

AFFYMAX INC
Form 10-Q
November 04, 2009
Table of Contents

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended September 30, 2009

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)

Edgar Filing: AFFYMAX INC - Form 10-Q

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**

Edgar Filing: AFFYMAX INC - Form 10-Q

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

Edgar Filing: AFFYMAX INC - Form 10-Q

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

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

Large accelerated filer ☐

Accelerated filer ☒

Non-accelerated filer ☐

Smaller reporting company ☐

(Do not check if a smaller reporting company)

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 October 31, 2009, 19,122,167 shares of the registrant's common stock, \$0.001 par value, were outstanding.

Table of Contents

AFFYMAX, INC
TABLE OF CONTENTS

		Page
	<u>PART I FINANCIAL INFORMATION</u>	
<u>Item 1.</u>	<u>Financial Statements (unaudited)</u>	3
	<u>Condensed Balance Sheets as of September 30, 2009 and December 31, 2008</u>	3
	<u>Condensed Statements of Operations for the Three and Nine Months Ended September 30, 2009 and 2008</u>	4
	<u>Condensed Statements of Cash Flows for the Nine Months Ended September 30, 2009 and 2008</u>	5
	<u>Notes to Condensed Financial Statements</u>	6
<u>Item 2.</u>	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	16
<u>Item 3.</u>	<u>Quantitative and Qualitative Disclosure About Market Risk</u>	24
<u>Item 4.</u>	<u>Controls and Procedures</u>	24
	<u>PART II OTHER INFORMATION</u>	
<u>Item 1.</u>	<u>Legal Proceedings</u>	25
<u>Item 1A.</u>	<u>Risk Factors</u>	28
<u>Item 2.</u>	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	50
<u>Item 3.</u>	<u>Defaults Upon Senior Securities</u>	50
<u>Item 4.</u>	<u>Submission of Matters to a Vote of Security Holders</u>	50
<u>Item 5.</u>	<u>Other Information</u>	50
<u>Item 6.</u>	<u>Exhibits</u>	50
<u>SIGNATURES</u>		52

Table of Contents

PART I FINANCIAL INFORMATION

Item 1. Financial Statements

AFFYMAX, INC.

CONDENSED BALANCE SHEETS

(in thousands)

Edgar Filing: AFFYMAX INC - Form 10-Q

	September 30, 2009 (Unaudited)	December 31, 2008
Assets		
Current assets		
Cash and cash equivalents	\$ 67,336	\$ 24,046
Short-term investments	32,354	70,673
Receivable from Takeda	17,360	21,688
Income taxes receivable	110	2,665
Deferred tax assets	1,351	1,351
Prepaid expenses and other current assets	8,894	6,658
Total current assets	127,405	127,081
Property and equipment, net	5,963	6,952
Restricted cash	1,135	1,135
Long-term investments	4,139	22,945
Deferred tax assets, net of current	5,889	5,889
Other assets	401	3,718
Total assets	\$ 144,932	\$ 167,720
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities		
Accounts payable	\$ 2,464	\$ 614
Accrued liabilities	12,662	9,838
Accrued clinical trial expenses	37,696	27,806
Income taxes payable		163
Deferred revenue	67,446	54,930
Total current liabilities	120,268	93,351
Deferred revenue, net of current	16,986	54,915
Long term income tax liability	9,419	9,400
Other long term liabilities	991	1,070
Total liabilities	147,664	158,736
Contingencies (Note 5)		
Stockholders' equity (deficit)		
Common stock	19	15
Additional paid-in capital	357,748	306,824
Accumulated deficit	(360,542)	(298,328)
Accumulated other comprehensive gain	43	473
Total stockholders' equity (deficit)	(2,732)	8,984
Total liabilities and stockholders' equity (deficit)	\$ 144,932	\$ 167,720

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

Table of Contents

AFFYMAX, INC.

CONDENSED STATEMENTS OF OPERATIONS

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

Edgar Filing: AFFYMAX INC - Form 10-Q

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
Collaboration revenue	\$ 29,157	\$ 21,645	\$ 81,924	\$ 56,803
License and royalty revenue	4	3	13	690
Total revenue	29,161	21,648	81,937	57,493
Operating expenses:				
Research and development	37,237	39,780	118,462	96,093
General and administrative	10,657	8,308	26,763	23,639
Total operating expenses	47,894	48,088	145,225	119,732
Loss from operations	(18,733)	(26,440)	(63,288)	(62,239)
Interest income	164	821	826	3,913
Interest expense		(156)	(1)	(357)
Other income (expense), net	163	(436)	163	(2,024)
Net loss before benefit for income taxes	(18,406)	(26,211)	(62,300)	(60,707)
Benefit for income taxes	(24)		(86)	
Net loss	\$ (18,382)	\$ (26,211)	\$ (62,214)	\$ (60,707)
Net loss per share:				
Basic and diluted	\$ (0.97)	\$ (1.72)	\$ (3.43)	\$ (4.00)
Weighted-average number of shares used in computing basic and diluted net loss per share	18,951	15,235	18,120	15,193

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

Table of Contents

AFFYMAX, INC.

CONDENSED STATEMENTS OF CASH FLOWS

(in thousands)
(Unaudited)

Edgar Filing: AFFYMAX INC - Form 10-Q

	Nine Months Ended September 30,	
	2009	2008
Cash flows from operating activities		
Net loss	\$ (62,214)	\$ (60,707)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,560	914
Amortization of discount/premium on investments	10	185
Stock-based compensation expense	8,371	8,068
Loss on disposal of property and equipment	65	7
Other-than-temporary impairment on investments	160	2,065
Realized gain on investments	(372)	(89)
Realized loss on investments	62	
Unrealized loss on auction rate securities rights	69	
Changes in operating assets and liabilities:		
Receivable from Takeda	4,328	(17,547)
Income taxes receivable	2,555	(2,541)
Prepaid expenses and other current assets	(2,236)	3,165
Deferred tax assets		2,230
Other assets	3,317	121
Accounts payable	1,850	(5,730)
Accrued liabilities	2,830	5,145
Accrued clinical trial expenses	9,890	19,144
Income taxes payable	(163)	(739)
Deferred revenue	(25,413)	(3,166)
Long-term income tax liability	19	324
Other long term liabilities	(79)	293
Net cash used in operating activities	(55,391)	(48,858)
Cash flows from investing activities		
Purchases of property and equipment	(653)	(3,084)
Purchases of investments	(8,083)	(116,554)
Proceeds from sales of investments	1,826	44,310
Proceeds from maturities of investments	63,023	53,579
Proceeds from sale of property and equipment	17	17
Net cash provided by (used in) investing activities	56,130	(21,732)
Cash flows from financing activities		
Repurchase of common stock	(1)	
Proceeds from issuance of common stock upon exercise of stock options	461	291
Proceeds from issuance of common stock under employee stock purchase plan	522	454
Proceeds from issuance of common stock and warrants, net of issuance costs	41,569	
Principal payments under capital lease obligations		(113)
Net cash provided by financing activities	42,551	632
Net decrease in cash and cash equivalents	43,290	(69,958)
Cash and cash equivalents at beginning of the period	24,046	108,215
Cash and cash equivalents at end of the period	\$ 67,336	\$ 38,257

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

Table of Contents

AFFYMAX, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS

(Unaudited)

1. The Company

Edgar Filing: AFFYMAX INC - Form 10-Q

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

2. Summary of Significant Accounting Policies

Basis of Presentation

Edgar Filing: AFFYMAX INC - Form 10-Q

Our accompanying condensed financial statements 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, consisting of only normal recurring adjustments, which in the opinion of management, are necessary to fairly state the financial position at, and the results of operations and cash flows for, the interim periods presented. In June 2009, the Financial Accounting Standards Board (FASB) established general standards of accounting and disclosure for events that occur after the balance sheet date but before financial statements are issued. We evaluated subsequent events through November 3, 2009 upon the issuance of our financial statements. The financial information included herein should be read in conjunction with our Annual Report on Form 10-K for the year ended December 31, 2008, which includes our audited financial statements and the notes thereto.

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

Reclassifications

Edgar Filing: AFFYMAX INC - Form 10-Q

Certain amounts in prior period financial statements have been reclassified to conform to the current period presentation. We separated the line item proceeds from sales and maturities of investments into two line items proceeds from sales of investments and proceeds from maturities of investments in the condensed statement of cash flows for the nine months ended September 30, 2008. This reclassification did not change previously reported net loss, total assets, stockholders' equity (deficit), or cash provided by or used by investing activities.

Comprehensive Loss

Comprehensive loss consists of net loss plus the change in unrealized gains and losses on investments. At each balance sheet date presented, our other comprehensive loss consists solely of unrealized gains and losses on investments. Comprehensive loss for the three and nine months ended September 30, 2009 and 2008 are as follows (in thousands):

Table of Contents

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
Net loss	\$ (18,382)	\$ (26,211)	\$ (62,214)	\$ (60,707)
Change in unrealized gains (losses) on investments	(77)	(90)	(430)	(160)
Comprehensive loss	\$ (18,459)	\$ (26,301)	\$ (62,644)	\$ (60,867)

Concentration of Risk and Uncertainties

Edgar Filing: AFFYMAX INC - Form 10-Q

Financial instruments that potentially subject us to a concentration of credit risk consist of cash, cash equivalents and investments. We deposit excess cash in accounts with three major financial institutions in the United States. Deposits in these banks may exceed the amount of insurance provided on such deposits. We have not experienced any realized losses on our deposits of cash and cash equivalents. Although our guideline for investment of excess cash is designed to maintain safety and liquidity through our policies on diversification and investment maturity, as of September 30, 2009, we held fair value of investments in auction rate securities (ARS) totaling \$15.7 million that have failed in auctions.

We have experienced significant operating losses since inception. At September 30, 2009, we had an accumulated deficit of \$360.5 million. We have generated no revenue from product sales to date. We have funded our operations to date principally from our collaboration agreements with Takeda Pharmaceutical Company Limited (Takeda) and the sale of equity securities. We expect to incur substantial additional operating losses for the next several years and will need to obtain additional financing in order to complete the development and commercialization of Hematide. There can be no assurance that such financing will be available or will be at terms acceptable to us.

Our accounts receivable balance contains receivables in connection with our two separate collaboration agreements (the Arrangement) with Takeda. We have not experienced any credit losses from our Arrangement with Takeda and none are expected.

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

Recent Accounting Pronouncements

Edgar Filing: AFFYMAX INC - Form 10-Q

In August 2009, the FASB issued Accounting Standards Update (ASU) No. 2009-05, which revised the basis for measuring the fair value of our liabilities and clarifying how to measure the fair value of liabilities in circumstances when a quoted price in an active market for the identical liability is not available. ASU 2009-05 is effective for the first reporting period beginning after the issuance of this standard. We are currently assessing the potential impact that the adoption of ASU 2009-05 will have on our financial statements.

In June 2009, the FASB issued ASU 2009-01, which establishes the FASB Accounting Standards Codification as the source of authoritative U.S. GAAP recognized by the FASB to be applied by nongovernmental entities. The guidance which changes the referencing of financial standards is effective for interim or annual financial periods ending after September 15, 2009. We adopted ASU 2009-01 during the period ended September 30, 2009. The adoption of the guidance did not have a significant impact on our financial statements.

Table of Contents

Investments

Investments are classified as available-for-sale and are carried at their fair market value at the balance sheet date. Realized gains and losses on sales of all such securities are reported in earnings and computed using the specific identification method. Unrealized gains and losses are reported as a separate component of stockholders' equity until realized.

Effective April 2009, the FASB collectively established a new method of recognizing and reporting other-than-temporary impairments of debt securities. The guidance also contains additional disclosure requirements related to debt and equity securities. The adoption of the guidance did not have a significant impact on our financial statements.

Effective January 2008, we adopted the FASB authoritative guidance on fair value measurements and disclosures, which defines fair value, establishes a framework for measuring fair value under GAAP, and expands disclosures about fair value measurements. The guidance does not require any new fair value measurements, but provides direction on how to measure fair value by providing a fair value hierarchy used to classify the source of the information. Effective January 2009, we adopted the amended authoritative guidance on fair value measurements and disclosures, which delays the effective date of fair value measurements and disclosures for all nonfinancial assets and liabilities except for those recognized or disclosed at least annually. The adoption of this guidance did not have a significant impact on our financial statements. In October 2008, the FASB issued guidance on fair value of a financial asset when the market for that asset is not active. The authoritative guidance clarifies the application of fair value measurements and disclosures in a market that is not active.

Effective April 2009, we adopted FASB authoritative guidance on determining fair value when the volume and level of activity for the asset or liability have significantly decreased and identifying transactions that are not orderly. The guidance amends fair value measurements and disclosures to provide additional direction on estimating fair value when the volume and level of activity for an asset or liability have significantly decreased in relation to normal market activity for the asset or liability and on circumstances that may indicate that a transaction is not orderly. The adoption of the guidance did not have a significant impact on our financial statements.

Effective January 2008, we adopted FASB authoritative guidance on the fair value option for financial assets and financial liabilities, which permits entities to choose to measure many financial instruments and certain other items at fair value that are not currently required to be measured at fair value. We did not elect to adopt the fair value option for financial assets and financial liabilities, except for the Series C-2 ARS Rights, as more fully described in Note 4.

Revenue Recognition

Collaboration Revenue

We recognize revenue in accordance with the SEC's authoritative guidance, revenue recognition in financial statements. When evaluating multiple element arrangements, we consider whether the components of the arrangement represent separate units of accounting as defined in the authoritative guidance for revenue arrangements with multiple deliverables. Application of this guidance requires subjective determinations and requires management to make judgments about the fair value of the individual elements and whether such elements are separable from the other aspects of the contractual relationship. Effective January 2009, we adopted the provisions of the authoritative guidance for accounting for collaborative arrangements, which defines collaborative arrangements and establishes reporting and disclosure requirements for transactions between participants in a collaborative arrangement and between participants in the arrangements and third parties. The adoption of this guidance did not have a significant impact on our financial statements.

Table of Contents

We evaluated the multiple elements under the combined single arrangement in accordance with the provisions of the guidance for revenue arrangements with multiple deliverables. We recognize revenue using the Contingency-Adjusted Performance Model (CAPM). Under the CAPM, revenue is eligible for recognition in the period the payment is earned under the Arrangement including amounts that are either received or due from Takeda. Revenue initially recognized is based on the percentage of time elapsed from inception of the Arrangement in June 2006 to the period in which the payment is earned in relation to the total projected development period, which is currently estimated to end on January 1, 2011. The remaining portion of the payment is then recognized on a straight-line basis over the remaining estimated duration of the development period of the Arrangement. Payments during the development period include amounts due for upfront license fees, milestone payments earned, purchases of active pharmaceutical ingredient (API) and reimbursement of development and commercial expenses. In the event our estimate of the development period were to extend past January 1, 2011, then the remaining deferred collaboration revenue would be recognized over a longer period.

We have recognized \$29.2 million and \$21.6 million of collaboration revenue during the three months ended September 30, 2009 and 2008, respectively, and \$81.9 million and \$56.8 million for the nine months ended September 30, 2009 and 2008, respectively. As of September 30, 2009, the amount receivable from Takeda was \$17.4 million. As of December 31, 2008, the amount receivable from Takeda was \$21.7 million.

Clinical Trial Expense

Edgar Filing: AFFYMAX INC - Form 10-Q

We record expense for estimated clinical study external costs, which are a significant component of research and development (R&D) expenses. These clinical trial costs were \$20.6 million and \$24.5 million during the three months ended September 30, 2009 and 2008, respectively, and \$68.8 million and \$52.7 million during the nine months ended September 30, 2009 and 2008, respectively. Clinical studies are administered by third-party contract research organizations (CROs). CROs typically perform most of the total start-up activities for the trials, including document preparation, site identification, pre-study visits, training as well as on-going program management. For the Phase 3 studies, which represent the vast majority of the clinical trial expense, the expense recorded is based on reporting received from CROs and internal analyses. We accrue costs for work performed by CROs based on the achievement of contracted activities during the period. Expense for investigator fees, which include patient costs, is based on internal estimates of activities using patient enrollment and contractual or estimated rates. For the Phase 2 studies, the expense is activities based such as patient monitoring as reported by the CROs and achievement of milestones. Other costs such as testing and drug materials are expensed as incurred.

For all studies, CRO reporting is reviewed by us for appropriateness and adjustments are made as deemed necessary to ensure that the expenses reflect the actual effort incurred by the CROs. However, if we do not receive complete and accurate information from the vendors or underestimate activity levels associated with a study at a given point in time, we may have to record adjustments, including potentially significant additional R&D expenses in subsequent periods.

Net Loss Per Share

Edgar Filing: AFFYMAX INC - Form 10-Q

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

Table of Contents

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
	(in thousands, except per share data)			
Numerator:				
Net loss	\$ (18,382)	\$ (26,211)	\$ (62,214)	\$ (60,707)
Denominator:				
Weighted-average shares outstanding	18,951	15,238	18,121	15,197
Less: Weighted-average unvested shares subject to repurchase		(3)	(1)	(4)
Weighted-average number of shares used in computing basic and diluted net loss per share	18,951	15,235	18,120	15,193
Basic and diluted net loss per share	\$ (0.97)	\$ (1.72)	\$ (3.43)	\$ (4.00)

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

	As of September 30,	
	2009	2008
Options to purchase common stock	2,420	2,124
Common stock subject to repurchase		2
Common stock issuable pursuant to the 2006 Employee Stock Purchase Plan	33	27
Restricted stock units	107	192
Warrants to purchase common stock	426	2

3. Stockholders' Equity (Deficit)

Common Stock

Edgar Filing: AFFYMAX INC - Form 10-Q

In September 2009, we entered into a common stock purchase agreement, sometimes referred to as an equity line of credit arrangement, with Azimuth Opportunity Ltd. (Azimuth) that provides that, upon the terms and subject to the conditions set forth in the purchase agreement, Azimuth is committed to purchase up to \$60.0 million worth of shares of our common stock over the 24-month term of the purchase agreement; provided, however, in no event may we sell under the purchase agreement more than such number of shares of common stock which is equal to one share less than 20% of our outstanding shares or 3,796,353 of common stock on the effective date of the purchase agreement, and provided, further, that in no event shall Azimuth be obligated to purchase under the purchase agreement any shares of our common stock which, when aggregated with all other shares of our common stock then owned beneficially by Azimuth, would result in the beneficial ownership by Azimuth of more than 9.9% of the then issued and outstanding shares of our common stock. The per share purchase price for these shares equals the daily volume weighted average price of our common stock on each date during the Azimuth draw down period on which shares are purchased, less a discount ranging from 3.75% to 5.75%, based on a minimum price of \$8.00 as specified in the agreement. Upon each sale of our common stock to Azimuth, we have agreed to pay Reedland Capital Partners a placement fee equal to 1% of the aggregate dollar amount of common stock purchased by Azimuth. The term of the purchase agreement ends October 1, 2011. There have been no purchases by Azimuth under this agreement to date.

In March 2009, institutional investors purchased \$42.0 million of our common stock in a private placement. The net proceeds were \$41.6 million after offering expenses. Under the terms of one of two purchase agreements, we sold 2,844,708 newly issued shares of our common stock at a purchase price of \$11.25 per share. In the other purchase agreement, we sold 652,262 newly issued units at a purchase price of \$15.33 per unit, with each unit consisting of one share of common stock and one warrant to purchase 0.65 of a share of common stock. The warrants are immediately exercisable at \$16.78 per share and expire in March 2014.

Table of Contents

We estimated that the fair value of the warrants issued in connection with the March 2009 private placement was \$3.3 million using the Black-Scholes valuation model with the following assumptions: expected volatility of 86%, risk-free interest rate of 1.86%, dividend yield of 0% and expected term of five years. The warrants were considered as a cost of the equity financing, therefore the fair value of the warrants was recorded to contra-equity.

Stock-Based Compensation

Edgar Filing: AFFYMAX INC - Form 10-Q

We recognized stock-based compensation expense related to employee and director stock options, restricted stock units and stock purchase rights of \$2.4 million and \$2.5 million for the three months ended September 30, 2009 and 2008, respectively, and \$7.2 million and \$7.1 million for the nine months ended September 30, 2009 and 2008, respectively, under the authoritative guidance for share-based payments. As of September 30, 2009, unrecognized compensation costs related to employee and director stock options and restricted stock units totaled \$14.8 million. The cost is expected to be recognized over a weighted-average amortization period of 1.66 years.

4. Investments and Fair Value Measurements

Edgar Filing: AFFYMAX INC - Form 10-Q

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

As of September 30, 2009					
	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Other-Than- Temporary Impairment	Fair Value
Short-term investments:					
Certificates of deposit	\$ 3,746	\$	\$	\$	\$ 3,746
Government securities	16,954	43			16,997
Auction rate securities	14,175			(2,564)	11,611
Total short-term investments	\$ 34,875	\$ 43	\$	\$ (2,564)	\$ 32,354
Long-term investments:					
Auction rate securities	\$ 5,000	\$	\$	\$ (861)	\$ 4,139

As of December 31, 2008					
	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Other-Than- Temporary Impairment	Fair Value
Short-term investments:					
Corporate securities	\$ 3,500	\$	\$ (5)	\$	\$ 3,495
Certificates of deposit	1,499	3			1,502
Government securities	65,261	418	(3)		65,676
Total short-term investments	\$ 70,260	\$ 421	\$ (8)	\$	\$ 70,673
Long-term investments:					
Government securities	\$ 5,273	\$ 60	\$	\$	\$ 5,333
Auction rate securities	21,250			(3,638)	17,612
Total long-term investments	\$ 26,523	\$ 60	\$	\$ (3,638)	\$ 22,945

Table of Contents

Fair Value Measurements

Edgar Filing: AFFYMAX INC - Form 10-Q

We measure certain financial assets at fair value on a recurring basis, including cash equivalents and available for sale securities. The fair value of these assets was determined based on a three-tier hierarchy under the authoritative guidance for fair value measurements and disclosures that prioritizes the inputs used in measuring fair value as follows:

- Level 1 observable inputs such as quoted prices in active markets.
- Level 2 inputs other than quoted prices in active markets that are observable either directly or indirectly through corroboration with observable market data.
- Level 3 unobservable inputs in which there is little or no market data, which would require us to develop our own assumptions.

Our cash equivalents and investments, other than ARS, are classified within Level 1 or Level 2 of the fair value hierarchy because they are valued using quoted market prices in active markets, broker or dealer quotations, or alternative pricing sources with reasonable levels of price transparency. The types of investments that are generally classified within Level 1 of the fair value hierarchy include money market securities. The types of investments that are generally classified within Level 2 of the fair value hierarchy include corporate securities, certificates of deposits and U.S. government securities. Our investments in ARS are classified within Level 3 of the fair value hierarchy because of the lack of observable inputs.

ARS are structured to provide liquidity by an auction process that resets the applicable interest rate at predetermined calendar intervals, usually every 28 days but have stated or contractual maturities that are generally greater than one year. Through mid-February 2008, every auction reset date of the ARS held by us was successful. In mid-February, overall market liquidity concerns resulted in the failure of a majority of the auctions in the ARS markets. In the following month, approximately one-fifth of the auctions for ARS held by us were successful. Since mid-March 2008, the overall ARS markets have continued to deteriorate and the ARS held by us have failed in all but a single successful auction. During this period through September 30, 2009, the par value of our ARS holdings decreased by \$10.6 million to \$19.2 million primarily due to redemptions at par value by the issuers. Our sales or redemptions of ARS through September 30, 2009 have not resulted in any loss of principal, except for a \$62,000 loss of par value upon acceptance of a tender offer below market. The majority of the ARS held by us continue to pay interest, most recently in a range of 1-13%, though certain student loan issuances are temporarily at a zero coupon rate due to the particular interest provisions of the issuances. As of September 30, 2009, our \$19.2 million of par value of ARS were comprised of \$16.6 million of municipal issuances that are collateralized by student loans guaranteed by the U.S. government under the Federal Family Education Loan Program and a \$2.6 million closed end preferred issuance. The ARS held by us are rated A through AAA by a major credit rating agency.

As a result of the continued auction market failures, quoted prices in active markets are not available. Due to the lack of observable inputs, we determined the fair value of our ARS at September 30, 2009 using a discounted cash flow analysis. The analysis considers, among other things, the amount and timing of coupon payments, contractual terms, underlying collateralization and credit risk. In addition, we included in our analysis an illiquidity factor to estimate the discount necessary to sell a security for which there is no active market. The analysis considers that issuers have continued to meet interest payment obligations and are expected to continue to do so at levels consistent with issuer's credit risk. The analysis is based on dynamic market conditions and changes in our assumptions could lead to a significant change in determined value. Our analysis resulted in a net decrease in fair value of ARS totaling \$3.4 million through September 30, 2009. The decrease in fair value was deemed to be other-than-temporary and was recorded as an impairment charge to other income (expense), net. We have the intent to sell the ARS and, more likely than not, we would be required to sell the ARS before anticipated recovery. For the nine months ended September 30, 2009 and 2008, we recorded an impairment charge of \$160,000 and \$2.0 million, respectively, to other income (expense), net related to the decrease in the fair value of our ARS.

Table of Contents

As a result of a settlement between various regulatory agencies, including the SEC, and UBS entities relating to sales and marketing practices of ARS, in October 2008, we received an offer from UBS AG of Series C-2 ARS Rights (ARS Rights) in connection with the \$14.2 million of par value of ARS as of September 30, 2009 that were purchased through UBS. In November 2008, we accepted the terms of the ARS Rights and delivered the required legal release of claims against the UBS entities. These ARS Rights give us the option to require UBS to repurchase, at par, the ARS beginning on June 30, 2010, and prior to such date, UBS has the option to buy, at par, the ARS. In connection with the ARS Rights, UBS is also making available loans to eligible borrowers. Currently, we are in the process of applying for such loans from UBS Financial Services, Inc., an affiliate of UBS AG. The loan facility would allow us to draw up to 75% of the stated value of our ARS portfolio, as determined by UBS Financial Services, Inc., and is subject to collateral maintenance requirements. These loans would be secured by the ARS and ARS Rights as collateral.

We determined that the ARS Rights do not meet the definition of a derivative security as described in the authoritative guidance for accounting for derivative instruments and hedging activities because the ARS Rights are non-transferrable, and we must tender the related ARS to receive the cash settlement. Therefore, we elected to measure the ARS Rights separately under the authoritative guidance pertaining to the fair value option for financial assets and financial liabilities in order to partially offset the changes in the fair value of the ARS to the ARS Rights. We did not elect to adopt the guidance for the fair value option for financial assets and financial liabilities to measure financial instruments, except for the ARS Rights. We determined the value of the ARS Rights was \$2.3 million as of September 30, 2009 using a discounted cash flows analysis based on, among other things, the timing and likelihood of the recovery of the par value of the ARS from UBS. We recorded the fair value of the ARS Rights as an other current asset with a corresponding credit to other income (expense), net, partially offsetting the unrecognized losses incurred to date on the related ARS, during the three and nine months ended September 30, 2009. The recognition of the ARS Rights and the other-than-temporary impairment on the related ARS resulted in a net impact of \$118,000 and \$69,000, respectively, to other income (expense), net for the three and nine months ended September 30, 2009.

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

As of September 30, 2009				
	Fair Value Measurements Using			
	Total	Level 1	Level 2	Level 3
Cash equivalents	\$ 60,492	\$ 59,490	\$ 1,002	\$
Short-term investments:				
Certificates of deposit	\$ 3,746	\$	\$ 3,746	\$
Government securities	16,997		16,997	
Auction rate securities	11,611			11,611
Total short-term investments	\$ 32,354	\$	\$ 20,743	\$ 11,611
Long-term investments:				
Auction rate securities	\$ 4,139	\$	\$	\$ 4,139
ARS Rights	\$ 2,344	\$	\$	\$ 2,344

As of December 31, 2008				
	Fair Value Measurements Using			
	Total	Level 1	Level 2	Level 3
Cash equivalents	\$ 20,643	\$ 20,643	\$	\$
Short-term investments:				
Corporate securities	\$ 3,495	\$	\$ 3,495	\$
Certificates of deposit	1,502		1,502	
Government securities	65,676		65,676	
Total short-term investments	\$ 70,673	\$	\$ 70,673	\$

Edgar Filing: AFFYMAX INC - Form 10-Q

Long-term investments:				
Government securities	\$	5,333	\$	5,333
Auction rate securities		17,612		17,612
Total long-term investments	\$	22,945	\$	17,612
ARS Rights	\$	2,414	\$	2,414

Table of Contents

The following table presents changes in Level 3 investments measured at fair value on a recurring basis for the nine months ended September 30, 2009 and 2008 (in thousands):

	Nine Months Ended September 30,	
	2009	2008
Balance at beginning of the period	\$ 20,026	\$ 36,405
Transfers in and/or out of Level 3		
Total unrealized losses related to ARS		
Included in net loss	(160)	(2,065)
Total realized gains related to ARS		
Included in net loss	372	89
Total realized loss related to ARS		
Included in net loss	(62)	
Total unrealized losses related to ARS Rights		
Included in net loss	(126)	
Total unrealized gains related to ARS Rights		
Included in net loss	57	
Settlements	(2,013)	(14,755)
Balance at end of the period	\$ 18,094	\$ 19,674

5. Contingencies

Edgar Filing: AFFYMAX INC - Form 10-Q

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

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

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

Table of Contents

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

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

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

In June 2007, J&J filed a motion to compel discovery of information relating to Hematide and then filed a substitute motion to compel. In July 2007, we filed an opposition to J&J's motion to compel and a motion for protective order. In September 2007, the arbitrators ruled that J&J could obtain limited discovery on Hematide, but that J&J could not obtain discovery on Hematide product formulas, sequences, laboratory notebooks containing such information, experimental results, clinical trial results and strategies, or internal business planning. The arbitration hearing commenced in September 2009 and is scheduled to be completed by the end of 2009. A decision is expected in early 2010. The outcome of the matter is uncertain and regardless of outcome, the matter may have an adverse impact on us because of legal costs, diversion of management resources and other factors.

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

6. Development and Commercialization Agreements with Takeda

Edgar Filing: AFFYMAX INC - Form 10-Q

In February 2006, we granted an exclusive license to Takeda for development and commercialization of Hematide in Japan. Pursuant to this agreement, Takeda paid us approximately \$27 million, consisting of \$17 million in upfront licensing fees and approximately \$10 million for the purchase of equity. In addition, we are 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 us. Assuming Hematide is approved and launched in Japan, we 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 was responsible for the first \$50 million of third party expenses related to development in pursuit of U.S. regulatory

Table of Contents

approval of Hematide. Of the first \$50 million of third-party expenses related to the development in pursuit of U.S. regulatory approval of Hematide to be borne by Takeda, a total of \$36.3 million was utilized by both parties through December 31, 2007 and the remainder was utilized during the first quarter of 2008. Currently, Takeda bears 70% of the third party U.S. development expenses, while we are responsible for 30% of the expenses. We retain responsibility for 100% of our internal development expenses. Under the June 2006 agreement, Takeda paid us an upfront license fee of \$105 million, and we are eligible to receive from Takeda up to an aggregate of \$280 million upon the successful achievement of clinical development and regulatory milestones, the majority of which relate to the renal program, including milestone payments upon completion of database lock of the Phase 3 clinical trials of \$15 million for dialysis and \$15 million for pre-dialysis, \$20 million milestone payments upon FDA acceptance of the submission of the new drug application, or NDA, and \$95 million of milestone payments upon approval by the FDA in dialysis and pre-dialysis indications. Further, we may receive from Takeda up to an aggregate of \$150 million upon the achievement of certain worldwide annual net sales milestones. We and Takeda will share equally in the net profits and losses of Hematide in the United States, which include expenses related to the marketing and launch of Hematide. Takeda will pay us a variable royalty based on annual net sales of Hematide outside the United States. The agreement establishes a joint steering committee to oversee the development, regulatory approval and commercialization of Hematide.

We share responsibility with Takeda for clinical development activities required for U.S. regulatory approval of Hematide. Specifically, we have primary responsibility for Hematide's clinical development plan and clinical trials in the dialysis and pre-dialysis indications, while Takeda has primary responsibility in the chemotherapy induced anemia and anemia of cancer indications to the extent any such indication is developed. We and Takeda have agreed to suspend the development of Hematide to treat chemotherapy-induced anemia and to focus all development efforts for Hematide on the treatment of chronic renal failure anemia. We are responsible for 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.

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

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

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

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

Edgar Filing: AFFYMAX INC - Form 10-Q

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, 2008 and our unaudited condensed financial statements for the three and nine month periods ended September 30, 2009.

Forward-Looking Statements

Edgar Filing: AFFYMAX INC - Form 10-Q

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,"

Table of Contents

expect, plan, anticipate, believe, estimate, project, predict, potential and similar expressions intended to identify forward-looking statements. These forward-looking statements include statements regarding the timing, design and results of our clinical trials and drug development program, the continuation and success of our collaboration with Takeda, and the timing and likelihood of the commercialization of Hematide. These statements involve known and unknown risks, uncertainties and other factors, which may cause our actual results, performance, time frames or achievements to be materially different from any future results, performance, time frames or achievements expressed or implied by the forward-looking statements. We discuss many of these risks, uncertainties and other factors in this Quarterly Report on Form 10-Q under Item 1A Risk Factors, including risks relating to the continued safety and efficacy of Hematide in clinical development, the potential for once per month dosing and room temperature stability, the cardiovascular event rate in our phase 3 clinical program, the timing of patient accrual in ongoing and planned clinical studies, regulatory requirements and approvals, research and development efforts, industry and competitive environment, reimbursement coverage, intellectual property rights and disputes and other matters. Given these risks, uncertainties and other factors, you should not place undue reliance on these forward-looking statements. Also, these forward-looking statements represent our estimates and assumptions only as of the date of this filing. You should read this Quarterly Report on Form 10-Q completely and with the understanding that our actual future results may be materially different from what we expect. We hereby qualify our forward-looking statements by these cautionary statements. Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

Overview

We are a biopharmaceutical company committed to developing novel drugs to improve the treatment of serious and often life-threatening conditions. Our product candidate, Hematide™, is designed to treat anemia associated with chronic renal failure. Anemia is a serious condition in which blood is deficient in red blood cells and hemoglobin. It is common in patients with chronic renal failure, cancer, heart failure, inflammatory diseases and other critical illnesses, as well as in the elderly. If left untreated, anemia may lead to chronic fatigue or increase the risk of other diseases or death. Currently recombinant EPO, or rEPO, is used to manage the anemia of dialysis, pre-dialysis and cancer patients. According to IMS Health Incorporated, rEPO generated \$11.5 billion in worldwide revenues for 2008, of which we believe approximately \$6.8 billion was generated in the U.S. Of this \$6.8 billion, we estimate that over one-half is attributable to use of rEPO in patients with chronic renal failure, and the remainder is attributable to other indications, primarily cancer patients. Hematide is a synthetic peptide-based erythropoiesis stimulating agent, or ESA, designed to stimulate production of red blood cells. Hematide is designed to be longer acting than currently marketed ESAs in the U.S. and therefore has the potential to offer both better care for patients and reduced cost and complexity for healthcare providers.

We are conducting Phase 3 clinical trials in patients suffering from chronic renal failure. Our Phase 3 clinical program includes four open-label, randomized controlled clinical trials. Of these trials, two trials, called PEARL 1 and PEARL 2, are being conducted in pre-dialysis patients and are designed to evaluate the safety and efficacy of Hematide compared to darbepoetin alfa to correct anemia and maintain hemoglobin in a corrected range over time. The other two trials, called EMERALD 1 and EMERALD 2, are being conducted in dialysis patients and are designed to evaluate the safety and efficacy of Hematide and its ability to maintain hemoglobin levels in a corrected range compared to epoetin alpha or epoetin beta when switched to Hematide. Enrollment of PEARL 1 was completed in July 2008, months in advance of the PEARL 2 and EMERALD studies, which completed enrollment during the last quarter of 2008. Although each study was originally planned to continue only until the last patient in the study was treated for approximately 52 weeks, we extended PEARL 1 into the fourth quarter of 2009 to complete treatment of patients concurrent with the other studies. 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. In addition, the assessment of safety will include a composite cardiovascular endpoint from a pooled safety database. To date, no ESA other than Hematide has been required to achieve this composite safety endpoint for initial regulatory approval.

Table of Contents

To date, we have not generated any product revenue. We have funded our operations primarily through the sale of equity securities, reimbursement for development expenses and active pharmaceutical ingredient, API, production, license fees and milestone payments from collaborative partners, operating and capital lease financings, interest earned on investments and limited license fees and royalties from licensing intellectual property. Since inception, we have incurred net losses and expect to incur substantial and increasing losses for the next several years in order to complete the development and commercialization of Hematide. As of September 30, 2009, we had an accumulated deficit of \$360.5 million.

In September 2009, we entered into a common stock purchase agreement, sometimes referred to as an equity line of credit arrangement, with Azimuth Opportunity Ltd. (Azimuth) that provides that, upon the terms and subject to the conditions set forth in the purchase agreement, Azimuth is committed to purchase up to \$60.0 million worth of shares of our common stock over the 24-month term of the purchase agreement; provided, however, in no event may we sell under the purchase agreement more than such number of shares of common stock which is equal to one share less than 20% of our outstanding shares or 3,796,353 of common stock on the effective date of the purchase agreement, and provided, further, that in no event shall Azimuth be obligated to purchase under the purchase agreement any shares of our common stock which, when aggregated with all other shares of our common stock then owned beneficially by Azimuth, would result in the beneficial ownership by Azimuth of more than 9.9% of the then issued and outstanding shares of our common stock. The per share purchase price for these shares equals the daily volume weighted average price of our common stock on each date during the Azimuth draw down period on which shares are purchased, less a discount ranging from 3.75% to 5.75%, based on a minimum price of \$8.00 as specified in the agreement. Upon each sale of our common stock to Azimuth, we have agreed to pay Reedland Capital Partners a placement fee equal to 1% of the aggregate dollar amount of common stock purchased by Azimuth. The term of the purchase agreement ends October 1, 2011. There have been no purchases by Azimuth under this agreement to date.

In March 2009, we completed a private placement raising \$41.6 million of net proceeds through the issuance of common stock and warrants exercisable for common stock. Under the terms of one of two purchase agreements, we sold 2,844,708 newly issued shares of our common stock at a purchase price of \$11.25 per share. In the other purchase agreement, we sold 652,262 newly issued units at a purchase price of \$15.33 per unit, with each unit consisting of one share of common stock and one warrant to purchase 0.65 of a share of common stock. The warrants are immediately exercisable at \$16.78 per share and expire in March 2014.

We believe that the existing cash, cash equivalents and investments together with the interest thereon will enable us to maintain our currently planned operations for at least 12 months. However, we expect that we will need to raise additional funding to complete the development and commercialization of Hematide. The current worldwide capital markets have been extremely volatile, and biotechnology companies have been limited or unsuccessful in obtaining funding in this environment. We intend to evaluate the capital markets from time to time to determine whether to raise additional capital, in the form of equity or otherwise, depending upon market conditions relative to our need for funds at such time. Continuation of this market may significantly limit our ability to raise funds such that there can be no assurance we can raise the additional funds to support our continuing operations and maintain current development timelines, and funding may not be available to us on acceptable terms, or at all. Further, we have had to reduce our research capabilities and efforts, including the elimination of certain research programs, and even some activities related to the support of Hematide. If we are unable to raise additional funds when needed, we could be required to further delay, scale back or eliminate some or all of our development programs and other operations. We may seek to raise additional funds through public or private financing, strategic partnerships or other arrangements. Any additional equity financing would be dilutive to stockholders and debt financing, if available, may involve restrictive covenants. Further, any strategic or licensing arrangements, if available, may require us to relinquish product rights that we would otherwise seek to develop or commercialize ourselves. Our failure to raise capital when needed may harm our business and operating results.

Table of Contents

Critical Accounting Policies and Significant Judgments and Estimates

Edgar Filing: AFFYMAX INC - Form 10-Q

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

Our critical accounting policies and the use of estimates are consistent with those noted in our Annual Report on Form 10-K for the year ended December 31, 2008.

Results of Operations

Revenue

Edgar Filing: AFFYMAX INC - Form 10-Q

	Three Months Ended September 30, 2009				Nine Months Ended September 30, 2009									
	2009		2008		Increase/ (Decrease)	% Increase/ (Decrease)	2009		2008		Increase/ (Decrease)	% Increase/ (Decrease)		
(in thousands, except percentages)														
Collaboration revenue	\$	29,157	\$	21,645	\$	7,512	35%	\$	81,924	\$	56,803	\$	25,121	44%
License and royalty revenue		4		3		1	33%		13		690		(677)	(98)%
Total revenue	\$	29,161	\$	21,648	\$	7,513	35%	\$	81,937	\$	57,493	\$	24,444	43%

Edgar Filing: AFFYMAX INC - Form 10-Q

We have recognized \$29.2 million and \$21.6 million of collaboration revenue for the three months ended September 30, 2009 and 2008, respectively, and \$81.9 million and \$56.8 million for the nine months ended September 30, 2009 and 2008, respectively. The increase in collaboration revenue for the three and nine months ended September 30, 2009 compared to the three and nine months ended September 30, 2008 was primarily due to the growth in third-party development expenses reimbursed by Takeda related to our Phase 3 clinical trials which completed enrollment in the last quarter of 2008. We expect collaboration revenue to be directly affected by milestone payments and expenses that are eligible for reimbursement from Takeda under the Arrangement in future periods. In the event our estimate of the development period were to extend past January 1, 2011, then the remaining deferred collaboration revenue would be recognized over a longer period.

Research and Development Expenses

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2009	2008	Increase/ (Decrease)	% Increase/ (Decrease)	2009	2008	Increase/ (Decrease)	% Increase/ (Decrease)
	(in thousands, except percentages)							
Research and development expenses	\$ 37,237	\$ 39,780	\$ (2,543)	(6)%	\$ 118,462	\$ 96,093	\$ 22,369	23%

The decrease in research and development expenses for the three months ended September 30, 2009 compared to the three months ended September 30, 2008 was primarily due to reduced purchases of comparator drugs used in our clinical trials. The increase in research and development expenses for the nine months ended September 30, 2009 compared to the nine months ended September 30, 2008 was primarily due to increased clinical trial costs resulting from full enrollment of the Phase 3 clinical program in the last quarter of 2008. Compared to the three quarters of 2009, we do not expect quarterly research and development expenses to increase or decrease substantially in the remainder of 2009.

Table of Contents*General and Administrative Expenses*

	Three Months Ended September 30,				Nine Months Ended September 30,				
	2009	2008	Increase/ (Decrease)	% Increase/ (Decrease)	2009	2008	Increase/ (Decrease)	% Increase/ (Decrease)	
(in thousands, except percentages)									
General and administrative expenses	\$ 10,657	\$ 8,308	\$ 2,349	28%	\$ 26,763	\$ 23,639	\$ 3,124	13%	

The increase in general and administrative expenses for the three and nine months ended September 30, 2009 compared to the three and nine months ended September 30, 2008 was primarily due to higher legal fees. We expect to incur increasing general and administrative expenses in future periods to support our preparation for the NDA for Hematide, costs associated with our J&J litigation and expansion of commercial capabilities.

Interest Income (Expense), Net

	Three Months Ended September 30,				Nine Months Ended September 30,				
	2009	2008	Increase/ (Decrease)	% Increase/ (Decrease)	2009	2008	Increase/ (Decrease)	% Increase/ (Decrease)	
(in thousands, except percentages)									
Interest income (expense), net	\$ 164	\$ 665	\$ (501)	(75)%	\$ 825	\$ 3,556	\$ (2,731)	(77)%	

The decrease in interest income, net, was due primarily to lower interest rates and lower level of cash, cash equivalents and investments during the three and nine months ended September 30, 2009 compared to the same period in 2008.

Other Income (Expense), Net

	Three Months Ended September 30,				Nine Months Ended September 30,				
	2009	2008	Increase/ (Decrease)	% Increase/ (Decrease)	2009	2008	Increase/ (Decrease)	% Increase/ (Decrease)	
(in thousands, except percentages)									
Other income (expense), net	\$ 163	\$ (436)	\$ 599	(137)%	\$ 163	\$ (2,024)	\$ 2,187	(108)%	

Other income (expense), net, for the nine months ended September 30, 2008 of \$2.0 million includes the initial other-than-temporary impairment charge related to the decrease in fair value of our investments in ARS in comparison to the nine months ended September 30, 2009 which only reflects the subsequent adjustment to fair value. Based on projected cash usage, we may be required to sell the ARS prior to the resumption of successful auctions or other liquidity events. As a result, we deemed the impairment as other-than-temporary and recorded the charge in the three and nine months ended September 30, 2009 and 2008.

Benefit for Income Taxes

	Three Months Ended September 30, 2009			September 30, 2008			Increase/ (Decrease)			% Increase/ (Decrease)			Nine Months Ended September 30, 2009			September 30, 2008			Increase/ (Decrease)			% Increase/ (Decrease)																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																				
(in thousands, except percentages)																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																										
Benefit for income taxes	\$		(24)	\$		(24)																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																				</

We are subject to federal and California state income tax. We anticipate being in a net operating loss position for 2009. We recorded no combined federal and state tax liability for the three and nine months ended September 30, 2009. We recorded \$24,000 and \$86,000 of federal tax benefit for the three and nine months ended September 30, 2009 due to a research and development credits refund available to us pursuant to a provision within the American Recovery and Reinvestment Tax Act of 2009. We were also in a taxable loss position for our year ended December 31, 2008 and therefore recorded no combined federal and state tax liability for the three and nine months ended September 30, 2008.

[Table of Contents](#)

Liquidity and Capital Resources

Edgar Filing: AFFYMAX INC - Form 10-Q

Since our inception, we have financed our operations through sale of capital stock, license fees, milestone payments and reimbursement for development and commercial expenses and manufacturing costs from collaborative partners, operating and capital lease financing, interest earned on investments and limited license fees and royalties from licensing intellectual property. From inception through September 30, 2009, we have received net proceeds of \$301.3 million from the issuance of equity securities and \$122 million of upfront license fees, a \$10 million milestone payment and \$155.3 million for the reimbursement of development and commercial expenses and purchase of API from our Arrangement with Takeda. The first \$50 million of third-party expenses related to the development in pursuit of U.S. regulatory approval of Hematide was borne by Takeda under the Arrangement, of which \$36.3 million was utilized by both parties through December 31, 2007 and the remainder was utilized during the first quarter of 2008. Currently, Takeda bears 70% of the third-party U.S. development expenses, while we are responsible for 30% of the expenses.

In September 2009, we entered into a common stock purchase agreement, sometimes referred to as an equity line of credit arrangement, with Azimuth Opportunity Ltd. (Azimuth) that provides that, upon the terms and subject to the conditions set forth in the purchase agreement, Azimuth is committed to purchase up to \$60.0 million worth of shares of our common stock over the 24-month term of the purchase agreement; provided, however, in no event may we sell under the purchase agreement more than such number of shares of common stock which is equal to one share less than 20% of our outstanding shares or 3,796,353 of common stock on the effective date of the purchase agreement, and provided, further, that in no event shall Azimuth be obligated to purchase under the purchase agreement any shares of our common stock which, when aggregated with all other shares of our common stock then owned beneficially by Azimuth, would result in the beneficial ownership by Azimuth of more than 9.9% of the then issued and outstanding shares of our common stock. The per share purchase price for these shares equals the daily volume weighted average price of our common stock on each date during the Azimuth draw down period on which shares are purchased, less a discount ranging from 3.75% to 5.75%, based on a minimum price of \$8.00 as specified in the agreement. Upon each sale of our common stock to Azimuth, we have agreed to pay Reedland Capital Partners a placement fee equal to 1% of the aggregate dollar amount of common stock purchased by Azimuth. The term of the purchase agreement ends October 1, 2011. There have been no purchases by Azimuth under this agreement to date.

In March 2009, we completed a private placement raising \$41.6 million of net proceeds through the issuance of common stock and warrants exercisable for common stock. Under the terms of one of two purchase agreements, we sold 2,844,708 newly issued shares of our common stock at a purchase price of \$11.25 per share. In the other purchase agreement, we sold 652,262 newly issued units at a purchase price of \$15.33 per unit, with each unit consisting of one share of common stock and one warrant to purchase 0.65 of a share of common stock. The warrants are immediately exercisable at \$16.78 per share and expire in March 2014.

As of September 30, 2009, we had \$103.8 million in unrestricted cash, cash equivalents and short-term and long-term investments. Our cash and investment balances are held in a variety of interest bearing instruments, including obligations of U.S. government agencies, certificates of deposit, commercial paper, ARS, and money market funds. Cash in excess of immediate requirements is invested in accordance with our investment policy primarily with a view to liquidity and capital preservation.

As of September 30, 2009, we had fair value of ARS totaling \$15.7 million that were comprised of municipal issuances that are collateralized by student loans guaranteed by the U.S. government under the Federal Family Education Loan Program and a closed end preferred issuance. The ARS held by us are rated A through AAA by a major credit rating agency. ARS are structured to provide liquidity by an auction process that resets the applicable interest rate at predetermined calendar intervals, usually every 28 days but have stated or contractual maturities that are generally greater than one year. Since mid-March 2008, the overall ARS market has continued to deteriorate and the ARS held by us have failed in all but a single auction.

Table of Contents

We determined the fair value of our ARS at September 30, 2009 using a discounted cash flow analysis. The analysis considers, among other things, the amount and timing of coupon payments, contractual terms, underlying collateralization and credit risk. In addition, we included in our analysis an illiquidity factor to estimate the discount necessary to sell a security for which there is no active market. The analysis considers that issuers have continued to meet interest payment obligations and are expected to continue to do so at levels consistent with issuer's credit risk. Our analysis resulted in a net decrease in fair value of ARS totaling \$3.4 million through September 30, 2009. The decrease in fair value was deemed to be other-than-temporary and was recorded as an impairment charge to other income (expense), net. We have the intent to sell the ARS and, more likely than not, we would be required to sell the ARS before anticipated recovery. For the nine months ended September 30, 2009 and 2008, we recorded an impairment charge of \$160,000 and \$2.0 million, respectively, to other income (expense), net related to the decrease in fair value of our ARS. Our analysis is based on dynamic market conditions and further deterioration in the ARS markets or changes in our assumptions could lead to significant reductions in determined value thus resulting in impairments in future periods.

In November 2008, UBS AG issued us ARS Rights in connection with the \$14.2 million of par value of ARS as of September 30, 2009. The ARS Rights are not transferable and give us the option to require UBS to repurchase at par our ARS beginning on June 30, 2010, and prior to such date, UBS has the option to buy, at par, the ARS. In connection with the ARS Rights, UBS is also making loans available to eligible borrowers. Currently, we are in the process of applying for such loans from UBS Financial Services, Inc., an affiliate of UBS AG. The loan facility would allow us to draw up to 75% of the stated value of our ARS portfolio, as determined by UBS Financial Services, Inc., and is subject to collateral maintenance requirements. These loans would be secured by the ARS and ARS Rights as collateral. We determined the value of the ARS Rights was \$2.3 million as of September 30, 2009 using a discounted cash flow analysis based on, among other things, the timing and likelihood of the recovery of the par value of the ARS from UBS. We recorded the fair value of the ARS Rights as an other current asset with a corresponding credit to other income (expense), net, partially offsetting the unrecognized losses incurred to date on the related ARS, during the three and nine months ended September 30, 2009. The recognition of the ARS Rights and the other-than-temporary impairment on the related ARS resulted in a net impact of \$118,000 and \$69,000, respectively, to other income (expense), net for the three and nine months ended September 30, 2009. We anticipate that future changes in the fair value of the ARS Rights will be offset by the changes in the fair value of related ARS with no material net impact to net loss.

Based on our expected cash usage and our balance of cash and other investments, we do not anticipate the current illiquidity of these investments will affect our ability to operate our business as currently planned for at least 12 months. However, there can be no assurance as to the timing of when, or if the market for ARS will recover in a manner that will allow us to receive a return of some or all of our principal or to meet our liquidity needs. Although our ARS continue to pay interest according to their stated terms, if the illiquidity continues, these investments may be subject to a further decline in value, which would require us to recognize additional impairments in future periods. We may also be required to sell these investments at prices significantly below par or assessed fair value. If we are unable to liquidate our ARS to obtain funds when needed we may be unable to fund our operations. UBS AG may not be able to maintain the financial resources necessary to satisfy its obligations with respect to the ARS Rights in a timely manner or at all.

	September 30, 2009	December 31, 2008
	(in thousands)	
Cash, cash equivalents, short-term investments	\$ 99,690	\$ 94,719
Working capital	\$ 7,137	\$ 33,730
Long-term investments	\$ 4,139	\$ 22,945

	Nine Months Ended September 30, 2009	2008
	(in thousands)	
Cash provided by (used in):		
Operating activities	\$ (55,391)	\$ (48,858)
Investing activities	\$ 56,130	\$ (21,732)

Edgar Filing: AFFYMAX INC - Form 10-Q

Financing activities	\$	42,551	\$	632
Capital expenditures (included in investing activities above)	\$	(653)	\$	(3,084)

Table of Contents

Net cash used in operating activities for the nine months ended September 30, 2009 and 2008 primarily reflects the net loss for the period, which was reduced in part by non-cash activities including stock-based compensation, an other-than-temporary impairment charge related to our investments in ARS, realized gain and loss on investments, depreciation and amortization, as well as changes in operating assets and liabilities due to timing of payments made in connection with our Phase 3 clinical trials for Hematide. Net cash provided by investing activities for the nine months ended September 30, 2009 and 2008 was primarily related to maturities and sales of investments, which was partially offset by purchases of investments and purchases of property and equipment. Net cash provided by financing activities for the nine months ended September 30, 2009 was primarily attributable to \$41.6 million of net proceeds from the private placement and, to a lesser extent, proceeds from issuance of common stock upon exercise of stock options and the purchase of common stock under our Employee Stock Purchase Plan. Net cash provided by financing activities for the nine months ended September 30, 2008 was primarily attributable to the proceeds from issuance of common stock upon exercise of stock options and the purchase of common stock under our Employee Stock Purchase Plan, which was partially offset by principal payments under the capital lease obligations.

We believe that the existing cash, cash equivalents and investments together with the interest thereon, will enable us to maintain our currently planned operations for at least 12 months. However, we expect that we will need to raise additional funding to complete the development and commercialization of Hematide even after taking into account the potential milestone payments that may be received under our collaboration with Takeda. The current worldwide capital markets have been extremely volatile and inaccessible, and biotechnology companies have been limited or unsuccessful in obtaining funding in this environment. Securing funding has been particularly difficult for small companies of our size with limited capital resources. Continuation of this market may significantly limit our ability to raise funds such that there can be no assurance we can raise the additional funds to support our continuing operations and maintain current development timelines, and funding may not be available to us on acceptable terms, or at all. Hematide is the main focus of our business, which we expect to be the case for the foreseeable future. Further, we have had to reduce our research capabilities and efforts, including the elimination of certain research programs and even some activities related to support of Hematide. If we are unable to raise additional funds when needed, we could be required to further delay, scale back or eliminate some or all of our development programs and other operations. We may seek to raise additional funds through public or private financing, strategic partnerships or other arrangements. Any additional equity financing may be dilutive to stockholders and debt financing, if available, may involve restrictive covenants. Further, any strategic or licensing arrangements, if available, may require us to relinquish product rights that we would otherwise seek to develop or commercialize ourselves. Our failure to raise capital when needed may harm our business and operating results.

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

- the initiation, progress, timing and completion of preclinical studies and clinical trials for Hematide;
- our ability to maintain and achieve milestones under our collaboration agreements with Takeda;
- costs of litigation;
- outcome, timing and cost of regulatory approvals;

- delays that may be caused by changing regulatory requirements;
- the number of drug candidates that we pursue;
- the costs involved in filing and prosecuting patent applications and enforcing and defending patent claims;
- timing and terms of future in-licensing and out-licensing transactions;
- the cost and timing of establishing sales, marketing and distribution capabilities;

Table of Contents

- cost of procuring clinical and commercial supplies of Hematide and future product candidates, if any; and
- the extent to which we acquire or invest in businesses, products or technologies, although we currently have no commitments or agreements relating to any of these types of transactions.

Recent Accounting Pronouncements

Edgar Filing: AFFYMAX INC - Form 10-Q

For additional information on our recent accounting pronouncements, please refer to the discussion in Recent Accounting Pronouncements under Note 2 of the Notes to Condensed Financial Statements in this Quarterly Report on Form 10-Q and Item 7 of our Annual Report on Form 10-K for the year ended December 31, 2008.

Item 3. Quantitative and Qualitative Disclosure About Market Risk

Interest Rate Risk

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

As of September 30, 2009, we had fair value of ARS totaling \$15.7 million that were comprised of municipal issuances that are collateralized by student loans guaranteed by the U.S. government under the Federal Family Education Loan Program and a closed end preferred issuances. The ARS held by us are rated A through AAA by a major credit rating agency. Based on overall market liquidity concerns, we determined that there was a net decrease in fair value of ARS totaling \$3.4 million through September 30, 2009.

Foreign Exchange Risk

We have no investments denominated in foreign currencies, and therefore our investments are not subject to foreign currency exchange risk. At each quarter end, we may have liabilities for costs incurred by overseas suppliers of goods or services and clinical trial programs that are denominated in foreign currencies that are not hedged because of their relatively small size, uncertainty of payment date, and/or short time until settlement. An increase or decrease in exchange rates on these unhedged exposures may affect our operating results.

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 September 30, 2009. Disclosure controls and procedures are those controls and procedures designed to provide reasonable assurance that the information required to be disclosed in our Exchange Act filings is (1) recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission's rules and forms, and (2) accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of September 30, 2009, our disclosure controls and procedures were effective.

Table of Contents

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 September 30, 2009, that have materially affected, or are reasonably likely to materially affect our ability to record, process, summarize and report financial information.

PART II OTHER INFORMATION

Item 1. Legal Proceedings

J&J Intellectual Property Dispute

Edgar Filing: AFFYMAX INC - Form 10-Q

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

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

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

The Research and Development Agreement with J&J

Edgar Filing: AFFYMAX INC - Form 10-Q

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.

Table of Contents

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

Post-R&D Agreement Development Activities

Edgar Filing: AFFYMAX INC - Form 10-Q

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

Patent Applications Filed During and After the R&D Agreement

Edgar Filing: AFFYMAX INC - Form 10-Q

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.

Table of Contents

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

Litigation and Arbitration Chronology

Edgar Filing: AFFYMAX INC - Form 10-Q

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

On September 23, 2004, we filed a civil complaint in the U.S. District Court for the Northern District of Illinois, or the Illinois case, against J&J alleging claims for correction of inventorship and ownership of the above-referenced patents and patent applications assigned to J&J, for corresponding declaratory and injunctive relief, for breach of contract, and for unjust enrichment and constructive trust. The complaint alleges that the Affymax N.V. scientists are sole or co-inventors of the intellectual property in dispute, including the above-referenced J&J patents and patent applications, and that we are the sole or co-owner of them. The complaint also alleges that J&J breached the R&D Agreement by, among other things, engaging in a course of conduct designed to obtain patents for itself and to deny the Affymax Entities patents on the Affymax scientists' inventions. The complaint further alleges that 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.

Table of Contents

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

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

On April 12, 2006, we filed a demand for arbitration with the AAA claiming that we are the owner or co-owner of the intellectual property in dispute and alleging claims for correction of inventorship and ownership of the above-referenced patents and patent applications assigned to J&J, for corresponding declaratory and injunctive relief, for breach of contract, for unjust enrichment and constructive trust, and for breach of fiduciary duty. On May 8, 2006, J&J filed its answer and counterclaims, substantially restating their allegations made in the U.S. and German courts. In April 2007, we filed an amended demand for arbitration. In June 2007, J&J filed an amended counterdemand. The AAA has appointed a panel of arbitrators, and the arbitration has commenced. The parties have conducted discovery. In June 2007, J&J filed a motion to compel discovery of information relating to Hematide and then filed a substitute motion to compel. In July 2007, we filed an opposition to J&J's motion to compel and a motion for protective order. In September 2007, the arbitrators ruled that J&J could obtain limited discovery on Hematide, but that J&J could not obtain discovery on Hematide product formulas, sequences, laboratory notebooks containing such information, experimental results, clinical trial results and strategies, or internal business planning. The arbitration hearing has commenced and is scheduled to be completed by the end of 2009. A decision is expected in early 2010. The outcome of the matter is uncertain and regardless of outcome, the matter may have an adverse impact on us because of legal costs, diversion of management resources and other factors.

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

Item 1A. Risk Factors

Edgar Filing: AFFYMAX INC - Form 10-Q

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.

Table of Contents

Risks Related to Our Business

We are dependent on the success of Hematide, and we cannot give any assurance that it will receive regulatory approval. Recent safety concerns surrounding the use of ESAs may limit the ability to develop or successfully commercialize Hematide.

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

The FDA, the medical community, and others have recently raised significant safety concerns relating to commercially available ESAs as a result of reports of increased mortality and side effects from a number of clinical trials. These concerns have resulted in a number of negative actions affecting the market for ESAs, particularly in oncology, including the following:

- As a result of concerns associated with administering ESAs to target higher hemoglobin levels, the FDA required revised warnings, including black box warnings, be added to labels of currently marketed ESAs advising physicians to monitor hemoglobin levels and to use the lowest dose of ESA to increase the hemoglobin concentration to the lowest level sufficient to avoid the need for red blood cell transfusions.
- The FDA also issued a public health advisory re-evaluating the safe use of the ESA class and convened its Oncology Drugs Advisory Committee (ODAC) in May 2007 to consider recent information on risks associated with ESAs for use in the treatment of anemia in cancer patients. The ODAC recommended that the FDA institute restrictions on the usage of currently marketed ESAs, including limitations on the treatment of certain types of cancer and the duration of treatment.
- The FDA also convened a joint meeting in September 2007 of the Cardiovascular and Renal Drugs advisory committee and the Drug Safety and Risk Management advisory committee to review the risks and benefits of ESAs.
- The FDA approved revised black box warnings and other safety-related product labeling changes for commercially available ESAs during 2007 and 2008.
- In addition, the FDA convened another ODAC meeting in March 2008 to review data from more recent clinical trials with breast cancer patients and cervical cancer patients using currently marketed ESAs, and to consider additional action. The ODAC recommended the use of informed consents and further restrictions on the use of currently marketed ESAs for the treatment of chemotherapy-induced anemia, including the exclusion of patients with metastatic breast or head and neck cancer as well as those cancer patients potentially receiving curative treatment.
- In July 2008, the FDA announced additional safety-related label restrictions for the use of commercially available ESAs including revisions to the black box warnings to provide that ESAs are not indicated for patients undergoing chemotherapy expected to cure their cancer. In addition, the FDA required new prescribing information to assure that

ESA therapy is not initiated until the hemoglobin level drops below 10 g/dL.

In 2008, these factors and the uncertain regulatory climate resulted in our and Takeda's decision to suspend the development of Hematide to treat chemotherapy-induced anemia, which may have a material adverse effect on our business and future financial results.

Recently, Amgen announced the results of its large, randomized, double-blind, placebo-controlled Phase 3 study of patients with chronic kidney disease (CKD) (not requiring dialysis), anemia and type-2 diabetes (the Trial to Reduce Cardiovascular Endpoints with Aranesp Therapy, or TREAT). In this study, treatment of anemia with Aranesp to a target hemoglobin of 13 g/dL, which is higher than the 10 g/dL - 12 g/dL range approved by the FDA in the current label, reportedly failed to show benefit compared to placebo with regard to composite of time to all-cause mortality or cardiovascular morbidity (including heart failure, heart attack, stroke, or

Table of Contents

hospitalization for myocardial ischemia) and a composite of time to all-cause mortality or chronic renal replacement. In addition, higher rates of stroke were reported amongst patients treated with Aranesp compared to the placebo group. Further, among a subgroup of patients with a history of cancer at baseline, a statistically significant increase in deaths from cancer was observed in the Aranesp treated patients compared to placebo treated patients. However, Aranesp treatment reportedly was associated with a statistically significant reduction in blood transfusions and a modest improvement in patient reported fatigue.

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

The controversy surrounding ESAs and FDA concerns has, and may, further negatively affect patient enrollment and the cost, scope, size, risk, or timing of our clinical trials. These safety concerns may increase the risk of achieving regulatory approval or negatively affect the timing or costs associated with obtaining regulatory approval, including potential risk mitigation activities we may be required to complete either prior to or after product approval. Any of these factors could significantly delay commercialization of Hematide. The market for ESAs has been significantly reduced and to the extent that the medical community's perception of the risks of ESA usage continues to increase, these concerns are likely to further negatively impact the commercial potential of Hematide.

Our clinical development program for Hematide may not lead to a commercial drug either because we fail to demonstrate that it is safe and effective in clinical trials and we therefore fail to obtain necessary approvals from the FDA, and similar foreign regulatory agencies, or because we have inadequate financial or other resources to advance Hematide through the clinical trial process. Any failure to obtain approval of Hematide would have a material and adverse impact on our business as we would have to incur substantial expense and it would take a significant amount of time and resources to bring any future product candidate to market, if ever.

We have incurred significant operating losses since inception and anticipate that we will incur continued losses for the foreseeable future requiring substantial additional financing. If we fail to obtain additional financing, we will be unable to complete the development and commercialization of Hematide and may need to cease operations. Even if we obtain additional financing, we may never achieve or sustain profitability.

We have experienced significant operating losses since our inception in 2001. Currently, we have no products approved for commercial sale and, to date, we have not generated any revenue from product sales. At September 30, 2009, we had an accumulated deficit of \$360.5 million. Our operations have consumed substantial amounts of cash since our inception. We expect to continue to spend substantial amounts in order to:

- complete the Phase 3 clinical trials for the Hematide renal program and other clinical development of Hematide;
- prepare the submission of the New Drug Application, or NDA, for Hematide;

- validate the manufacturing process for Hematide at our contract manufacturers; and
- prepare to launch and commercialize Hematide, including building our own commercial organization, sales force and infrastructure to address renal markets.

We believe that existing cash, cash equivalents and investments and the interest thereon, will enable us to maintain our currently planned operations for at least 12 months. However, we expect that additional capital will need to be raised to complete the development and commercialization of Hematide. The current capital markets have been extremely volatile, and biotechnology companies have been limited or unsuccessful in obtaining funding in this environment. Securing funding has been particularly difficult for companies of our size with limited capital resources. Continuation of this market may significantly limit our ability to raise funds such that there can be no assurance we can raise the additional funds to support our continuing operations and maintain current development and commercialization timelines for Hematide.

Table of Contents

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 will experience dilution. Any debt financing, if available, may involve restrictive covenants, such as limitations on our ability to incur additional indebtedness, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. If we are unable to raise additional funds when required or on acceptable terms, we may have to:

- assume greater risks and significantly delay, scale back, or discontinue the development and/or commercialization of Hematide;
- relinquish greater rights to Hematide;
- eliminate or defer formulation research and development or other manufacturing efforts that may be required to successfully develop or commercially launch Hematide; or
- pursue merger and acquisition alternatives.

We expect to continue to incur substantial additional operating losses for the next several years as we pursue our clinical trials, prepare for the NDA and add infrastructure and operations to support commercialization of Hematide, and potentially begin new research and development programs. Our ability to generate revenue depends heavily on our ability to successfully develop and secure regulatory approval for, and commercially launch, our product candidate, Hematide. If due to lengthy and complicated development, clinical and regulatory requirements or any other reason, we are unable to commercialize Hematide, it will be a long time before we will be able to commercialize any future product candidates, if ever.

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

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

A portion of our investments consists of auction rate securities, or ARS, and the market for those securities has recently failed to provide liquidity, and if such illiquidity continues, may negatively impact our operations. Although we have received ARS rights from UBS AG, we may not be able to recover the value of our ARS under our settlement with UBS AG.

Since mid-March 2008, the overall ARS market has continued to deteriorate and our ARS have failed in all but a single auction. Accordingly, we have recorded a \$3.4 million net reduction of fair value of ARS through September 30, 2009. The decrease in fair value was deemed to be other-than-temporary and we recorded an impairment charge of \$160,000 to other income (expense), net for the three and nine months ended September 30, 2009. As of September 30, 2009, the fair value balance of our ARS totaled \$15.7 million. Our valuation analysis is based on dynamic market conditions and further deterioration in the ARS markets or changes in our assumptions could lead to significant reductions in determined value thus resulting in additional impairments in future periods. We may also be required to sell these investments at prices significantly below par or assessed fair value. There can be no assurance as to the timing of when, or if the market for ARS will recover in a manner that will allow us to receive a return of some or all of our principal or to meet our liquidity needs. If we are unable to liquidate our ARS to obtain funds when needed we may be unable to fund our operations. We have entered into a settlement agreement with UBS AG relating to the failed auctions of our ARS through which UBS AG and its affiliates may provide us with additional funds based on these ARS. However, if we are unable to access the funds underlying or secured by these investments in a timely manner, we may need to find alternate sources of funding for certain of our operations, which may not be available on favorable terms, or at all, and our business could be adversely affected.

Table of Contents

In accepting the settlement offer from UBS AG relating to the failed auctions of our ARS, we agreed to give up certain rights and accept certain risks. Under this settlement, UBS AG issued us ARS Rights. The ARS Rights are not transferable and give us the option to require UBS to repurchase at par our ARS beginning on June 30, 2010, and prior to such date, UBS has the option to buy, at par, the ARS. As part of the settlement, UBS is also making available loans to eligible borrowers, potentially up to 75% of the fair value of the ARS as determined by UBS, which would be secured by the ARS. Currently, we are in the process of applying for such loans from UBS Financial Services, Inc., an affiliate of UBS AG. However, there can be no assurance we will be successful in obtaining advances of funds from UBS or even if obtained, such funds may be required to be repaid by UBS upon demand and therefore unavailable to support our operations if needed.

While we entered into the settlement in expectation that UBS AG will fulfill its obligations in connection with the ARS Rights, UBS AG may not have sufficient financial resources to satisfy these obligations. The U.S. and worldwide financial markets have recently experienced unprecedented volatility, particularly in the financial services sector. While UBS AG has stated that it believes it has the financial resources necessary to perform its obligations under the ARS Rights, UBS AG may not be able to maintain the financial resources necessary to satisfy its obligations with respect to the ARS Rights in a timely manner or at all. The obligations of UBS AG under the ARS Rights are not secured by the assets of UBS AG or otherwise and are not guaranteed by any other entity. UBS AG is not required to obtain any financing to support its obligations. If UBS AG is unable to perform its obligations under the settlement, we may have no source of liquidity or means of obtaining value for our ARS. In addition, UBS AG is a Swiss bank and all or a substantial portion of its assets are located outside the U.S. As a result, it may be difficult for us to serve legal process on UBS AG or its management or have any of them appear in a U.S. court. Judgments based solely on the U.S. securities laws may not be enforceable in Switzerland. As a result, if UBS AG fails to fulfill its obligations, we may not be able to effectively seek recourse against it while the release of claims provided to UBS and its affiliates may still be held to be enforceable.

We have initiated binding arbitration and related litigation with Johnson & Johnson Pharmaceutical Research & Development, L.L.C., and Ortho-McNeil Pharmaceutical, Inc., or collectively, J&J, over ownership of intellectual property related to certain erythropoietin receptor, or EPO-R, agonists. An adverse result in this binding arbitration or litigation, together with adverse results in subsequent litigation J&J 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 certain EPO-R agonists, or the intellectual property in dispute. We believe that we are the sole owner or co-owner of the intellectual property in dispute. J&J, on the other hand, alleges that it is the sole owner or co-owner of the intellectual property in dispute, including several U.S. patents on which we are currently named as sole owner that relate to specified peptide compounds. Although we believe our position in this dispute is meritorious and that we have substantial defenses to J&J's counterclaims, litigation is time consuming and expensive and the outcome is inherently uncertain. A number of outcomes in the dispute 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 patent rights that are deemed to encompass one or more elements of Hematide, that party could initiate proceedings, an adverse result in which could prevent us from manufacturing or commercializing Hematide, either for ourselves or with Takeda, in the U.S.

If the intellectual property in dispute is deemed broad enough to cover Hematide, then under the laws applicable to most relevant jurisdictions outside the U.S., a finding of joint ownership would permit us to manufacture and sell Hematide, but may not allow us to license third parties to

do so. Because our strategy is to commercialize Hematide worldwide through our partnership with Takeda, a finding of joint ownership of the patents

Table of Contents

and applications in question could materially affect our business plans outside the U.S. Within the U.S., joint ownership of a patent gives each joint owner the right to license third parties, so even if the patents in question are held to be jointly owned by us and J&J, we do not believe we would be prevented from pursuing our partnership strategy for Hematide in the U.S. If the arbitration panel determines that J&J is the sole owner of one or more of the U.S. patents in dispute, J&J may seek to assert such patent against us in the U.S.

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

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

Our commercial success depends upon attaining significant market acceptance of Hematide among physicians, patients, health care payors and the major operators of dialysis clinics as well as reaching an agreement with one or more of such major operators of dialysis clinics.

Hematide has not been approved or commercialized for any indication. Even if approved for sale by the appropriate regulatory authorities, physicians may not prescribe Hematide, in which case we would not generate revenue or become profitable. In particular, the therapeutic indications targeted by Hematide have been served by our competitors' products for many years. These products may now be said to be the standard of care, and it may be difficult to encourage healthcare providers to switch from products with which they and their patients have become comfortable.

The dialysis market, which is one of the largest and most established markets that Hematide will attempt to penetrate, is highly concentrated, with two companies serving a significant majority of all dialysis patients on Medicare. In addition, dialysis clinics using ESAs could incur substantial expense in administration and training if they were to switch from current ESAs to Hematide. The concentration of customers for ESAs within the dialysis market may pose a risk to our ability to obtain revenues or favorable margins on Hematide, if approved. If we cannot come to agreements with one or more of the major companies operating dialysis clinics in the U.S. or even if we do, we cannot do so on favorable terms or on a timely basis, the revenue opportunity of Hematide could be significantly reduced. In October 2006, Amgen 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.

Edgar Filing: AFFYMAX INC - Form 10-Q

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

Table of Contents

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

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

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

- the clinical indications for which Hematide is approved;
- acceptance by physicians and patients of Hematide as a safe and effective treatment;
- perceived advantages over alternative treatments;
- the cost of treatment in relation to alternative treatments;
- the availability of adequate reimbursement by third parties;
- the continued use of ESA treatments generally for anemia;
- relative convenience and ease of administration; and
- the prevalence and severity of side effects.

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

We face competition from established and emerging pharmaceutical and biotechnology companies, as well as from academic institutions, government agencies and private and public research institutions. Our commercial opportunity will be reduced or eliminated if our competitors develop and commercialize products that are more effective, have fewer side effects or are less expensive than Hematide or any other future products that we may develop and commercialize. In addition, significant delays in the development of Hematide could allow our competitors to bring new products to market before we do and impair our ability to commercialize Hematide. Competitors may also reduce the price of their ESAs in order to gain market share. These price reductions could force us to lower the price of Hematide in order to compete effectively, resulting in lower revenues and reduced margins on the sales of Hematide.

We anticipate that, if approved, Hematide would compete with EPOGEN and Aranesp, which are both marketed by Amgen, PROCrit, which is marketed by Ortho Biotech Products, L.P. (a subsidiary of J&J), NeoRecormon and Mircera, which are currently marketed outside the U.S. by Roche. Aranesp is approved for once-monthly dosing for treatment of anemia in pre-dialysis patients in Europe. In the U.S., Amgen is reportedly in the process of seeking approval for once-monthly dosing of Aranesp for treatment of anemia in pre-dialysis patients. If Amgen is successful in obtaining approval for once-monthly dosing or our competitors' products are administered in practice on a less frequent basis than prescribed by their labels, the market for Hematide may be decreased. In addition, Roche's Mircera has recently launched in Europe. Mircera reportedly has greater plasma stability and is longer acting than any rEPO product that is currently on the market. As a result of the patent litigation between Roche and Amgen, Mircera has been found to infringe several U.S. patents owned by Amgen and has been enjoined from being sold in the U.S. until the expiration of these patents in 2013. Further proceedings are expected that relate

Table of Contents

to the validity of certain Amgen patents and infringement by Mircera. The outcome of these proceedings could shorten or extend the duration of the injunction. If Mircera enters the U.S. market before Hematide or upon its entry, we believe that Mircera will be in direct competition with Hematide, and therefore could potentially limit the market for Hematide, because of its ability to be longer acting. In addition, Merck recently announced plans to develop its own version of EPO in yeast cells instead of mammalian cells which, if successful, may permit Merck to launch its product prior to the expiration of Amgen's U.S. patents. Another potential competitor, FibroGen, Inc., or FibroGen, is developing small molecules designed to promote the production of greater levels of naturally-occurring EPO in patients. The introduction of biosimilars into the ESA market, or new market entrants, could also prove to be a significant threat to us as it could not only limit the market for Hematide, but could also drive down the price of ESAs.

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

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

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

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

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

As previously disclosed, we notified clinical trial sites to complete treatment of patients on Hematide in the Phase 3 clinical program by the end of 2009 based on estimates of the rate of accrual of cardiovascular events. If our estimate of the event rate ultimately proves to be inaccurate, then we may not accumulate sufficient events for the composite safety endpoint analysis to meet the pre-defined non-inferiority criteria causing a possible failure of our clinical program. Even if the cardiovascular events accrue at the estimated rate, we could still fail to establish that Hematide is non-inferior to the comparator drugs upon analysis of the data from our Phase 3 clinical program. To date, no ESA other than Hematide has been required to achieve this composite safety endpoint for initial regulatory approval. Regardless of whether Hematide is determined to be non-inferior to the comparator drugs upon completion of the composite safety endpoint analysis, Hematide could still fail to

Edgar Filing: AFFYMAX INC - Form 10-Q

establish that it is sufficiently safe for regulatory approval. Further, our Phase 3 clinical program could be suspended or terminated prior to completion based on safety or other concerns, including recommendations of the data monitoring committee, which will be

Table of Contents

meeting periodically to review the interim safety data from our trials. In addition, the completion of clinical trials for Hematide and the submission of our NDA may be delayed or fail for many other reasons, including:

- safety issues, including serious adverse events associated with Hematide, and concerns surrounding use of ESAs generally;
- difficulties of executing our Phase 3 clinical program, for Hematide, which is large and complex, involving numerous third parties, approximately 2,600 patients and 400 sites in the U.S. and Europe, compliance with a variety of government regulations, and a number of significant new initiatives and systems for which we do not have any prior experience implementing, including the adjudication of cardiovascular events by an independent review committee;
- regulators or institutional review boards may not authorize us to continue clinical trials or we may suspend or terminate such trials for various reasons, including recommendations of the data monitoring committee, exposure of the participating patients to unacceptable health risks or noncompliance with regulatory requirements;
- our inability, or the inability of our collaborators or licensees, to manufacture or obtain from third parties materials of a quality or quantity sufficient to complete our preclinical studies, clinical trials or registration stability studies;
- 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;
- risks associated with data integrity and difficulty in obtaining complete and accurate data on a timely basis which may result from our unusual Phase 3 trial design whereby all patients end treatment in each trial in the same timeframe or for a variety of other reasons, including shortage of resources, failure to follow the clinical trial protocols, inadequate monitoring or training of sites, or problems maintaining contact with patients after treatment;
- poor effectiveness or safety concerns during clinical trials;
- the failure of patients to complete clinical trials due to the length of our clinical program, side effects, dissatisfaction with Hematide or other reasons;

- governmental or regulatory delays and changes in regulatory requirements, policy and guidelines; and
- varying interpretation of data by FDA and similar foreign regulatory agencies.

Patients participating in the trials may not live through completion of the trial or may suffer adverse medical effects unrelated to treatment with Hematide. The results from earlier preclinical testing and prior clinical trials may not be predictive of results obtained in other preclinical models, which we are continuing to conduct, or later and larger clinical trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in clinical trials, even in advanced clinical trials after showing promising results in earlier clinical trials. Our failure to adequately demonstrate the safety and effectiveness of Hematide will prevent us from receiving regulatory approval and will have a material adverse impact on our business.

It is possible that Hematide will not complete clinical trials in any markets. We also do not know and are unable to predict whether the data arising from the clinical trials for Hematide will be satisfactory to the FDA and, if not, whether the FDA will require us to conduct additional trials or alter the scope, size or design of such trials, which could result in additional delays in bringing Hematide to market, if ever. Accordingly, we may not receive the regulatory approvals needed to market Hematide. Any failure or delay in completing clinical trials or submitting our NDA to the FDA would delay commercialization of Hematide and severely harm our business and financial condition.

Table of Contents

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

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

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

The success of Hematide is dependent upon the strength and performance of our collaboration with Takeda. If we fail to maintain our existing collaboration with Takeda, such termination would likely have a material adverse effect on our ability to continue to develop Hematide and our business. If we fail to enter into new, strategic collaborations with other future product candidates we pursue, we may have to reduce or delay our product candidate development efforts or increase our expenditures.

The maintenance and successful performance of our strategic collaboration with Takeda for development of Hematide is an important part of our business model. Our collaboration with Takeda is extremely complex particularly with respect to financial provisions, allocations of responsibilities, and the respective rights of the parties with respect to decision making. Accordingly, significant aspects of the development and

commercialization of Hematide require Takeda's agreement or approval prior to implementation, which can cause delays. Further, if we are not able to reach agreement with Takeda or maintain our existing collaboration with Takeda to develop and commercialize Hematide, our business could be severely adversely affected. Takeda has the ability to terminate each of the collaboration agreements upon an uncured material breach by us or even in the absence of a material breach with six-months' notice. Currently, Takeda could provide us notice of termination of either or both of our collaboration agreements, which would likely have a material adverse effect on the advancement of our Hematide program and our business. The suspension of the Hematide oncology program may increase the likelihood that Takeda terminates the collaboration or affect the resources Takeda is willing to commit to Hematide. Through the collaboration, Takeda currently provides development funding and performs important functions, including conduct of certain clinical trials and manufacturing activities, and is expected to pay us milestone payments upon the completion of certain events, all of which would be unavailable to us in the case of an early termination of the collaboration. Even in the absence of a termination, Takeda's failure to provide funding or perform its obligations on a timely basis may have a material adverse effect on our business and the success of Hematide.

In addition, if we fail to maintain the Takeda collaboration or establish and maintain additional strategic collaborations for any other potential product candidates that we may pursue:

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

Table of Contents

- 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.

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

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

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

In addition, in response to the FDA's recent black box warning and public health advisories, CMS has recently significantly restricted coverage of ESAs. In July 2007, CMS issued its National Coverage Decision Memorandum for Use of Erythropoiesis Stimulating Agents in Cancer and Neoplastic Conditions, or the National Coverage Decision, that determined that ESA treatment was not reasonable or necessary for certain medical conditions, including any anemia of cancer not related to cancer treatment, among others. The National Coverage Decision also established the ESA reimbursement policy for Medicare and other government beneficiaries who are treated for chemotherapy-induced anemia

and contains a coverage restriction for hemoglobin levels greater than 10g/dL, which has had a material adverse effect on the use of ESAs. In July 2007, CMS also issued revisions to its reimbursement policies for the use of ESAs for end stage renal disease in cases where hemoglobin levels exceed 13 g/dL and also decreased the monthly dosing limits. In July 2008, CMS announced that ESAs are a potential topic for another National Coverage Decision citing adverse effects in cancer and chronic kidney disease patients, including dialysis patients while noting the large costs but uncertain benefits. In August 2009, CMS announced that a meeting would be held in March 2010 to review the available evidence on the use of ESAs to manage anemia in patients who have chronic kidney disease. Independent of any additional action the FDA may take as to ESAs, CMS may further decrease coverage which could have a materially negative impact on the size of the ESA market in the United States and reduce the overall size of the market Hematide is expected to compete in at the time of launch.

Table of Contents

As a result of these reimbursement and other legislative proposals and the trend towards managed health care in the U.S., third-party payors are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement of new drugs. They may also refuse to provide any coverage of approved products for medical indications other than those for which the FDA has granted market approvals. In addition, major third-party payors have begun to follow CMS's restrictive reimbursement policies, which has further decreased the market for ESAs. As a result, significant uncertainty exists as to whether and how much third-party payors will reimburse patients for their use of newly approved drugs, which in turn will put pressure on the pricing of drugs. We expect to experience pricing pressures in connection with the sale of our products due to the trend toward managed health care, the increasing influence of health maintenance organizations and additional legislative proposals.

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

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

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

CMS currently reimburses healthcare providers for use of ESAs at ASP plus 6%. However, the 2008 Medicare Legislation replaces ASP plus 6% reimbursement with a new bundled payment system to be implemented commencing in January 2011. Although significant aspects of the bundled payment system have yet to be established, providers are expected to be reimbursed a fixed amount per patient. We cannot guarantee that Hematide will be reimbursed by CMS in a method that will support physician adoption and depending upon the details of the bundled payment system that are ultimately implemented, may not be favorable to the entry of new ESAs such as Hematide. In fact, a capitated reimbursement payment methodology may create incentives for significantly lower utilization or dosing of ESAs, including Hematide, and reduce the commercial potential for Hematide.

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

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

Edgar Filing: AFFYMAX INC - Form 10-Q

Although we rely on these third parties to conduct our clinical trials, we are responsible for confirming that each of our clinical trials is conducted in accordance with its general investigational plan and protocol. Moreover, FDA and foreign regulatory agencies require us to comply with regulations and standards, commonly referred to as good clinical practices, for conducting, recording and reporting the results of clinical trials to assure that the data and results are credible and accurate and that the trial participants are adequately protected. Our reliance on third parties does not relieve us of these responsibilities and requirements.

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

Table of Contents

If these third parties do not successfully carry out their duties under their agreements with us, if the quality or accuracy of the data they obtain is compromised due to failure to adhere to our clinical protocols or regulatory requirements, or if they otherwise fail to comply with clinical trial protocols or meet expected deadlines, our clinical trials may not meet regulatory requirements. If our clinical trials do not meet regulatory requirements or if these third parties need to be replaced, our preclinical development activities or clinical trials may be extended, delayed, suspended or terminated. If any of these events occur, we may not be able to obtain regulatory approval of Hematide.

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

The Hematide manufacturing process is a complicated, time-consuming process. Manufacture of Hematide active pharmaceutical ingredient, or API, involves long lead times. We do not currently have the infrastructure or capability internally to manufacture the Hematide needed to conduct our clinical trials or to commercialize Hematide. We are and will continue to rely upon contract manufacturers to produce our clinical trial materials and in the future commercial supplies of Hematide. For the foreseeable future, we expect to continue to rely on contract manufacturers, partners and other third parties to produce sufficient quantities of Hematide for use in our clinical trials. If our contract manufacturers or other third parties fail to deliver materials for the manufacture of Hematide or Hematide itself for clinical use or for our registration stability studies on a timely basis, with sufficient quality and at commercially reasonable prices, and if we fail to find replacement manufacturers or to develop our own manufacturing capabilities, we may be required to delay or suspend clinical trials or our planned NDA filing or otherwise discontinue development and production.

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

- stability or formulation issues including the potential failure of product registration studies to establish sufficient stability to obtain adequate shelf life at refrigerated or room temperature;
- cost overruns, process scale-up, process reproducibility;
- difficulties in maintaining or upgrading equipment and manufacturing facilities on a timely basis; and
- regulatory issues or changes that may cause significant modifications in the manufacturing process or facilities or otherwise impact our ability to offer competitive product presentations or formulations.

Edgar Filing: AFFYMAX INC - Form 10-Q

We have transferred responsibility of manufacture of Hematide finished product to Takeda and we therefore have limited control and ability to address risks associated with that portion of the manufacturing process. Further, some of suppliers and manufacturing arrangements, including the provision of bulk poly(ethylene) glycol reagent for the manufacture of Hematide from Nektar Therapeutics AL, Corporation, or Nektar, are currently single-sourced, leaving us at greater risk of supply interruptions and potential delays.

We, Takeda, and our third-party manufacturers are required to comply with applicable FDA manufacturing practice regulations. If there is any failure by us, Takeda or one of our third-party manufacturers or suppliers to maintain compliance with these regulations, the production of Hematide could be interrupted, resulting in delays and additional costs. Additionally, our third-party manufacturers must pass a pre-approval inspection before we can obtain regulatory approval for Hematide. If for any reason these third parties are unable or unwilling to perform

Table of Contents

under our agreements or enter into new agreements with us, we may not be able to locate alternative manufacturers or enter into favorable agreements with them in an expeditious manner. We could also experience manufacturing delays if our third-party manufacturers, Takeda or suppliers give greater priority to the production of other products over Hematide. Any inability to acquire sufficient quantities of Hematide or components thereof in a timely manner from third parties could delay clinical trials or result in product shortages and prevent us from developing and commercializing Hematide in a cost-effective manner or on a timely basis. Further, our lack of experience providing reliable supply of product may deter health care providers and dialysis centers from selecting or otherwise switching to Hematide from our competitors products.

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

Our dependence on Takeda for our global collaboration with Hematide and our other collaboration arrangements, subjects us to a number of risks. Our ability to develop and commercialize drugs that we develop with our collaboration partners depends on our collaboration partners abilities to establish the safety and efficacy of Hematide, obtain and maintain regulatory approvals and achieve market acceptance of Hematide once commercialized. Under our collaboration with Takeda, we co-develop and co-commercialize Hematide in the U.S. Because we share responsibility with Takeda for clinical development activities in the U.S., the progress of the Hematide program is dependent on the efforts of Takeda of which we have no control. In fact, during 2008, Takeda has taken responsibility for conducting several clinical trials including among others, a study in patients with peritoneal dialysis and a study involving the conversion of Aranesp-treated chronic renal patients (on dialysis and not on dialysis). Accordingly, failure of Takeda to act in a timely manner may delay our ability to develop Hematide in accordance with our timelines. Takeda holds an exclusive license to develop and commercialize Hematide outside of the U.S. and any progress and commercial success in those territories is dependent solely on Takeda's efforts and commitment to the program. Takeda may delay, reduce or terminate development efforts relating to Hematide, independently develop products that compete with Hematide, or fail to commit sufficient resources to the marketing and distribution of Hematide. Competing products or programs, either developed by Takeda or to which our collaboration partners have rights or acquire in the future, may result in our partners' withdrawal of support for Hematide.

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

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

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

Table of Contents

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

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

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

- others may be able to make similar compounds but that are not covered by the claims of our patents, or for which we are not licensed under our license agreements;
- we or our licensors or collaborators might not have been the first to make the inventions covered by our pending patent application or the pending patent applications and issued patents of our licensors;
- we or our licensors or collaborators might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not result in issued patents;
- our issued patents and the issued patents of our licensors or collaborators may not provide us with any competitive advantages, or may be held invalid or unenforceable as a result of legal challenges by third parties;

- we may not develop additional proprietary technologies that are patentable; or
- the patents of others may have an adverse effect on our business.

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

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

Table of Contents

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

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

The failure to obtain adequate patent protection would have a material adverse effect on us and may adversely affect our ability to enter into, or affect the terms of, any arrangement for the further development and marketing of 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 sections entitled Business Intellectual Property and Legal Proceedings. We have incurred substantial expense as a result of our litigation and arbitration proceedings and we expect to incur even greater expense in the future. In addition, any future patent litigation, interference or other administrative proceedings will result in additional expense and distraction of our personnel. An adverse outcome in such litigation or proceedings may expose us or our collaborators to loss of our proprietary position or to significant liabilities, or require us to seek licenses that may not be available from third parties on commercially acceptable terms or at all. In addition, we may be restricted or prevented from manufacturing, developing or commercializing Hematide or from developing, manufacturing and selling any future products in the event of an adverse determination in a judicial or administrative proceeding or if we fail to obtain necessary licenses. If it is determined that we have infringed an issued patent, we could be compelled to pay significant damages, including punitive damages.

Virtually all of our competitors are able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations, in-license technology that we need, out-license our existing technologies or enter into collaborations that would assist in commercially exploiting any technology.

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

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

Table of Contents

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

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

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

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

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

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

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

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

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

Table of Contents

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

Risks Related to Our Industry

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

The research, testing, manufacturing, selling and marketing of drug candidates are subject to extensive regulation by the FDA and other regulatory authorities in the U.S. and other countries, and regulations may differ from country to country. Neither we nor Takeda is permitted to market Hematide in the U.S. until we receive approval of a NDA, from the FDA. We have not received marketing approval for Hematide. Further, we have not previously prepared an NDA submission, which involves compliance with governmental regulations and successful completion of a number of significant and complicated undertakings for which we do not have any prior experience implementing. Obtaining approval of an NDA can be a lengthy, expensive and uncertain process. In addition, failure to comply with FDA and other applicable U.S. and foreign regulatory requirements may subject our company to administrative or judicially imposed sanctions, including warning letters, civil and criminal penalties, injunctions, product seizure or detention, product recalls, total or partial suspension of production and refusal to approve pending NDAs or supplements to approved NDAs.

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

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

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

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

Table of Contents

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

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

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

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

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

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

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

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

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

Table of Contents

- decreased demand for Hematide;
- injury to our reputation;
- withdrawal of clinical trial participants;
- costs of related litigation;
- diversion of management's attention and resources;
- substantial monetary awards to patients;
- product recalls;
- loss of revenue; and
- the inability to commercialize Hematide.

Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of pharmaceutical products we 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

Edgar Filing: AFFYMAX INC - Form 10-Q

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

The trading price of our common stock has been highly volatile. For the 52 weeks ended October 31, 2009, the price ranged between a high of \$25.15 per share and a low of \$8.52 per share. Our stock is expected to be subject to wide fluctuations in price in response to various factors, many of which are beyond our control, including:

- actual or anticipated results from, and any delays in, our clinical trials;
- actual or anticipated changes in our capital resources and our ability to obtain financing and the terms thereof;
- actual or anticipated actions taken by regulatory agencies with respect to ESAs generally or specifically as to Hematide;
- new products or services introduced or announced by us or our collaboration partners, or our competitors, including Roche's Mircera, and the timing of these introductions or announcements;
- issuance of patents to competitors, including the expected issuance of patents to J&J in Europe;
- developments in and the outcome of our litigation with J&J, including both substantive and procedural rulings by the arbitration panel;
- actual or anticipated regulatory approvals of Hematide or competing products;
- actions taken by regulatory agencies with respect to clinical trials, manufacturing process or sales and marketing activities;
- changes in laws or regulations applicable to Hematide, including but not limited to clinical trial requirements for approvals;
- the success of our development efforts and clinical trials;

Table of Contents

- 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; and

- trading volume of our common stock.

In addition, the stock market in general and the market for biotechnology and biopharmaceutical companies in particular have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance. In the past, following periods of volatility in the market, securities class-action litigation 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 March 15, 2009, our executive officers, directors and principal stockholders, together with their respective affiliates, owned approximately 61% of our voting stock. Accordingly, these stockholders will be able to exert a significant degree of influence over our management and affairs and over matters requiring stockholder approval, including the election of our board of directors and approval of significant corporate transactions. This concentration of ownership could have the effect of delaying or preventing a change in our control or otherwise discouraging a potential acquirer from attempting to obtain control of us, which in turn could have a material and adverse effect on the fair market value of our common stock.

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

The Sarbanes-Oxley Act of 2002 requires, among other things, that we maintain effective internal control over financial reporting and disclosure controls and procedures. We have in the past identified material weaknesses in the operation of our internal controls over financial reporting, as defined in Public Company Accounting Oversight Board Standard No. 5. Although we believe these material weaknesses have been fully remediated and none were identified as of December 31, 2008, we cannot assure you that material weaknesses will not be identified in future periods. There can be no assurance that we will successfully and timely report on the effectiveness of our internal control over financial reporting in future periods. If we do experience a material weakness in future periods, then investor confidence, our stock price and our ability to obtain additional financing on favorable terms could be adversely affected.

Table of Contents

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

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

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

We are at risk of securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and biopharmaceutical companies have experienced significant stock price volatility in recent years. If we were to face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

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

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

These provisions include:

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

- prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders;
- eliminating the ability of stockholders to call a special meeting of stockholders;
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings; and
- our board of directors is classified, consisting of three classes of directors with staggered three-year terms, with each class consisting as nearly as possible of one third of the total number of directors.

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

[Table of Contents](#)

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

Unregistered Sales of Equity Securities

Not applicable.

Use of Proceeds from the Sale of Registered Securities

Edgar Filing: AFFYMAX INC - Form 10-Q

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 September 30, 2009, approximately \$80.8 million of aggregate net proceeds from our initial public offering are maintained in investment accounts and we have used the remaining proceeds of approximately \$15.2 million to fund our development of Hematide and other working capital and general corporate purposes, including the expansion of commercial capabilities.

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

Issuer Purchases of Equity Securities

Edgar Filing: AFFYMAX INC - Form 10-Q

The following table provides information relating to repurchases of our common stock in the three months ended September 30, 2009:

Period	Total Number of Shares Purchased	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
July 1, 2009 - July 31, 2009		\$	N/A	N/A
August 1, 2009 - August 31, 2009			N/A	N/A
September 1, 2009 - September 30, 2009			N/A	N/A
Total		\$	N/A	N/A

Item 3. Defaults Upon Senior Securities

Not applicable.

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

Not applicable.

Item 5. Other Information

Not applicable.

Item 6. Exhibits

Edgar Filing: AFFYMAX INC - Form 10-Q

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

- 3.3 Amended and Restated Certificate of Incorporation (1)
- 3.5 Amended and Restated Bylaws (2)
- 4.1 Reference is made to exhibits 3.3 and 3.5
- 4.2 Specimen Common Stock Certificate (1)
- 4.3 Warrant to purchase shares of Series C Preferred Stock (1)
- 4.4 Amended and Restated Investor Rights Agreement, dated September 7, 2006, by and between the Registrant and certain of its stockholders (1)
- 4.5 Form of Warrant to purchase shares of Common Stock (3)

Edgar Filing: AFFYMAX INC - Form 10-Q

Table of Contents

10.29	Common Stock Purchase Agreement, dated as of September 25, 2009, between Affymax, Inc and Azimuth Opportunity Ltd. (4)
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)

Edgar Filing: AFFYMAX INC - Form 10-Q

- (1) Incorporated by reference to the indicated exhibit of our registration statement on Form S-1, as amended, registration no. 333-136125, declared effective by the Securities and Exchange Commission on December 14, 2006.
- (2) Incorporated by reference to the indicated exhibit in our Form 8-K as filed with the Securities and Exchange Commission on September 10, 2007.
- (3) Incorporated by reference to the indicated exhibit in our Form 8-K as filed with the Securities and Exchange Commission on February 19, 2009.
- (4) Previously filed as Exhibit 10.35 of our Current Report on Form 8-K as filed with the Securities and Exchange Commission on September 25, 2009 and incorporated herein by reference.

Table of Contents

SIGNATURES

Edgar Filing: AFFYMAX INC - Form 10-Q

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

AFFYMAX, INC.

Dated: November 3, 2009

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

Dated: November 3, 2009

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

[Table of Contents](#)

EXHIBIT INDEX

Edgar Filing: AFFYMAX INC - Form 10-Q

Exhibit Number	Description
3.3	Amended and Restated Certificate of Incorporation (1)
3.5	Amended and Restated Bylaws (2)
4.1	Reference is made to exhibits 3.3 and 3.5
4.2	Specimen Common Stock Certificate (1)
4.3	Warrant to purchase shares of Series C Preferred Stock (1)
4.4	Amended and Restated Investor Rights Agreement, dated September 7, 2006, by and between the Registrant and certain of its stockholders (1)
4.5	Form of Warrant to purchase shares of Common Stock (3)
10.29	Common Stock Purchase Agreement, dated as of September 25, 2009, between Affymax, Inc and Azimuth Opportunity Ltd. (4)
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)

Edgar Filing: AFFYMAX INC - Form 10-Q

- (1) Incorporated by reference to the indicated exhibit of our registration statement on Form S-1, as amended, registration no. 333-136125, declared effective by the Securities and Exchange Commission on December 14, 2006.
- (2) Incorporated by reference to the indicated exhibit in our Form 8-K as filed with the Securities and Exchange Commission on September 10, 2007.
- (3) Incorporated by reference to the indicated exhibit in our Form 8-K as filed with the Securities and Exchange Commission on February 19, 2009.
- (4) Previously filed as Exhibit 10.35 of our Current Report on Form 8-K as filed with the Securities and Exchange Commission on September 25, 2009 and incorporated herein by reference.