and license or acquire additional product candidates. There can be no assurance that such financing will be available or will be at terms acceptable to the Company.

The Company is currently developing its first product offering and has no products that have received regulatory approval. Any products developed by the Company 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 the Company's products will receive the necessary approvals. If the Company is denied such approvals or such approvals are delayed, it could have a material adverse effect on the Company. To achieve profitable operations, the Company must successfully develop, test, manufacture and market products. There can be no assurance that any such products can be developed successfully or manufactured at an acceptable cost and with appropriate performance characteristics, or that such products will be successfully marketed. These factors could have a material adverse effect on the Company's future financial results.

### **Revenue Recognition**

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The Company recognizes revenue in accordance with the Securities and Exchange Commission's Staff Accounting Bulletin No. 104, *Revenue Recognition in Financial Statements*. 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 (EITF) 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 Company has entered into two separate collaboration agreements (collectively, the Arrangement) with Takeda Pharmaceutical Company Limited (Takeda) which 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.

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 is currently indefinite. As a result, revenue for the single unit of accounting is recorded on a proportional performance basis as long as the overall Arrangement is determined to be profitable.

The Company accounts for the Arrangement using a zero profit proportional performance model (i.e., revenue will be recognized equal to direct costs incurred, but not in excess of cash received or receivable assuming that the overall Arrangement is expected to be profitable). The Company uses an input based measure, specifically direct costs, to determine proportional performance because the Company believes that the inputs are representative of the value being conveyed to Takeda through the research and development activities and delivery of the active pharmaceutical ingredients (API). The Company believes that using direct costs as the unit of measure of proportional performance also most closely reflects the level of effort related to the Company's performance under the Arrangement. Direct costs are those costs that directly result in the culmination of an earnings process for which Takeda receives a direct benefit. The nature of these costs are third party and internal costs associated with conducting clinical trial activities, 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 exclude 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 will be 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 are recorded as deferred revenue until the earlier of (i) when the Company can meet the criteria for separate recognition of each element under the guidance of EITF 00-21 or (ii) after the Company has fulfilled all of its contractual obligations under the Arrangement.

The Company is required to assess the profitability of the overall Arrangement on a periodic basis throughout the life of the Arrangement when events or circumstances indicate a potential change in facts. Profitability is defined as a net cash inflow resulting from the Arrangement over its life. Such assessment is based on estimates to determine the most likely outcome based on available facts and circumstances at each assessment date. The estimates include the consideration of factors such as the progress and timing of clinical trials, competitive ESAs (erythropoiesis stimulating agents) 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 indicate a loss will result from performance under the Arrangement, costs will continue to be recognized as they are incurred. However, revenue will be deferred until either: (i) the Arrangement becomes profitable, at which point revenue will continue to be recognized under the zero profit proportional performance model, or (ii) the end of the Arrangement.

#### **Net Loss per Common Share**

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Basic and diluted net loss per common 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, common stock issuable pursuant to the Company's 2006 Employee Stock Purchase Plan, mandatorily redeemable convertible preferred stock and redeemable convertible preferred stock were not included in the diluted net loss per common share calculation for all periods presented because the inclusion of such shares would have had an antidilutive effect.

	Three Months Ended		Six Months Ended	
	June 30, 2007	2006	June 30, 2007	2006
<b>(in thousands, except per share data)</b>				
<b>Numerator:</b>				
Net loss attributable to common stockholders	\$ (9,248 )	\$ (28,053 )	\$ (16,419 )	\$ (34,918 )
<b>Denominator:</b>				
Weighted-average common shares outstanding	14,897	1,205	14,891	775
Less: Weighted-average unvested common shares subject to repurchase	(18 )	(11 )	(21 )	(7 )
Weighted-average number of common shares outstanding used in computing basic and diluted net loss per common share	14,879	1,194	14,870	768
Basic and diluted net loss per common share	\$ (0.62 )	\$ (23.49 )	\$ (1.10 )	\$ (45.44 )

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

	<b>As of June 30, 2007</b>	<b>2006</b>
Mandatorily redeemable convertible preferred stock (as if converted)		8,463
Redeemable convertible preferred stock (as if converted)		530
Options to purchase common stock	1,765	1,034
Common stock subject to repurchase	16	40
Common stock issuable pursuant to the Employee Stock Purchase Plan	8	
Warrants to purchase common stock	2	438
Warrants to purchase mandatorily redeemable convertible preferred stock		2

### **Reclassifications**



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Certain amounts in prior years' 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.

### **Revisions to Previously Reported Financial Information**

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The quarterly financial data presented have been adjusted to correct an overstatement of stock-based compensation for the six months ended June 30, 2006. In addition, the financial statements for the six months ended June 30, 2006 include an out of period adjustment of \$2.4 million related to an overstatement of stock-based compensation expense in 2005.

### **Recent Accounting Pronouncements**

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In September 2006, the FASB issued Statement of Financial Accounting Standards ( SFAS ) No. 157, *Fair Value Measurements*, or SFAS No. 157, which 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 is effective for fiscal years beginning after November 15, 2007. The Company is currently assessing the potential impact that the adoption of SFAS No. 157 will have on its financial statements.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities Including an amendment of FASB Statement No. 115*, or SFAS No. 159, which is effective for fiscal years beginning after November 15, 2007. SFAS No. 159 permits the Company to choose to measure many financial instruments and certain other items at fair value. The objective is to improve financial reporting by providing entities with the opportunity to mitigate volatility in reported earnings caused by measuring related assets and liabilities differently without having to apply complex hedge accounting provisions. SFAS No. 159 is expected to expand the use of fair value measurement, which is consistent with the FASB's long-term measurement objectives for accounting for financial instruments. The Company is currently evaluating the impact, if any, that the adoption of SFAS No. 159 will have on its financial statements.

In June 2007, the EITF issued Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities*, or EITF No. 07-3, which is expected to be effective for fiscal years beginning after December 15, 2007. 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 Company is currently assessing the potential impact that the adoption of EITF No. 07-3 will have on its financial statements.

3. Stock-Based Compensation

**Stock-Based Compensation**

The Company's financial statements as of and for the three and six months ended June 30, 2007 and 2006 reflect the impact of SFAS No. 123(R), *Share-Based Payment*.

The Company estimated the fair value of employee stock options using the Black-Scholes valuation model. The fair value of employee stock options is being recognized on a straight-line basis over the requisite service period of the awards. During the three months ended June 30, 2007 and 2006, the Company granted 48,900 and 0 stock options, respectively, to employees with a weighted-average grant date fair value of \$22.34 and \$0.00 per share, respectively. During the six months ended June 30, 2007 and 2006, the Company granted 475,150 and 514,468 stock options, respectively, to employees with a weighted-average grant date fair value of \$24.31 and \$13.40 per share, respectively. The fair value of employee stock options was estimated using the following weighted-average assumptions for the three and six months ended June 30, 2007 and 2006:

	Three Months Ended		Six Months Ended	
	June 30, 2007	2006 (1)	June 30, 2007	2006 (1)
Expected volatility	81 %		82 %	88 %
Risk-free interest rate	5.62 %		4.70 %	4.54 %
Dividend yield	0.00 %		0.00 %	0.00 %
Expected term (in years)	5.61		5.83	5.77

(1) The Company did not grant any stock options to employees during the three months ended June 30, 2006.

The Company also estimated the fair value of employee stock purchase rights granted under the 2006 Employee Stock Purchase Plan, which became effective in December 2006 upon the effectiveness of the Company's initial public offering, using the Black-Scholes valuation model. For the three and six months ended June 30, 2007, the weighted-average fair value of each stock purchase right was \$9.70 per share. The fair value of employee stock purchase rights is being recognized on a straight-line basis over the requisite service period of the purchase rights. The fair value of employee stock purchase rights were estimated using the following assumptions for the three and six months ended June 30, 2007:

	Three Months Ended		Six Months Ended	
	June 30, 2007	2006 (2)	June 30, 2007	2006 (2)
Expected volatility	59% - 65%		59% - 65%	
Risk-free interest rate	4.67% - 4.95%		4.67% - 4.95%	
Dividend yield	0.00%		0.00%	
Expected term (in months)	4.5 - 24		4.5 - 24	

(2) The 2006 Employee Stock Purchase Plan became effective upon the effectiveness of the Company's initial public offering in December 2006.

The Company recognized stock-based compensation expense related to employee stock options and stock purchase rights of \$1.5 million and \$407,000 for the three months ended June 30, 2007 and 2006, respectively, and \$3.3 million and \$668,000 for the six months ended June 30, 2007 and 2006, respectively. As of June 30, 2007, unrecognized compensation costs related to employee stock options totaled \$16.4 million. The cost is expected to be recognized over a weighted-average amortization period of 2.80 years.

*Stock Option Activity*

The following table summarizes stock option activity for the six months ended June 30, 2007:

	Shares Available for Grant	Options Outstanding Number of Shares	Weighted-Average Exercise Price
<b>Balances at December 31, 2006</b>	1,212,500	1,332,575	\$ 6.67
Additional shares authorized	669,523		
Options granted	(480,150 )	480,150	33.78
Options exercised		(671 )	1.71
Options forfeited	46,837	(46,837 )	24.32
Stock repurchased	4,863		
<b>Balances at June 30, 2007</b>	1,453,573	1,765,217	\$ 13.58

#### 4. Investments

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

<b>As of June 30, 2007</b>			
	<b>Cost</b>	<b>Unrealized Loss</b>	<b>Fair Value</b>
<b>Short-term investments:</b>			
Corporate securities	\$ 19,824	\$ (27 )	\$ 19,797
Foreign securities	3,382	(6 )	3,376
Certificates of deposit	9,406	(7 )	9,399
Government securities	76,084	(56 )	76,028
Auction rate securities	30,955		30,955
<b>Total short-term investments</b>	<b>\$ 139,651</b>	<b>\$ (96 )</b>	<b>\$ 139,555</b>

<b>As of December 31, 2006</b>			
	<b>Cost</b>	<b>Unrealized Gain (Loss)</b>	<b>Fair Value</b>
<b>Short-term investments:</b>			
Corporate securities	\$ 12,342	\$ (7 )	\$ 12,335
Foreign securities	3,196	(1 )	3,195
Certificates of deposit	5,507	2	5,509
Government securities	13,000	(28 )	12,972
Auction rate securities	42,740		42,740
<b>Total short-term investments</b>	<b>\$ 76,785</b>	<b>\$ (34 )</b>	<b>\$ 76,751</b>
<b>Long-term investments:</b>			
Government securities	\$ 6,143	\$ (10 )	\$ 6,133

### 5. Commitments and Contingencies

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The Company leases certain equipment under capital lease arrangements expiring at various dates through November 2008 at interest rates of 2.2% to 7.2%. The capital leases are collateralized by certain assets of the Company.

The Company rents its office facilities and certain equipment under noncancelable operating leases, which expire at various dates through September 2014. Under the terms of the leases, the Company is responsible for certain taxes, insurance and maintenance expenses.

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*Legal Proceedings*

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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 we are 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. J&J alleges, among other things, that Affymax N.V., Affymax Technologies, N.V. and Affymax Research Institute, or the Affymax Entities, filed in their own name certain patent applications allegedly claiming inventions of J&J employees without notifying or consulting with J&J, that during patent prosecution the Affymax Entities improperly removed the names of J&J employees from certain patent applications on which those employees had been identified as inventors, and that these and other alleged breaches entitle J&J to damages and waive all rights we may have had to the intellectual property in dispute.

J&J requested that the Illinois case be dismissed and the matter decided under the R&D Agreement's arbitration provisions. In February 2006, the Illinois court entered an order that the appropriate forum for us and J&J to resolve the inventorship, ownership, breach of contract and related claims was binding arbitration under the American Arbitration Association, or AAA, rules in Illinois. The Illinois court held that the claims pending in the German court were also subject to arbitration and required us to dismiss the German complaint, which 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. 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 and await ruling on motions relating to the scope of discovery and protective order. 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 motion to compel and a motion for protective order. The arbitration hearing is scheduled to occur during the second half of 2008. 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**

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

In February 2006, 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.

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 is responsible for the first \$50 million of third-party expenses related to development in pursuit of U.S. regulatory approval of Hematide. Thereafter, Takeda will bear 70% of the third-party U.S. development expenses, while the Company will be 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. 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 Arrangement, Takeda also obtained a right of first refusal or negotiation to any backup products for Hematide developed by the Company for a period of ten years. In May 2007, the Company entered into a research agreement with Takeda for reimbursement and funding of certain research activities for a two year period beginning in June 2006.

The Company has recognized \$9.7 million and \$127,000 of revenue under the Arrangement with Takeda during the three months ended June 30, 2007 and 2006, respectively, and \$17.0 million and \$127,000 during the six months ended June 30, 2007 and 2006, respectively. In December 2006, Takeda completed a Phase 1 trial of Hematide in Japan resulting in the payment in January 2007 to the Company of a \$10 million milestone under the collaboration. As of June 30, 2007, the amount receivable from Takeda was \$10.0 million for the reimbursement of third-party expenses related to development in pursuit of U.S. regulatory approval of Hematide and the reimbursement of expenses for research activities related to backup products, which was recorded as a related party receivable.

## 7. Income Taxes

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The Company is subject to federal and California state income tax. The Company's combined federal and state tax liability was \$1.3 million for the six months ended June 30, 2007, based on alternative minimum tax rates and limitations in 2007. The Company recorded a provision for income taxes of \$925,000 and \$1.3 million for the three and six months ended June 30, 2007, respectively. The Company was in a net operating loss position in 2006 and all prior periods and therefore did not record a provision for income taxes for the three and six months ended June 30, 2006.

The Company has substantial federal and California net operating losses. Under the provisions of Sections 382 and 383 of the Internal Revenue Code, substantial changes in the Company's ownership may limit the amount of net operating loss carryforwards and research and development credits that can be utilized in the future to offset taxable income. The Company has completed its analysis of this issue and determined that it experienced a change in ownership during December 2006. Notwithstanding such ownership change, the Company believes that it will be able to utilize a portion of its net operating loss carryforwards in 2007 against the income recognized for tax purposes.

The Company adopted the provisions of FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes* (FIN No. 48), effective January 1, 2007. The cumulative effect of adopting FIN No. 48 resulted in no FIN No. 48 liability on the balance sheet. At the adoption date of January 1, 2007, the Company had \$2.0 million of unrecognized tax benefits, all of which would affect the effective tax rate if recognized.

During the three months ended March 31, 2007, the Company recorded a \$4.4 million liability for an uncertain income tax position, which was reflected as a long-term liability on its condensed balance sheet. A corresponding deferred tax asset was recognized because the FIN No. 48 liability formed the basis for potential taxable income. Based on current authority issued during the second quarter of 2007, the Company has 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. The uncertain income tax position relates to the upfront license fees which were received in 2006 pursuant to the Arrangement with Takeda and included in taxable income in 2007 and the limitation of the net operating loss carryforwards that can be utilized in the future to offset taxable income under the provisions of Section 382 of the Internal Revenue Code resulting

from the change in ownership which occurred upon the Company's initial public offering. Although no penalties or interest are currently accrued, such amounts would be recognized as a component of other expense and interest expense, respectively, if they are incurred.

As of June 30, 2007, the Company's federal returns for the years ended 2003 through the current period and state returns for the years ended 2002 through the current period are still open to examination. In addition, all of the net operating losses and research and development credit 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.

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



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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, 2006 and our unaudited financial statements and related notes thereto included in this Quarterly Report on Form 10-Q.

### **Forward-Looking Statements**

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*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. We discuss many of these risks, uncertainties and other factors in this Quarterly Report on Form 10-Q under Item 1A Risk Factors. 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**

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We are a biopharmaceutical company focused on developing novel peptide-based drug candidates to improve the treatment of serious and often life-threatening conditions. Our lead 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, and therefore has the potential to offer both better care for patients and reduced cost and complexity for healthcare providers.

We are currently planning to commence Phase 3 clinical trials in patients suffering from chronic renal failure, on dialysis and not on dialysis, in the fourth quarter of 2007. Based on our discussions with the FDA on the design of our Phase 3 program, we are planning to conduct four open-label, randomized controlled clinical trials involving chronic renal failure patients on dialysis and predialysis. Of these trials, two trials will be conducted in pre-dialysis patients and will be 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 will be conducted in dialysis patients and will be 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. Treatment in each study will be continued until the last patient has been treated for 52 weeks. Assessment of safety will include a composite cardiovascular endpoint from a pooled safety database.

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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.

We are also seeking to build a proprietary pipeline of other novel drug candidates which are designed to offer advantages over first generation therapeutics currently addressing large markets.

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 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 as we expand our research and development activities and move our product candidates into later stages of development. As of June 30, 2007, we had an accumulated deficit of approximately \$185.2 million.

In December 2006, we issued 4,255,000 shares of our common stock in connection with our initial public offering, including the issuance of 555,000 shares upon the full exercise of the underwriters' option to cover over-allotments. The aggregate net proceeds from the offering, including the shares issued upon exercise of the over-allotment option, were approximately \$96 million, after deducting underwriting discounts and commissions and other offering expenses.

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

Our critical accounting policies and the use of estimates are consistent with those noted in our Annual Report on Form 10-K for the year ended December 31, 2006 and this Quarterly Report on Form 10-Q. We believe the following policies to be the most critical to an understanding of our financial condition and results of operations because they require us to make estimates, assumptions and judgments about matters that are inherently uncertain.

#### ***Preclinical Study and Clinical Trial Accruals***

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We estimate our preclinical study and clinical trial expenses based on our estimates of the services received pursuant to contracts with several research institutions and clinical research organizations that conduct and manage preclinical studies and clinical trials on our behalf. The financial terms of these agreements vary from contract to contract and may result in uneven expenses and payment flows. Preclinical study and clinical trial expenses include the following:

- fees paid to contract research organizations in connection with preclinical studies;
- fees paid to contract research organizations and clinical research organizations in connection with clinical trials;  
and
- fees paid to contract manufacturers and service providers in connection with the production and testing of active pharmaceutical ingredients and drug materials for preclinical studies and clinical trials.

Payments under some of these contracts depend on factors such as the milestones accomplished, successful enrollment of certain numbers of patients, site initiation and the completion of clinical trial milestones. In accruing

service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we will adjust the accrual accordingly. If we do not identify costs that we have begun to incur or if we underestimate or overestimate the level of services performed or the costs of these services, our actual expenses could differ from our estimates.

***Income Taxes***

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In June 2006, the FASB issued FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes - an interpretation of FASB Statement No. 109*, or FIN No. 48, which clarifies the accounting for uncertainty in tax positions. FIN No. 48 requires that we recognize the impact of a tax position in our financial statements if that position is more likely than not to be sustained on audit, based on the technical merits of the position. The provisions of FIN No. 48 are effective as of the beginning of our 2007 fiscal year, with the cumulative effect, if any, of the change in accounting principle recorded as an adjustment to opening retained earnings.

We adopted the provisions of FIN No. 48 on January 1, 2007. The cumulative effect of adopting FIN No. 48 resulted in no FIN No. 48 liability on the balance sheet. At the adoption date of January 1, 2007, we had \$2.0 million of unrecognized tax benefits, all of which would affect the effective tax rate if recognized.

During the three months ended March 31, 2007, we recorded a \$4.4 million liability for an uncertain income tax position, which was reflected as a long-term liability on our condensed balance sheet. A corresponding deferred tax asset was recognized because the FIN No. 48 liability formed the basis for potential taxable income. Based on current authority issued during the second quarter of 2007, we have reevaluated and reduced our uncertain income tax position for the six months ended June 30, 2007 to \$326,000, which was reflected as a long-term liability on our condensed balance sheet with a corresponding deferred tax asset. The uncertain income tax position relates to the upfront license fees which were received in 2006 pursuant to our two collaboration agreements, or the Arrangement, with Takeda and included in taxable income in 2007 and the limitation of the net operating loss carryforwards that can be utilized in the future to offset taxable income under the provisions of Section 382 of the Internal Revenue Code resulting from the change in ownership which occurred upon our initial public offering. Although no penalties or interest are currently accrued, if incurred, they would be recognized as a component of other expense and interest expense, respectively.

### **Results of Operations**

*Revenue*



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	Three Months Ended				Six Months Ended			
	June 30, 2007	2006	Increase/ (Decrease)	% Increase/ (Decrease)	June 30, 2007	2006	Increase/ (Decrease)	% Increase/ (Decrease)
Total revenue	\$ 9,669	\$ 141	\$ 9,528	6,757 %	\$ 16,993	\$ 149	\$ 16,844	11,305 %

We have recognized revenue under our Arrangement with Takeda of \$9.7 million and \$17.0 million during the three and six months ended June 30, 2007, respectively, under the zero profit proportional performance model, as discussed in the notes to our unaudited financial statements included in this Quarterly Report. We recognized immaterial revenues for the three and six months ended June 30, 2006 from royalty payments and revenue under our Arrangement with Takeda.

*Research and Development Expenses*

	Three Months Ended				Six Months Ended			
	June 30, 2007	2006	Increase/ (Decrease)	% Increase/ (Decrease)	June 30, 2007	2006	Increase/ (Decrease)	% Increase/ (Decrease)
Research and development expenses	\$ 14,730	\$ 25,525	\$ (10,795 )	(42 )%	\$ 26,588	\$ 31,978	\$ (5,390 )	(17 )%

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The decrease in research and development expenses for the three and six months ended June 30, 2007 compared to the three and six months ended June 30, 2006 was primarily due to a milestone payment of \$17.6 million in connection with the Nektar license that was expensed during the three months ended June 30, 2006, which was offset by an increase of \$5.2 million and \$8.5 million, respectively, in clinical trial costs resulting from additional clinical trials and enrollment of higher number of patients and an increase of \$1.6 million and \$3.2 million, respectively, in personnel costs resulting from increased headcount.

### *General and Administrative Expenses*

	Three Months Ended				Six Months Ended				
	June 30, 2007	2006	Increase/ (Decrease)	% Increase/ (Decrease)	June 30, 2007	2006	Increase/ (Decrease)	% Increase/ (Decrease)	
General and administrative expenses	\$ 6,195	\$ 3,314	\$ 2,881	87	% \$ 11,527	\$ 4,201	\$ 7,326	174	%

(in thousands, except percentages)

The increase in general and administrative expenses for the three and six months ended June 30, 2007 compared to the three and six months ended June 30, 2006 was primarily due to an increase of \$1.3 million and \$5.2 million, respectively, in personnel costs resulting from higher headcount and stock-based compensation expenses and an increase of \$1.3 million and \$1.6 million, respectively, in Sarbanes-Oxley and other consulting fees.

### *Interest Income (Expense), Net*

	Three Months Ended				Six Months Ended				
	June 30, 2007	2006	Increase/ (Decrease)	% Increase/ (Decrease)	June 30, 2007	2006	Increase/ (Decrease)	% Increase/ (Decrease)	
Interest income (expense), net	\$ 2,913	\$ 863	\$ 2,050	238	% \$ 5,923	\$ 1,520	\$ 4,403	290	%

(in thousands, except percentages)

The increase in interest income, net, was due primarily to higher level of cash, cash equivalents and short-term investments as well as higher interest rates during the three and six months ended June 30, 2007 compared to the same periods in 2006.

### *Other Income (Expense), Net*

	Three Months Ended				Six Months Ended				
	June 30, 2007	2006	Increase/ (Decrease)	% Increase/ (Decrease)	June 30, 2007	2006	Increase/ (Decrease)	% Increase/ (Decrease)	
Other income (expense), net	\$ 20	\$ (2 )	\$ 22	1,100	% \$ 35	\$ 1	\$ 34	3,400	%

(in thousands, except percentages)

Other income (expense), net, was immaterial for the three and six months ended June 30, 2007 and 2006.

### *Provision for Income taxes*

	Three Months Ended				Six Months Ended				
	June 30, 2007	2006	Increase/ (Decrease)	% Increase/ (Decrease)	June 30, 2007	2006	Increase/ (Decrease)	% Increase/ (Decrease)	
Provision for income taxes	\$ 925	\$	\$ 925	100	% \$ 1,255	\$	\$ 1,255	100	%

(in thousands, except percentages)

We are subject to federal and California state income tax. We recorded a provision for income taxes for the three and six months ended June 30, 2007, respectively, based on alternative minimum tax rates and limitations in 2007.



*Accretion of Redeemable Convertible Preferred Stock to Redemption Value*

	Three Months Ended			Six Months Ended				
	June 30, 2007	2006	Increase/ (Decrease)	% Increase/ (Decrease)	June 30, 2007	2006	Increase/ (Decrease)	% Increase/ (Decrease)
<i>(in thousands, except percentages)</i>								
Accretion of redeemable convertible preferred stock to redemption value	\$	\$ (216 )	\$ (216 )	(100 )%	\$	\$ (409 )	\$ (409 )	(100 )%

Our convertible preferred stock was redeemable at the request of the holders on or after July 11, 2010. We were accreting the carrying value of the preferred stock to the mandatory redemption amount using the effective interest method through periodic charges to additional paid in capital. We recorded accretion on the preferred stock through the date of the automatic conversion of all of our outstanding preferred stock into common stock upon the closing of our initial public offering in December 2006.

**Liquidity and Capital Resources**

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Since our inception, we have financed our operations through sale of capital stock, license fees and milestone payments from collaborative partners, operating and capital lease financing, interest earned on investments and limited license fees and royalties from licensing intellectual property. Through June 30, 2007, we have received net proceeds of \$256.6 million from the issuance of common stock and convertible preferred stock and \$122 million of upfront license fees and a \$10 million milestone payment from our collaboration agreements with Takeda. As of June 30, 2007, we had \$217.9 million in unrestricted cash, cash equivalents and short-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, auction rate securities 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.

	<b>June 30, 2007 (in thousands)</b>	<b>December 31, 2006</b>
Cash, cash equivalents, short-term investments and long-term investments	\$ 217,879	\$ 230,425
Working capital	\$ 218,080	\$ 228,138

	<b>Six Months Ended June 30, 2007 (in thousands)</b>	<b>2006</b>
<b>Cash provided by (used in):</b>		
Operating activities	\$ (10,900 )	\$ 519
Investing activities	\$ (58,556 )	\$ (15,537 )
Financing activities	\$ 239	\$ 9,958
Capital expenditures (included in investing activities above)	\$ (1,875 )	\$ (588 )

Net cash used in operating activities for the six months ended June 30, 2007 primarily reflects the net loss for the period, a \$10 million milestone payment 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, non-cash stock-based compensation and non-cash changes in operating assets and liabilities. Net cash provided by operating activities for the six months ended June 30, 2006 primarily reflects the net loss for the period and a \$17 million in upfront license fees received from Takeda, which was reduced in part by depreciation and amortization and non-cash changes in operating assets and liabilities. Net cash used in investing activities for the six months ended June 30, 2007 and 2006 was primarily related to net purchases of investments and, to a lesser extent, purchase of property and equipment. Net cash used in investing activities for the six months ended June 30, 2007 includes the investment of cash received from Takeda and our initial public offering. Net cash provided by financing activities for the six months ended June 30, 2006 was primarily attributable to the issuance of Series E preferred stock to Takeda.

Our future contractual obligations, including financing costs, at June 30, 2007 were as follows:

Contractual Obligations	Payments Due by Period				
	Total (in thousands)	Less Than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Capitalized lease obligations	\$ 291	\$ 241	\$ 50	\$	\$
Operating lease obligations	\$ 20,317	2,809	5,145	5,599	6,764
Total fixed contractual obligations	\$ 20,608	\$ 3,050	\$ 5,195	\$ 5,599	\$ 6,764

In April 2004, we entered into a License, Manufacturing and Supply Agreement with Nektar Therapeutics AL, Corporation, or Nektar, under which we obtained from Nektar a worldwide, non-exclusive license, with limited rights to grant sublicenses, under certain intellectual property covering pegylation technology to manufacture, develop and commercialize Hematide. In consideration of the license grant, we agreed to pay royalties on the sales of Hematide. We also agreed to pay milestone payments totaling up to \$7 million, plus possible additional milestones in connection with our partnering activities relating to Hematide or merger and acquisition activities. In July 2006, we paid Nektar a \$17.6 million milestone payment triggered by the collaboration agreements signed with Takeda in February and June 2006.

Under the agreement, we also engaged Nektar for the manufacture and supply of our requirements of bulk poly(ethylene) glycol reagent for the manufacture of Hematide. This relationship is managed by a management committee formed by representatives from both us and Nektar. Nektar is obligated to engage a third-party manufacturer in the event of Nektar's failure (as defined in the agreement) to supply reagent. This agreement expires, on a country by country basis, upon the expiration of our royalty payment obligations. The agreement may be terminated by either party for the other party's material breach provided that such other party has been given a chance to cure such breach, or by Nektar for our challenge of the validity or enforceability of any patents licensed thereunder.

In September 2006, we entered into an operating lease for additional office space in Palo Alto, California. The lease commenced in November 2006 and terminates in December 2010. The total square footage covered by the new lease is 30,630 square feet, of which we leased 15,315 square feet starting in November 2006 and the remaining 15,315 square feet starting in September 2007.

In December 2006, we entered into an extension of the operating lease for office space in Palo Alto, California. The lease extension commences in October 2007 and terminates in September 2014. The total square footage covered by the lease extension is 84,460 square feet, of which we lease 53,830 square feet starting in October 2007 and the remaining 30,630 square feet starting in January 2011.

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 our drug candidates and potential drug candidates;
- our ability to 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;
- the cost and timing of establishing sales, marketing and distribution capabilities;
- cost of procuring clinical and commercial supplies of our product candidates; 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, short-term investments and long-term investments together with the interest thereon, will enable us to maintain our currently planned operations through at least 18 months. However, we may be required to raise additional capital to complete the development and commercialization of Hematide. Our capital requirements are likely to increase. As a result, we may need to raise additional funds to support our operations, and such funding may not be available to us on acceptable terms, or at all. If we are unable to raise additional funds when needed we may not be able to continue development of our product candidates or we could be required to 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. If we raise funds through collaborative or licensing arrangements, we may be required to relinquish, on terms that are not favorable to us, rights to some of our technologies or product candidates 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**

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In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements*, or SFAS No. 157, which 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 is effective for fiscal years beginning after November 15, 2007. We are currently assessing the potential impact that the adoption of SFAS No. 157 will have on our financial statements.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities Including an amendment of FASB Statement No. 115*, or SFAS No. 159, which is effective for fiscal years beginning after November 15, 2007. SFAS No. 159 permits us to choose to measure many financial instruments and certain other items at fair value. The objective is to improve financial reporting by providing entities with the opportunity to mitigate volatility in reported earnings caused by measuring related assets and liabilities differently without having to apply complex hedge accounting provisions. SFAS No. 159 is expected to expand the use of fair value measurement, which is consistent with the FASB's long-term measurement objectives for accounting for financial instruments. We are currently evaluating the impact, if any, that the adoption of SFAS No. 159 will have on our financial statements.

In June 2007, the EITF issued Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities*, or EITF No. 07-3, which is expected to be effective for fiscal years beginning after December 15, 2007. EITF No. 07-3 requires us 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 we do not expect the goods to be delivered or the services to be performed, the capitalized amounts should be expensed. We are currently assessing the potential impact that the adoption of EITF No. 07-3 will have on our financial statements.

### **Off-Balance Sheet Arrangements**



There were no significant off-balance sheet arrangements at June 30, 2007.

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**Item 3.** Quantitative and Qualitative Disclosure About Market Risks

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Our exposure to market risk is confined to our cash, cash equivalents and short-term investments. The goals of our investment policy are preservation of capital, fulfillment of liquidity needs and fiduciary control of cash and investments. We also seek to maximize income from our investments without assuming significant risk. To achieve our goals, we maintain a portfolio of cash equivalents and investments in a variety of securities of high credit quality. The securities in our investment portfolio are not leveraged, are classified as available for sale and are, due to their very short-term nature, subject to minimal interest rate risk. We currently do not hedge interest rate exposure. Because of the short-term maturities of our investments, we do not believe that an increase in interest rates would have a material negative impact on the value of our investment portfolio.

### **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, 2007. 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, 2007, our disclosure controls and procedures were not effective, at the reasonable assurance level, because of the material weaknesses in internal control over financial reporting described below.

Notwithstanding the material weaknesses 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 weaknesses 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 March 31, 2007, we did not maintain effective controls over the completeness and accuracy of our deferred income tax assets and liabilities and the income tax provision. Specifically, we did not maintain an accounting staff with sufficient knowledge of generally accepted accounting principles related to income tax accounting and reporting. This control deficiency did not prevent or detect an error in our accounting for deferred taxes related to upfront licensing fees. This control deficiency resulted in an auditor identified adjustment to the interim financial statements for the quarter ended March 31, 2007 affecting deferred tax assets, tax liabilities and the provisions for income taxes. Additionally, this control deficiency could result in a future misstatement to the aforementioned accounts that would result in a material misstatement to annual or interim financial statements that would not be prevented or detected. Accordingly, management determined that this control deficiency constitutes a material weakness.

As of June 30, 2007, we did not maintain effective controls over the accuracy of our collaboration revenue. Specifically, shipments of an active pharmaceutical ingredient ( API ) made to a customer during the quarter and recognized as revenue were inadvertently also included in the revenue calculation of direct costs that were recognized as revenue. Therefore revenue for these shipments was counted twice. This control deficiency resulted in an auditor identified adjustment to the interim financial statements for the quarter ended June 30, 2007 affecting collaboration revenue and deferred revenue. Additionally, this control deficiency could result in a misstatement to the aforementioned accounts that would result in a material misstatement to annual or interim financial statements that would not be prevented or detected. Accordingly, management determined that this control deficiency constitutes a material weakness.

*Plan for Remediation of Material Weaknesses.* We have discussed these material weaknesses with our independent registered public accounting firm and our Audit Committee. We have taken significant actions to remediate the material weakness related to our internal controls over the completeness and accuracy of our deferred income tax assets and liabilities and the income tax provision. We have recently hired additional accounting staff to augment our accounting and financial control function and are continuing to implement plans to enhance our reporting systems and procedures as well as provide for greater oversight in the accounting and finance functions. The accounting staff has been trained to identify and escalate material financial reporting related matters that involve a significant degree of subjectivity, complexity and/or judgment to the Chief Financial Officer for discussion with our senior management. Further, we retained additional consulting resources to evaluate matters where there may be a significant divergence of opinions. We will continue to strengthen our internal controls over income tax accounting during the remainder of the year.

With respect to the remediation of the material weakness related to our internal controls over the accuracy of our collaboration revenue, we will prepare and review detailed reconciliations of collaboration revenue, deferred revenue and accounts receivable balances against our accounting system to ensure the accuracy of the amounts reported in our financial statements. We have also recently hired additional accounting staff, consolidated duties relating to revenue recognition, and are continuing to implement plans to enhance our reporting systems and procedures.

As a newly public company, we are in the process of establishing 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 weaknesses we have identified prior to the end of fiscal year 2007, 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, 2007, 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.

**Item 4T. Controls and Procedures**

Not applicable.

**PART II OTHER INFORMATION**

**Item 1.** Legal Proceedings.

*J&J Intellectual Property Dispute*



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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 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***

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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*

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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 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*

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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 claimed 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.

***Litigation and Arbitration Chronology***

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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.



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. 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 and await ruling on motions relating to the scope of discovery and protective order. 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 motion to compel and a motion for protective order. The arbitration hearing is scheduled to occur during the second half of 2008. 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.

**Item 1A.** Risk Factors.

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*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 have positive clinical results, receive regulatory approval or be successfully commercialized.*

Hematide, an ESA, is a new chemical entity and our only product candidate in clinical development. We are planning to commence Phase 3 clinical trials for the treatment of anemia associated with chronic renal failure in the fourth quarter of 2007. All of our other compounds or potential product candidates are in the research stage. 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 successfully enroll patients or to otherwise execute the Phase 3 clinical trials in a timely or effective manner.

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.

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. The FDA recently 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 ODAC recommendations and FDA concerns may negatively affect the cost, scope, size, risk or timing of our clinical trials, including our Phase 2 clinical trials in cancer, increase the risk of achieving regulatory approval and significantly delay commercialization of Hematide. The FDA is also scheduled to convene a joint

meeting in September 2007 of the Cardiovascular and Renal Drugs advisory committee and the Drug Safety and Risk Management advisory committee to discuss the updated information on the risks and benefits of ESAs. Depending upon the outcome of this meeting, the timing and design of our clinical trials as well as the commercial potential of Hematide generally could be negatively impacted.

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 this product candidate through the clinical trial process. Any failure to obtain approval of Hematide or even delays in obtaining approval 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 our other product candidates to market.

Some of the recent safety concerns surrounding commercially available ESAs relate to clinical trials conducted in patients with anemia of cancer (AOC) suggests higher mortality and serious side effects associated with ESA treatment. The ODAC recommendations and the FDA implementation of or response to those recommendations may significantly limit the ability to develop the AOC indication and may have an adverse impact on other oncology supportive care indications. Restrictions on labeling or use of ESAs as a result of these concerns may limit the potential market opportunity such that even if the Company is ultimately successful in obtaining regulatory approval, the commercial market and potential for Hematide may also be negatively impacted.

***We are at an early stage of development as a company and have limited sources of revenue. Our current revenue recognition policy may limit our ability to report any profits, and we may never become profitable.***

We are a development stage biopharmaceutical company with a limited operating history. Currently, we have no products approved for commercial sale and, to date, we have not generated any revenue from product sales. Our ability to generate revenue depends heavily on our ability to successfully develop and secure regulatory approval for, and commercially launch, our lead product candidate, Hematide, and our other product candidates. If we are unable to commercialize Hematide, it will be a long time before we will be able to commercialize our other product candidates, if ever. Further, under our current revenue recognition policy, we will not recognize profits, if any, from our performance under the Takeda collaboration agreements until we can objectively determine the fair value of all our undelivered obligations under our Takeda collaboration agreements or when we have performed all of our obligations under those agreements. Since the duration of some of those obligations is indefinite, even if we successfully commercialize Hematide we may not be able to report any profits under generally accepted accounting principles until a number of years after our receipt of payments under the Takeda collaboration agreements.

Our existing product candidates 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 one or more of our product candidates or if sales revenue from any product candidate that receives marketing approval is insufficient, we may not achieve profitability, and we may be unable to continue our operations.

***We have initiated binding arbitration and related litigation with Johnson & Johnson Pharmaceutical Research & Development, L.L.C., and Ortho-McNeil Pharmaceutical, Inc., or collectively, J&J, over ownership of intellectual property related to 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 other intellectual property 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. If the arbitration panel rules that the scope of discovery includes information relating to Hematide, we expect that this 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.***

None of our product candidates has been approved or commercialized for any indication. Even if approved for sale by the appropriate regulatory authorities, physicians may not prescribe Hematide or any of our other product candidates, in which case we would not generate revenue or become profitable. In particular, the therapeutic indications targeted by our lead product candidate have been served by our competitors' products for many years. These products may now be said to be the standard of care, and it may be difficult to encourage healthcare providers to switch from products with which they and their patients have become comfortable.

The dialysis market, which is one of the largest and most established markets that Hematide will attempt to penetrate, is highly concentrated, with two companies serving a significant majority of all dialysis patients on

Medicare. In addition, dialysis clinics using ESAs could incur substantial expense in administration and training if they were to switch from current ESAs to Hematide. The concentration of customers for ESAs within the dialysis market may pose a risk to our ability to obtain 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.

Currently, the Centers for Medicare and Medicaid Services, or CMS, reimburse healthcare providers for use of ESAs at a rate of average sales price plus a 6% margin to the provider, or ASP plus 6%. We cannot be certain what reimbursement policies will be in effect at the time we seek to enter the chronic renal failure market in the U.S., or the effect these policies may have on our ability to compete effectively.

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 predialysis 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 predialysis 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 predialysis patients may be difficult, as these patients are spread thinly across a variety of treatment settings. Primary care physicians that treat predialysis 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 the product candidate is approved;
- acceptance by physicians and patients of each product candidate 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 at levels above those currently accepted as industry guidance;
- 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 any future products that we may develop, 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 our product candidates could allow our competitors to bring products to market before we do and impair our ability to commercialize our product candidates. 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.

We anticipate that, if approved, Hematide would compete with EPOGEN and Aranesp, which are both marketed by Amgen, PROCIT, which is marketed by Ortho Biotech Products, L.P. (a subsidiary of J&J), and NeoRecormon, currently marketed outside the U.S. by Roche. Aranesp is approved for once-monthly dosing for treatment of anemia in predialysis 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 predialysis patients. If Amgen is successful in obtaining approval for once-monthly dosing, the market for Hematide may be decreased. In addition, in April 2006 Roche filed for U.S. and European marketing approval for Mircera and recently received approval in Europe. Mircera reportedly has greater serum stability and is longer acting than any rEPO product that is currently on the market. Roche and Amgen are currently engaged in patent litigation. Amgen alleges that Mircera infringes six U.S. patents owned by Amgen. If Amgen does not seek or obtain a preliminary injunction, Mircera would likely 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 a small molecule which is designed to inhibit enzymes that promote the degradation of Hypoxia-Inducible Factor, or HIF, which plays a key role in activating genes that protect the body against low levels of oxygen, or hypoxia. By increasing the level of HIF in a patient's circulation, FibroGen's molecule may promote the production of greater levels of naturally-occurring EPO. 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.

All 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 our product candidates 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 2015.***

The last significant U.S. patent for epoetin alfa, a version of short-acting rEPO, expires in 2015. Patents related to epoetin alfa expired in the E.U. in 2004. Generic versions, or biosimilars, of short-acting rEPO are currently being developed in and for various markets outside the U.S., including the E.U. Shortacting rEPO biosimilars is 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 down, which may adversely affect our revenues.



*Any failure or delay in completing clinical trials for our product candidates could severely harm our business.*

Each of our product candidates 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 in initial indications for our most advanced product candidate, Hematide, will continue for at least four years, but could take significantly longer to complete. The completion of clinical trials for our product candidates may be delayed or halted for many reasons, including:

- 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;
- delays in patient enrollment, and variability in the number and types of patients available for 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 of product candidates during clinical trials;
- safety issues, including serious adverse events associated with Hematide;
- the failure of patients to complete clinical trials due to side effects, dissatisfaction with the product candidate 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 our product candidate. 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 any of our product candidates will prevent us from receiving regulatory approval and negatively impact our business.

It is possible that none of our product candidates will complete clinical trials in any of the markets in which we intend to sell those product candidates. We also do not know and are unable to predict what clinical trials the FDA will require us to conduct or the scope, size or design of such trials, which could result in additional delays in bringing our product candidates to market. Accordingly, we may not receive the regulatory approvals needed to market our product candidates. Any failure or delay in completing clinical trials for our product candidates would delay commercialization of our product candidates and severely harm our business and financial condition.

***All of our product candidates other than Hematide are in early stage research. If we are unable to develop, test and commercialize our other product candidates, our business will be adversely affected.***

A key element of our strategy is to discover, develop and commercialize a portfolio of new products in addition to Hematide. We are seeking to do so through our internal research programs and intend to explore 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 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 is not 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.

Our strategy also includes in-licensing or acquiring product candidates that leverage our product development strengths. We may not be able to license or acquire promising product candidates on reasonable terms, if at all.

***If we fail to maintain our existing, or enter into new, strategic collaborations, we may have to reduce or delay our product candidate development efforts or increase our expenditures.***

Our business model is based in part upon entering into strategic collaborations for development of our product candidates. 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. In addition, if we fail to establish and maintain additional strategic collaborations for our other potential product candidates:

- the development of our current 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.

***We have incurred significant operating losses since inception and anticipate that we will incur continued losses for the foreseeable future.***

We have experienced significant operating losses since our inception in 2001. At June 30, 2007, we had a deficit accumulated during the development stage of approximately \$185.2 million. We have generated no revenue from product sales to date. 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 our initial products, begin new development programs and add the necessary infrastructure to support operating as a public company. Even if we receive

regulatory approval for one or more products, we must successfully commercialize our products before we can become profitable. We anticipate that it will be at least several years before we can commercialize our lead product candidate, Hematide, and even longer for our current product candidates, if at all. Accordingly, we may never generate significant revenues and, even if we do generate significant revenues, we may never achieve or sustain profitability.

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***Reimbursement may not be available for our product candidates, which could diminish our sales or affect our ability to sell our products profitably.***

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

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 our products 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 is reviewing coverage of ESAs 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. 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.

***The Centers for Medicare and Medicaid Services, or 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 fact, the National Institute for Health and Clinical Excellence, the body that provides guidance to the U.K.'s National Health Service on what healthcare technologies to reimburse and at what levels, currently recommends against the wide use of ESAs in the treatment of chemotherapy induced anemia. In addition, further, as a result of the recent safety concerns relating to ESAs, the CMS policies has recently announced that it is reviewing policies relating to the use of ESAs. Further, 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. CMS currently reimburses healthcare providers for use of ESAs at ASP plus 6%. In the future, CMS may reimburse ESAs under methods other than ASP plus 6%, including capitation, a method that reimburses providers a fixed, per capita amount per patient regardless of the level of service provided. We cannot guarantee that Hematide, or any of our other product candidates, will be reimbursed by CMS to incentivise physician adoption. In fact, a capitated reimbursement payment methodology may create incentives for lower utilization or dosing of ESAs, including Hematide.

***If we fail to obtain additional financing, we may be unable to complete the development and commercialization of Hematide and our other product candidates, or to continue our research and development programs.***

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

- complete the clinical development of Hematide and our other product candidates;
- launch and commercialize any product candidates for which we receive regulatory approval, including building our own commercial organization and sales force to address certain markets;
- continue our research and development programs; and
- license or acquire additional product candidates.

We believe that existing cash, cash equivalents and short-term investments and the interest thereon, will enable us to maintain our currently planned operations through at least 18 months. However, we may be required to raise additional capital to complete the development and commercialization of Hematide. We may be required to raise additional capital to complete the development and commercialization of our current product candidates.

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 capital when required or on acceptable terms, we may have to significantly delay, scale back or discontinue the development and/or commercialization of one or more of our product candidates. We also may be required to:

- seek collaborators for our product candidates at an earlier stage than otherwise would be desirable and on terms that are less favorable than might otherwise be available; and
- relinquish or license on unfavorable terms our rights to technologies or product candidates that we otherwise would seek to develop or commercialize ourselves.

***We rely on third parties to conduct preclinical and clinical trials for our product candidates, and if they do not properly and successfully perform their obligations to us, we may not be able to obtain regulatory approvals for our product candidates.***

We design the clinical trials for our product candidates, but we rely on contract research organizations and other third parties to assist us in managing, monitoring and otherwise carrying out these 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 on acceptable terms. These third-party collaborators generally may terminate their engagements with us at any time and having to enter into alternative collaboration arrangements would delay introduction of our product candidates to market. As a result, we can control their activities only within certain limits, and they will devote only a certain amount of their time to conduct research on our product candidates and develop them.

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 our product candidates.

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

We do not currently have the infrastructure or capability internally to manufacture the drug products that we need to conduct our clinical trials. We have entered into agreements with contract manufacturers to produce our supplies of Hematide; however, we have no long term contracts for supply of Hematide or any of our other product candidates. Hematide is a new chemical entity that has never been produced at commercial scale, and as such, there are underlying risks associated with the manufacture of the substance, which could include: cost overruns, process scale-up, process reproducibility, stability issues and timely availability of raw materials, as well as regulatory issues associated with the manufacture of our product candidates. Any of these risks may prevent or delay us from successfully developing Hematide or other product candidates.

For the foreseeable future, we expect to continue to rely on contract manufacturers, partners and other third parties to produce sufficient quantities of our product candidates for use in our clinical trials. If our contract manufacturers or other third parties fail to deliver our product candidates for clinical use on a timely basis, with sufficient quality and at commercially reasonable prices, and we fail to find replacement manufacturers or to develop our own manufacturing capabilities, we may be required to delay or suspend clinical trials or otherwise discontinue development and production of our product candidates.

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 our product candidates 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 any of our product candidates. If for any reason these third parties are unable or unwilling to perform under our agreements or enter into new agreements with us, we may not be able to locate alternative manufacturers or enter into favorable agreements with them in an expeditious manner. We could also experience manufacturing delays if our third-party manufacturers give greater priority to the production of other products over our product candidates. Any inability to acquire sufficient quantities of our product candidates 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 our product candidates in a cost-effective manner or on a timely basis.

***The commercial success of our collaborations depends in part on the development and marketing efforts of our collaboration partners, over which we have limited control. If our collaborations are unsuccessful, our ability to develop and commercialize products through our collaborations, and to generate future revenue from the sale of these products, would be significantly reduced.***

Our dependence on collaboration arrangements subjects our company 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 our product candidates, obtain and maintain regulatory approvals and achieve market acceptance of a product once commercialized. Our collaboration partners may elect to delay or terminate development of one or more product candidates, independently develop products that compete

with ours, or fail to commit sufficient resources to the marketing and distribution of products developed through their collaboration with us. 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 our product candidates.

In the event that one or more of our collaboration partners fails to diligently develop or commercialize a product candidate covered by one of our collaboration agreements, we may have the right to terminate our partner's rights to such product candidate but we will not receive any future revenue from that product candidate unless we are either able to find another partner or to commercialize the product candidate on our own, which is likely to result in significant additional expense. Business combinations, significant changes in business strategy, litigation and/or financial difficulties may also adversely affect the willingness or ability of one or more of our collaboration partners to complete their obligations under our collaboration agreements. If our collaboration partners fail to perform in the manner we expect, our potential to develop and commercialize products through our collaborations and to generate future revenue from the sale of these products, would be significantly reduced. If a conflict of interest arises between us and one or more of our collaboration partners, they may act in their own self-interest and not in the interest of our company or our stockholders. If one or more of our collaboration partners were to breach or terminate their collaboration agreements with us or otherwise fail to perform their obligations thereunder in a timely manner, the preclinical or clinical development or commercialization of the affected product candidates or research programs 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 our product candidates, their use and the methods used to manufacture them, as well as successfully defending these patents against third-party challenges. Our ability to protect our product candidates 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 to product candidates 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. Because we may acquire rights to late-stage products, the remaining patent terms of licensed patents relating to those products may not provide meaningful protection. Moreover, third parties may challenge the patents, patent applications and other proprietary rights held by our licensors or collaborators. We generally do not unilaterally control the prosecution of patent applications licensed from third parties. Accordingly, we are unable to exercise the same degree of control over this intellectual property as we may exercise over internally developed intellectual property.

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

The failure to obtain adequate patent protection would have a material adverse effect on us and may adversely affect our ability to enter into, or affect the terms of, any arrangement for the further development and marketing of 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 bringing our product candidates to market.

***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 our product candidates successfully.***

We currently have no sales, marketing or distribution capabilities. To commercialize our product candidates, 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 any of our products 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 our products directly and without strategic partners include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe our products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating and sustaining an independent sales and marketing organization.

If we are not able to collaborate with a third party and are not successful in recruiting sales and marketing personnel or in building a sales and marketing infrastructure, we will have difficulty commercializing our product candidates, which would adversely affect our business and financial condition. If we do collaborate with and rely on pharmaceutical or biotechnology companies with established sales, marketing and distribution systems to market our products, 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 our product candidates, conduct our clinical trials and commercialize our 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 Robert Naso, our Executive Vice President, Research and Development. The loss of services of either Ms. Morris or Dr. Naso 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 our product candidates.

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. We do not carry key person insurance covering any members of our senior management. Each of our officers and key employees may terminate his 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 our product candidates 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 our product candidates 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.

#### **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 some or all of our product candidates.*

The research, testing, manufacturing, selling and marketing of drug candidates are subject to extensive regulation by FDA and other regulatory authorities in the U.S. and other countries, and regulations may differ from country to country. Neither we nor our collaboration partners are permitted to market our product candidates 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 any of our product candidates. 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. 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 a product candidate, 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 our future products.***

Any regulatory approvals that we or our collaboration partners receive for our product candidates 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 any of our product candidates, 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.

The FDA's policies may change and additional government regulations may be enacted that could prevent or delay regulatory approval of our product candidates. 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.***

We intend to market our future products in international markets. In order to market our future products 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. We may not obtain foreign regulatory approvals on a timely basis, if at all. We 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 our future products in both the U.S. and 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 our future product to other available therapies. If reimbursement of our future products 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 our product candidates.*

We face an inherent risk of product liability as a result of the clinical testing of our product candidates in clinical trials and will face an even greater risk if we commercialize any products. 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 our product candidates. 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 our product candidates;
- injury to our reputation;
- withdrawal of clinical trial participants;
- costs of related litigation;
- substantial monetary awards to patients;
- product recalls;
- loss of revenue; and
- the inability to commercialize our product candidates.

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 may be 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 is likely to be highly volatile and could be subject to wide fluctuations in price in response to various factors, many of which are beyond our control, including:

- new products or services introduced or announced by us or our commercialization partners, or our competitors, including Roche's Miricera, and the timing of these introductions or announcements;
- issuance of patents to competitors, including the expected issuance of patents to J&J in Europe;
- developments in 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 or our product candidates or competing products;

- actions taken by regulatory agencies with respect to our product candidates, or ESAs generally, clinical trials, manufacturing process or sales and marketing activities;
- changes in laws or regulations applicable to our products, including but not limited to clinical trial requirements for approvals;
- the success of our development efforts and clinical trials;
- the success of our efforts to discover, acquire or in-license additional products or product candidates;
- developments concerning our collaborations, including but not limited to those with our sources of manufacturing supply and our commercialization partners;
- actual or anticipated variations in our quarterly operating results;
- announcements of technological innovations by us, our collaborators or our competitors;
- actual or anticipated changes in earnings estimates or recommendations by securities analysts;
- conditions or trends in the biotechnology and biopharmaceutical industries;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- general economic and market conditions and other factors that may be unrelated to our operating performance or the operating performance of our competitors;
- changes in the market valuations of similar companies;
- 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 April 30, 2007 and prior to the expiration of the lock up agreements with the underwriters in connection with our initial public offering, our executive officers, directors and principal stockholders, together with their respective affiliates, owned approximately 65% 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.

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

As a public company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act of 2002, as well as rules subsequently implemented by the Securities and Exchange Commission and the Nasdaq Global Market, have imposed various new requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these new compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to incur substantial costs to maintain the same or similar coverage.

***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, 2007, 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 2007. For example, during our review of the results of operations for the quarter ended March 31, 2007, 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. 2, in connection with the accurate completion of deferred income tax assets and liabilities and income tax provision. Also, during the quarter ended June 30, 2007, we identified a material weakness in connection with the accurate completion of collaboration revenue. We have commenced efforts to remediate these material weaknesses through process and internal control improvements and the addition of staff and consulting resources. However, if we cannot correct the material weaknesses we have identified prior to the end of fiscal year 2007, 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.

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.

***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; and
- 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.

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

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

**Unregistered Sales of Equity Securities**

None.

**Use of Proceeds from the Sale of Registered Securities**

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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, 2007, 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**

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The following table provides information relating to repurchases of our common stock in the three months ended June 30, 2007:

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, 2007 - April 30, 2007	3,412	\$ 2.59	N/A	N/A
May 1, 2007 - May 31, 2007		\$	N/A	N/A
June 1, 2007 - June 30, 2007	1,341	\$ 4.36	N/A	N/A
Total	4,753	\$ 3.09	N/A	N/A

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(1) The shares of our common stock were repurchased by us from employees 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 of the Company was held on May 31, 2007 (the Meeting ). Of the 14,878,850 shares of Common Stock of the Company entitled to be voted at the Meeting, 12,017,419 shares of Common Stock were voted in person or by proxy, constituting a quorum.

The following matters were considered and voted at the Meeting:

(i) The stockholders voted to elect the Company's two (2) Class I director nominees. Of the votes cast, Ms. LaPorte received 11,965,939 votes for election, and 51,480 votes were withheld. Ms. Czerepak received 12,008,335 votes for election and 9,084 votes were withheld. Accordingly, the following persons were elected directors of the Company for a three year period expiring in 2010:

**Kathleen LaPorte**

**Elizabeth Czerepak**

Ms. Czerepak subsequently resigned from our board of directors effective as of June 8, 2007, as disclosed in our current report on form 8-K filed with the SEC on June 13, 2007. R. Lee Douglas, Nicholas Galakatos, Ph.D. and John P. Walker will continue in office as directors in the class of directors to be elected at our 2008 annual meeting of stockholders. 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.

(ii) The stockholders voted to ratify the appointment of PricewaterhouseCoopers LLP as the Company's independent registered public accounting firm for the fiscal year ending December 31, 2007.

Votes cast for	11,984,422
Votes cast against	32,897
Abstentions	100
Broker non-votes	0

**Item 5. Other Information**

Not applicable.

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**Item 6.** Exhibits

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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(1)
- 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)
- 10.37\* First Amendment to Collaboration and License Agreement, dated April 1, 2007, by and between the Registrant and Takeda Pharmaceutical Company Limited.
- 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)

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

\* Confidential treatment has been requested with respect to certain portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.

**SIGNATURES**

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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 10, 2007

By: /s/ ARLENE M. MORRIS  
Arlene M. Morris  
*President, Chief Executive Officer and Member of the Board of Directors*

Dated: August 10, 2007

By: /s/ PAUL B. CLEVELAND  
Paul B. Cleveland  
*Executive Vice President, Corporate Development and Chief Financial Officer (Principal Financial Officer)*

**EXHIBIT INDEX**



Exhibit

Number	Description
3.3	Amended and Restated Certificate of Incorporation(1)
3.5	Amended and Restated Bylaws(1)
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)
10.37*	First Amendment to Collaboration and License Agreement, dated April 1, 2007, by and between the Registrant and Takeda Pharmaceutical Company Limited. First Amendment to Collaboration and License Agreement, dated April 1, 2007, by and between the Registrant and Takeda Pharmaceutical Company Limited.
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)

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

\* Confidential treatment has been requested with respect to certain portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.