AFFYMAX INC
Form 10-Q
August 08, 2012
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended June 30, 2012

or

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

For the transition period from to

Commission File Number 001-33213

AFFYMAX, INC.

(Exact name of registrant as specified in its charter)

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

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

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

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

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

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

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

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

As of July 31, 2012, 36,191,758 shares of the registrant s common stock, $0.001 par value, were outstanding.

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AFFYMAX, INC

FORM 10-Q FOR THE QUARTER ENDED JUNE 30, 2012

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PART I FINANCIAL INFORMATION

Item 1. Financial Statements

AFFYMAX, INC.

CONDENSED BALANCE SHEETS

(in thousands, except share data)

	June 30, 2012 (Unaudited)	December 31, 2011
Assets		
Current assets		
Cash and cash equivalents	$ 88,734	$ 54,339
Short-term investments	29,342	44,165
Receivable from Takeda	3,230	6,937
Inventory	2,040	
Deferred tax assets	351	351
Prepaid expenses and other current assets	5,332	1,828
Total current assets	129,029	107,620
Property and equipment, net	3,186	3,013
Restricted cash	1,135	1,135
Deferred tax assets, net of current	6,888	6,888
Other assets	3,729	339
Total assets	$ 143,967	$ 118,995
Liabilities and Stockholders Equity		
Current liabilities		
Accounts payable	$ 3,050	$ 941
Accrued liabilities	11,801	13,733
Accrued clinical trial expenses	2,150	3,365
Deposit from Takeda	6,143	1,998
Notes payable, current	1,823	
Total current liabilities	24,967	20,037
Long-term income tax liability	10,479	10,411
Advance from Takeda	10,263	6,121
Deferred revenue	5,174	5,174
Notes payable, net of current	8,177	
Other long-term liabilities	818	1,255
Total liabilities	59,878	42,998
Commitments and contingencies		
Stockholders equity		
Common stock: $0.001 par value, 100,000,000 shares authorized, 36,146,356 and 35,733,181 shares issued and outstanding at June 30, 2012 and December 31, 2011, respectively	36	36
Additional paid-in capital	534,854	526,244
Accumulated deficit	(450,804)	(450,301)

Accumulated other comprehensive income		3		18
Total stockholders equity		84,089		75,997
Total liabilities and stockholders equity	$	143,967	$	118,995

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

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AFFYMAX, INC.

CONDENSED STATEMENTS OF COMPREHENSIVE LOSS

(in thousands, except per share data)

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2012	2011	2012	2011
Revenue:				
Collaboration revenue	$ 2,754	$ 14,146	$ 65,959	$ 30,825
License and royalty revenue	1	5	5	9
Total revenue	2,755	14,151	65,964	30,834
Operating expenses:				
Research and development	12,963	18,594	29,070	36,743
Selling, general and administrative	21,173	8,088	36,755	16,254
Total operating expenses	34,136	26,682	65,825	52,997
Income (loss) from operations	(31,381)	(12,531)	139	(22,163)
Interest income	20	47	33	91
Interest expense	(591)	(37)	(648)	(73)
Other income (expense), net	(4)	2	(26)	36
Net loss before provision for income taxes	(31,956)	(12,519)	(502)	(22,109)
Provision for income taxes			1	1
Net loss	$ (31,956)	$ (12,519)	$ (503)	$ (22,110)
Net loss per share:				
Basic and diluted	$ (0.89)	$ (0.35)	$ (0.01)	$ (0.72)
Weighted-average number of shares used in computing basic and diluted net loss per share	36,075	35,388	35,924	30,896
Total comprehensive loss	$ (31,961)	$ (12,488)	$ (517)	$ (22,071)

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

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AFFYMAX, INC.

CONDENSED STATEMENTS OF CASH FLOWS

(in thousands)

(Unaudited)

	Six Months Ended June 30,	
	2012	**2011**
Cash flows from operating activities		
Net loss	$ (503)	$ (22,110)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	945	1,140
Amortization/accretion of discount/premium on investments	(73)	(35)
Stock-based compensation expense	5,182	5,661
Gain (loss) on disposal of property and equipment	30	(26)
Changes in operating assets and liabilities:		
Receivable from Takeda	3,707	(4,234)
Inventory	(2,040)	
Prepaid expenses and other current assets	(3,290)	9
Other assets	(2,365)	(185)
Accounts payable	2,109	530
Accrued liabilities	(1,932)	(1,573)
Accrued clinical trial expenses	(1,215)	(2,718)
Payable to Takeda		(5,958)
Deferred revenue		(18,496)
Deposit from Takeda	4,145	
Long-term income tax liability	67	91
Advance from Takeda	4,142	
Other long-term liabilities	(437)	114
Net cash provided by (used in) operating activities	8,472	(47,790)
Cash flows from investing activities		
Purchases of property and equipment	(1,018)	(426)
Purchases of investments		(7,915)
Proceeds from maturities of investments	14,882	11,756
Proceeds from sale of property and equipment	25	41
Net cash provided by investing activities	13,889	3,456
Cash flows from financing activities		
Proceeds from issuance of common stock upon exercise of stock options	1,594	359
Proceeds from issuance of common stock under employee stock purchase plan	440	438
Proceeds from common stock issued upon public offering, net of issuance cost		53,629
Proceeds from notes payable	10,000	
Net cash provided by financing activities	12,034	54,426
Net increase in cash and cash equivalents	34,395	10,092
Cash and cash equivalents at beginning of the period	54,339	63,499
Cash and cash equivalents at end of the period	$ 88,734	$ 73,591
Supplemental schedule of non-cash financing activities:		
Warrants issued in connection with notes payable	$ 1,394	$

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

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AFFYMAX, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS

(Unaudited)

1. The Company

Affymax, Inc., a Delaware corporation, was incorporated in July 2001. We are a biopharmaceutical company committed to developing novel drugs to improve the treatment of serious and often life-threatening conditions. In March 2012, the U.S. Food and Drug Administration, or FDA, approved the company s first product, OMONTYS® (peginesatide) Injection for the treatment of anemia due to chronic kidney disease in adult patients on dialysis. OMONTYS is a synthetic, peptide-based erythropoiesis stimulating agent, or ESA, designed to stimulate production of red blood cells and is the only once-monthly ESA for anemia currently available to the adult dialysis patient population in the U.S. We are co-commercializing OMONTYS with our collaboration partner, Takeda Pharmaceutical Company Limited, or Takeda. In February 2012, Takeda and its wholly owned subsidiary, Takeda Global Research & Development Center (Europe) Ltd., announced the acceptance for assessment from the European Medicines Agency, or EMA, of a Marketing Authorization Application, or MAA, for OMONTYS for the treatment of symptomatic anemia associated with chronic kidney disease in adult patients on dialysis. The application is currently under review by that agency.

2. Summary of Significant Accounting Policies

Basis of Presentation

Our accompanying condensed financial statements have been prepared following the requirements of the Securities and Exchange Commission, or SEC, for interim reporting. As permitted under those rules, certain footnotes or other financial information that are normally required by U.S. generally accepted accounting principles, or GAAP, have been condensed or omitted. The condensed financial statements are unaudited and reflect all adjustments, consisting of only normal recurring adjustments, which, in the opinion of management, are necessary to fairly state the financial position at, and the results of operations and cash flows for, the interim periods presented. The financial information included herein should be read in conjunction with our Annual Report on Form 10-K for the year ended December 31, 2011, which includes our audited financial statements and the notes thereto.

Certain amounts in prior period financial statements have been reclassified to conform to the current period presentation. We reclassified $271,000 to accrued liabilities from other long-term liabilities in the December 31, 2011 balance sheet. These reclassifications did not change previously reported net loss, total assets, or stockholders equity.

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

Concentration of Risk and Uncertainties

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 major financial institutions in the U.S. Deposits in these banks may exceed the amount of insurance provided on such deposits. We have not experienced any realized losses on our deposits of cash and cash equivalents.

We have experienced significant operating losses since inception. At June 30, 2012, we had an accumulated deficit of $450.8 million. We have funded our operations to date principally from the sale of equity securities, upfront license fees, milestone payments and reimbursement for development and commercial expenses and manufacturing costs under our two separate collaboration agreements, or, together, the Arrangement, with Takeda, issuance of notes payable, operating and capital lease financing, interest earned on investments and limited license fees and royalties from licensing intellectual property. We may incur substantial additional operating losses in future periods and as a result, we may need to obtain additional financing in order to complete the commercialization of OMONTYS. There can be no assurance that such financing will be available or will be at terms acceptable to us.

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As of June 30, 2012 and December 31, 2011 our accounts receivable balance with Takeda was $3.2 million and $6.9 million, respectively. The receivable is comprised of the amounts due from Takeda for the reimbursement of development and commercial expenses we incurred during the quarter partially offset by amounts due to Takeda for reimbursement of development and commercial expenses they incurred in the same quarter. We have not experienced any credit losses from our Arrangement with Takeda and none are expected. We do not require collateral on our receivable.

OMONTYS is our first and only approved product in the U.S. To achieve profitable operations, we and Takeda must successfully manufacture and commercialize OMONTYS. There can be no assurance that OMONTYS can be manufactured at an acceptable cost and with appropriate performance characteristics on a consistent and reliable basis, or that OMONTYS will be successfully commercialized. These factors could have a material adverse effect on our future financial results.

Further, some of our and Takeda s operations, suppliers and manufacturing arrangements are currently single-sourced, leaving us at greater risk of supply interruptions and potential delays.

Use of Estimates

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

Revenue Recognition

Collaboration Revenue

We recognize revenue in accordance with the SEC Staff Bulletin No. 101, *Revenue Recognition in Financial Statement*s, as amended by Staff Accounting Bulletin or SAB, No. 104, *Revision of Topic 13* and Accounting Standards Codification, or ASC, 605-25, *Multiple Element Arrangements*. When evaluating multiple element arrangements, we consider whether the components of the arrangement represent separate units of accounting as defined in the authoritative guidance for revenue arrangements with multiple deliverables. Application of this guidance requires subjective determinations and requires management to make judgments about the fair value of the individual elements and whether such elements are separable from the other aspects of the contractual relationship. We continue to follow the guidance of ASC 605-25 to determine whether the components of the Arrangement represent separate units of accounting. To determine if a delivered item can be treated as a separate unit of accounting, we evaluate (1) if the delivered item has value to Takeda on a standalone basis; (2) there is objective and reliable evidence of fair value of the undelivered item(s) and (3) if a general right of return exists for the delivered item (eg. contingencies), delivery or performance of the undelivered item(s) is considered probable and is substantially within the control of the company. On January 1, 2011, we adopted Accounting Standards Update, or ASU, No. 2009-13, *Multiple Deliverable Revenue Arrangements*. This update amends the guidance on accounting for arrangements with multiple deliverables to require that each deliverable be evaluated to determine whether it qualifies as a separate unit of accounting. This determination is generally based on whether the deliverable has stand-alone value to the customer. This update also establishes a selling price hierarchy for determining how to allocate arrangement consideration to identified units of accounting. The selling price used for each unit of accounting will be based on vendor-specific objective evidence, or VSOE, if available, third-party evidence if

VSOE is not available, or estimated selling price if neither VSOE nor third-party evidence is available. We may be required to exercise considerable judgment in determining whether a deliverable is a separate unit of accounting and the estimated selling price of identified units of accounting for new agreements.

In June 2011, we moved into the commercialization period as defined under our Arrangement with Takeda. According to the Arrangement, this includes all activities undertaken before and after regulatory approval relating specifically to commercialization services such as pre-marketing, launch, promotions, marketing, sale and distribution of OMONTYS as well as development work that took place after our New Drug Application or NDA was filed with the FDA but before OMONTYS received FDA approval. Prior to approval of OMONTYS and commencement of profit sharing payments, our primary source of revenue during this period has consisted of milestone payments and Takeda s reimbursement of commercialization and development efforts including costs of internal and external activities. On March 27, 2012, we received FDA approval of OMONTYS injection for the treatment of anemia due to chronic kidney disease in adult patients on dialysis, and subsequently launched our product on April 24, 2012, when the product began shipping to wholesalers and distributors.

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In addition to the reimbursement of the services described above, the Arrangement provides us the potential to earn substantive at risk milestone payments upon achievement of contractual criteria and profit sharing payments subsequent to product launch. Upon the successful achievement of clinical development and regulatory milestones, we are eligible to receive from Takeda an additional $20 million related to the June 2006 agreement and $33 million related to the February 2006 agreement (see Note 3 of Notes to Condensed Financial Statements), both of which are related to renal indications. In addition, we are eligible to receive up to $150 million of sales-based milestones based on certain aggregate net sales reached during a fiscal year.

During the commercialization period, our obligations include ongoing regulatory work to obtain and maintain FDA approval and commercial efforts related to our product launch and sales and marketing of OMONTYS once launched. Post-marketing development activities incurred during the commercialization period are related to activities to obtain FDA approval after our NDA was filed, ongoing clinical trial activity on our Phase 3b trial and activities related to commercial readiness in anticipation of FDA approval and product launch. In addition, as mentioned in our approval action letter, the FDA outlined post-marketing requirements which include an observational study and a randomized controlled trial to evaluate cardiovascular safety and assess safety of long-term use in adult patients on dialysis, in particular in the incident patient population. We expect to start these studies in the near term.

For each source of collaboration revenue, we apply the following revenue recognition model:

- Revenues related to reimbursements by Takeda of third-party development expenses (70/30 split per the Arrangement) and commercial expenses (shared equally 50/50 according to the Arrangement) are recognized as revenue, in the period the related costs are incurred. Revenues related to reimbursement of costs of full time equivalents or FTEs engaged in development related activities such as post-marketing studies, are recognized as revenue in the period the related costs are incurred. Such reimbursement is based on contractually negotiated reimbursement rates for each FTE as specified in the Arrangement. Subsequent to the launch of OMONTYS and recognition of product revenue by Takeda, reimbursement of commercial expenses and development costs (both FTE and out of pocket costs) associated with post-marketing development activities, will be incorporated into the profit equalization payment required under the collaboration agreement in order to effect the 50/50 profit split, as described below. As OMONTYS product sales were minimal for the three months ended June 30, 2012, collaboration revenue for this period consisted entirely of expense sharing payments due to us from Takeda.

- Subsequent to the launch of OMONTYS and recognition of product revenue by Takeda, Takeda will be making quarterly profit equalization payments to us in order to effect the 50/50 profit split called for the Arrangement. The profit equalization payment will be calculated as the payment required to ensure that the profit or loss realized by both Affymax and Takeda on the product equates to 50% of the total product profit or loss. Total product profit or loss on OMONTYS will be calculated as gross product sales recorded by Takeda, less the following deductions: rebates and discounts, cost of goods, and other gross-to-net adjustments incurred by Takeda; commercial expenses (FTE related and out of pocket costs) incurred by both Takeda and us, and certain development costs associated with post-marketing development activities (FTE related and out of pocket costs) incurred by us. The profit equalization payment will be recognized as revenue in the period the product sales occur and product revenue is recognized by Takeda and in which the related expenses are incurred. As OMONTYS product sales were minimal for the three months ended June 30, 2012, collaboration revenue for this period consisted entirely of expense sharing payments due to us from Takeda.

- Payments received from Takeda for the shipment of commercial API are recorded as deferred revenue as the earnings process is not complete until either (1) the finished goods produced from each batch of API are sold and utilized for commercial purposes post-approval and charged back to us through the profit sharing each period or (2) the Arrangement has been terminated by Takeda or us.

- Amounts received from Takeda under the launch allowance, which is further described in Note 3 of Notes to Condensed Financial Statements, have been deferred and recorded as a liability under the caption Advance from Takeda as there is no certainty whether those amounts will be recouped by Takeda. The balance will be recognized as revenue as Takeda recoups the amounts paid via reductions in OMONTYS product sales included in the profit sharing each period.

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- We account for milestones under ASU No. 2010-17, *Milestone Method of Revenue Recognition*. Under the milestone method, contingent consideration received from the achievement of a substantive milestone is recognized in its entirety in the period in which the milestone is achieved, which we believe is more consistent with the substance of our performance under the collaboration. A milestone is defined as an event (i) that can only be achieved based in whole or in part on either the entity s performance or on the occurrence of a specific outcome resulting from the entity s performance, (ii) for which there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved, and (iii) that would result in additional payments being due to the entity. A milestone is substantive if the consideration earned from the achievement of the milestone is consistent with our performance required to achieve the milestone or the increase in value to the collaboration resulting from our performance, relates solely to our past performance, and is reasonable relative to all of the other deliverables and payments within the collaboration.

During the development period under the Arrangement with Takeda, which ended upon the submission of our NDA to the FDA for review, collaboration revenue was recognized using the Contingency Adjusted Performance Model or CAPM. As a result, any payments from Takeda under the Arrangement were recorded as deferred revenue and recognized ratably over the estimated development period. Below is a summary of the components of our collaboration revenue for the three months and six months ended June 30, 2012 and 2011 (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2012	2011	2012	2011
Revenue recognized under CAPM	$	$ 9,926	$	$ 26,606
Net expense reimbursement after CAPM	2,754	4,220	7,959	4,219
Milestone payments			58,000	
Total collaboration revenue	$ 2,754	$ 14,146	$ 65,959	$ 30,825

License and Royalty Revenue

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

Inventory

Upon receiving FDA approval of OMONTYS, we commenced capitalization of manufacturing costs related to the manufacturing of API for OMONTYS. Previously, we expensed manufacturing costs related to the production of inventory as research and development or R&D expense in the period incurred. We continue to expense costs associated with clinical trial material as R&D expense.

We value our inventories at the lower of cost or net realizable value. We determine the cost of inventory using the specific identification method on a first-in, first-out basis. We analyze our inventory levels quarterly and write down inventory that has become obsolete or has a cost basis in excess of its expected net realizable value, as well as any inventory quantities in excess of expected requirements. Any expired inventory is disposed of and the related costs are recognized as expense in the statement of comprehensive loss.

Investments

Investments are classified as available-for-sale and are carried at their fair market value based upon quoted market prices for these or similar instruments at the balance sheet date. Unrealized gains and losses are reported as a separate component of stockholders equity until realized. The amortized cost of these securities is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization as well as realized gains and

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

Net Loss Per Common Share

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

The computations for basic and diluted net loss per share were as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2012	2011	2012	2011
Numerator:				
Net loss used in basic and diluted	$ (31,956)	$ (12,519)	$ (503)	$ (22,110)
Denominator for basic and diluted net loss per common share:				
Weighted-average shares outstanding used in basic and diluted net loss per share	36,075	35,388	35,924	30,896
Basic net loss per share	$ (0.89)	$ (0.35)	$ (0.01)	$ (0.72)
Diluted net loss per share	$ (0.89)	$ (0.35)	$ (0.01)	$ (0.72)

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2012	2011	2012	2011
Options to purchase common stock	5,693	4,121	5,693	4,121
Common stock issuable pursuant to the 2006 Employee Stock Purchase Plan	51	39	51	39
Restricted stock units	448	521	448	521
Warrants to purchase common stock	557	426	557	426

New Accounting Standards Recently Adopted

Effective January 1, 2012, we adopted revised guidance related to the presentation of comprehensive income that increases comparability between U.S. GAAP and International Financial Reporting Standards. We have elected to disclose comprehensive income in a single continuous statement during interim reporting periods.

3. Development and Commercialization Agreements with Takeda

We entered into two separate collaboration agreements with Takeda in February 2006 and June 2006, which have been combined for accounting purposes due to their proximity of negotiation. Consideration from these collaboration agreements includes nonrefundable upfront license fees, reimbursement for sales of API, clinical and regulatory milestone payments, reimbursement of third party U.S. clinical development expenses, product profit share revenues (as co-promotion revenues) and royalties. The February 2006 agreement and the June 2006 agreements are collectively referred to herein as the Arrangement.

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Under the February 2006 agreement, we granted an exclusive license to Takeda for development and commercialization of OMONTYS in Japan. In December 2011, Takeda announced that it has decided not to commercialize OMONTYS in Japan. Takeda is conducting a Phase 3 clinical program in Japan for the treatment of patients with anemia associated with chronic kidney disease, which Takeda expects to complete notwithstanding its decision not to commercialize OMONTYS in Japan. In Japan, the majority of Phase 2 and Phase 3 clinical trials are completed. We and Takeda are actively exploring other options for the commercialization rights for OMONTYS in the Japanese market, including potentially licensing it to a third party. Upon Takeda s successful achievement of clinical development and regulatory milestones, we are eligible to receive from Takeda an additional aggregate of $33 million relating to the Japan renal program. Takeda is responsible for all development and commercialization costs in Japan and will purchase the API for OMONTYS from us. Assuming OMONTYS is approved and launched in Japan, we will receive a royalty from Takeda on product sales in Japan.

Under the June 2006 agreement, we expanded our collaboration to develop and commercialize OMONTYS worldwide, which includes the co-development and co-commercialization of OMONTYS in the U.S. Takeda received an exclusive license to develop and commercialize the product outside of the U.S. During the development period of the collaboration, beginning January 1, 2007, Takeda was responsible for the first $50 million of third party expenses related to development in pursuit of U.S. regulatory approval of OMONTYS, which was fully utilized through the first quarter of 2008. Thereafter, Takeda has borne 70% of the third party U.S. development expenses while we have been responsible for 30% of third party expenses. In the first quarter of 2012, we earned a $5 million milestone in February 2012 upon acceptance for review of the MAA filing for OMONTYS by the EMA, and a $50 million milestone in March 2012 upon FDA approval of OMONTYS in the dialysis indication. Upon the successful achievement of as yet unmet clinical development and regulatory milestones, we are eligible to receive from Takeda an additional aggregate of $20 million relating to the renal program. In addition, we are eligible to receive up to $150 million of sales-based milestones based on certain aggregate net sales reached during a fiscal year. We and Takeda will share equally in the net profits and losses of OMONTYS in the U.S., which include certain expenses related to the marketing and launch of OMONTYS and other joint costs related to commercialization. Takeda will record product sales of OMONTYS and will provide us a profit sharing payment each period.

During the commercialization period under the Arrangement, which commenced in June 2011, Takeda bears responsibility for 70% of all third-party expenses related to U.S. development and 50% of all third party expenses related to the commercialization of OMONTYS in the U.S. Certain employee-related expenses supporting preparation for commercialization of OMONTYS in the U.S. are also shared equally. Such employee-related costs include the cost of certain employees that would be required to commercialize OMONTYS such as field sales representatives, sales operations, medical science liaisons, nurse educators, conversion specialists, national accounts managers and reimbursement specialists. In addition, costs of certain employees in clinical, regulatory and other development functions supporting any post-marketing development activities such as additional clinical trials required by the FDA as a condition of the approval of OMONTYS in March 2012 or other activities separately agreed to by the parties in the U.S. are shared equally.

We have also received a launch allowance from Takeda to help fund the initial costs associated with preparing to launch OMONTYS in the U.S. Under the allowance, Takeda funded the first $20 million of U.S. commercial expenses. This launch allowance is non-refundable; however, upon FDA approval of OMONTYS and product profits being earned., Takeda is entitled to deduct up to 8% of net sales from the profit share amounts which would have otherwise been due to us each period until they have recouped an amount equal to $11 million. As a result of the potential reductions in payments from the profit sharing arrangements from the launch allowance, we have reflected amounts we received under the terms of the launch allowance as a liability on our balance sheet. We have fully utilized and received a total of $10.0 million under the launch allowance, which is reflected as Advance from Takeda on our balance sheet. Those amounts paid by Takeda under the launch allowance will ultimately be recaptured by Takeda via reductions in OMONTYS revenues included in the profit sharing payment in future periods. We will recognize previously deferred amounts under the launch allowance as revenue each period in an amount equal to the reduction in our revenues being incurred as a result of Takeda s reductions in OMONTYS revenues included in the profit sharing. As noted above, Takeda books product sales of OMONTYS and will provide us this information as part of the profit sharing payment each period.

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The Arrangement establishes a joint steering committee to oversee the development, regulatory approval and commercialization of OMONTYS. We share responsibility with Takeda for clinical development activities required for U.S. regulatory approval of OMONTYS. Specifically, we have primary responsibility for OMONTYS clinical development plan and clinical trials in the dialysis indication, and the non-dialysis indication to the extent of any further development, while Takeda has primary responsibility in the chemotherapy induced anemia and anemia of cancer indications to the extent any such indication is developed. We are responsible for U.S. regulatory filings in the dialysis and other potential indications, including holding the NDAs for those indications. Takeda is responsible for regulatory filings outside the U.S. and the creation of a global safety database.

Takeda bears all costs for product clinical development in support of regulatory approval for all territories outside the U.S. and will pay us a variable royalty based on annual net sales of the product outside the U.S. In February 2012, Takeda announced the acceptance for assessment from the EMA of a MAA for OMONTYS for the treatment of symptomatic anemia associated with chronic kidney disease in adult patients on dialysis. The application is currently under review by that agency.

Collaboration revenue for the three months and six months ended June 30, 2012 consists of the net reimbursement of development and commercial expenses, and milestone payments. We recognized $2.8 million and $14.1 million of collaboration revenue during the three months ended June 30, 2012, and 2011, respectively and $66.0 million and $30.8 million for the six months ended June 30, 2012 and 2011, respectively.

The amount due from Takeda as of June 30, 2012 and December 31, 2011 was $3.2 million and $6.9 million, respectively. Going forward, we expect collaboration revenue to be directly affected by milestone payments and expenses that are eligible for reimbursement from Takeda under the Arrangement as well as by profit sharing payments resulting from product sales of OMONTYS in future periods.

In November 2011, as contemplated under the Arrangement, we and Takeda executed a Commercial API Supply Agreement which formalizes our respective responsibilities as they relate to the manufacture of OMONTYS API by Affymax and the purchase of that API by Takeda for commercial manufacturing and sales of OMONTYS. We are also responsible for the manufacture and supply of all quantities of API to be used in the development and commercialization of OMONTYS worldwide. Takeda remains responsible for the fill and finish steps in the manufacture of OMONTYS worldwide under the Arrangement. Under the terms of the Commercial API Supply Agreement, Takeda agreed to pay an aggregate of $10.8 million in deposits for commercial API manufactured by us, all of which had been received as of June 30, 2012. In addition, during the six months ended June, 30, 2012, Takeda also paid us another deposit of $0.5 million to be applied to future purchases of commercial API. Through June 30, 2012, we have received $11.3 million and shipped $5.2 million of API that reduced the deposit balance to $6.1 million. The value of the API shipped to Takeda has been recorded as deferred revenue. The remainder of the amount paid by Takeda has been recorded as a liability on our balance sheet.

In November 2011, we entered into a settlement and license agreement, or the Settlement and License Agreement, with Janssen Biotech, Inc. (a subsidiary of Johnson & Johnson), and certain of its affiliated companies, or, collectively, Janssen, under which we obtained a non-exclusive license to the intellectual property in dispute, a covenant not to sue and a release of all claims associated with the arbitration and dispute. The Settlement and License Agreement also provides for the dismissal of all pending proceedings.

In November 2011, concurrent with the execution of the Settlement and License Agreement with Janssen (see Note 4 of Notes to Condensed Financial Statements), we and Takeda entered into an amendment to the Arrangement. Under the terms of this amendment, Takeda has agreed to pay up to $6.5 million in additional milestones to us in consideration of the upfront and milestone payments we are required to make to Janssen under the Settlement and License Agreement. $5.25 million of these milestones are earned based on regulatory and commercial events in the

U.S. and the remaining $1.25 million is tied to regulatory events in the European Union or E.U. We recognized $3.0 million of these milestones in the first quarter of 2012 as it was earned as a result of FDA approval in March 2012. An additional $2.25 million of these milestones was earned in July 2012 as a result of progress on the commercial launch of OMONTYS, and will be recognized in the third quarter of 2012. There are no royalties to Janssen on U.S. sales of OMONTYS, but we are solely responsible for the royalty payment to Janssen on sales of OMONTYS in certain regions outside of the U.S. when it is approved in those regions.

In February 2012, as contemplated under the Arrangement, we and Takeda entered into a Co-Promotion Agreement to further specify and formalize terms and conditions relating to the joint U.S. commercialization activities for OMONTYS including a corporate governance structure and division of roles and responsibilities between us and Takeda, including deployment of resources. We will deploy the sales force and the medical affairs

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field force but share marketing, account management and payer reimbursement related activities with Takeda. In addition, as we and Takeda split profits 50/50 in the U.S., the Co-Promotion Agreement provides further detail relating to the treatment of FTE expenses used to calculate eligible commercial expenses incurred by us and Takeda thereunder. Consistent with the terms of the Arrangement, Takeda retains final decision making authority with respect to terms related to pricing and contracting and responsibility for distribution activities.

4. Settlement and License Agreement with Janssen

In November 2011, we entered into the Settlement and License Agreement with Janssen under which we obtained a non-exclusive license to the intellectual property in dispute, a covenant not to sue and a release of all claims associated with the arbitration and dispute. The Settlement and License Agreement also provides for the dismissal of all pending proceedings. The Settlement and License Agreement requires us to make two fixed payments to Janssen, $6.0 million, which was paid in December 2011, and $2.0 million which was paid in June 2012. Upon execution of the Settlement and License Agreement in the fourth quarter of 2011, we recorded $8.0 million of R&D expense relating to the fixed payments. The Settlement and License Agreement also required us to make a $2.5 million milestone payment to Janssen upon FDA regulatory approval of OMONTYS, and requires us to make a $2.5 million milestone payment to Janssen upon regulatory approval of OMONTYS in the first major European country. Upon FDA approval in March 2012, we capitalized $2.5 million related to the first milestone payment during the first quarter of 2012. The resulting asset will be amortized over the expected life of the related patent family, the last-expiring patent of which expires in June 2016. This $2.5 million milestone payment was paid to Janssen in April 2012.

In addition, Janssen will be entitled to low, single-digit royalties on sales of OMONTYS in Europe, Japan and certain other countries outside of the United States until mid-2016.

5. Investments

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

	As of June 30, 2012				
	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Other-Than Temporary Impairment	Fair Value
Short-term investments:					
Certificates of deposit	$	$	$	$	$
Government agency securities	29,338	4			29,342
Total short-term investments	$ 29,338	$ 4	$	$	$ 29,342

	As of December 31, 2011				
	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Other-Than Temporary Impairment	Fair Value
Short-term investments:					
Certificates of deposit	$ 2,241	$	$	$	$ 2,241
Government agency securities	41,905	23	(4)		41,924

Total short-term investments	$ 44,146	$ 23	(4)	$	$	44,165

The investments mature in August 2012.

6. Fair Value Measurements

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

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

- Level 2 inputs other than quoted prices in active markets that are observable either directly or indirectly through corroboration with observable market data.

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

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

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

	As of June 30, 2012			
		Fair Value Measurements Using		
	Total	Level 1	Level 2	Level 3
Cash equivalents	$ 73,283	$ 72,287	$ 996	$
Short-term investments:				
Certificates of deposit	$	$	$	$
Government securities	29,342		29,342	
Total short-term investments	$ 29,342	$	$ 29,342	$

	As of December 31, 2011			
		Fair Value Measurements Using		
	Total	Level 1	Level 2	Level 3
Cash equivalents	$ 45,244	$ 44,248	$ 996	$
Short-term investments:				
Certificates of deposit	$ 2,241	$	$ 2,241	$
Government securities	41,924		41,924	
Total short-term investments	$ 44,165	$	$ 44,165	$

7. Loan and Security Agreement

In March 2012, we entered into a loan and security agreement, or the Loan Agreement, with Oxford Finance Corporation and Silicon Valley Bank, or, collectively, the Lenders, under which we may borrow up to a total of $30.0 million in two tranches.

The first tranche of $10.0 million was borrowed in March 2012. Subject to our continued compliance with the terms and conditions under the Loan Agreement, the second tranche of $20.0 million will be available for drawdown at our option during the period commencing on the later of (i) October 31, 2012 and (ii) the date our revenues from the sale of OMONTYS in the U.S. reach at least $5.0 million, and ending on the earlier of (i) March 31, 2013 or (ii) the occurrence of an event of default, as defined in the Loan Agreement. The interest rate for each tranche will be fixed upon drawdown of the respective tranche at a per annum rate equal to the greater of 8.95% or 8.57% plus the then effective U.S. Treasury note yield to maturity for a 36 month term determined three (3) business days prior to the funding date of the tranche (but in any event not less than thirty-eight basis points (0.38%)). The interest rate related to the drawdown of the first tranche is 9.11%.

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Payments under the Loan Agreement for the first tranche are interest-only through February 1, 2013, followed by equal monthly payments of principal and interest through the scheduled maturity date on July 1, 2015. If the second tranche is utilized, payments under the Loan Agreement for the second tranche are interest-only from the funding date through the first day of the next calendar month plus an additional 12 months, followed by 30 equal monthly payments of principal and interest. In addition, a final payment equal to 5% of the aggregate amount drawn will be due with the last amortized payment, or such earlier date as specified in the Loan Agreement.

Our obligations under the Loan Agreement are secured by a first priority security interest in substantially all of our assets, other than our intellectual property. We have also agreed not to pledge or otherwise encumber our intellectual property assets, except for permitted licenses, as defined in the Loan Agreement.

We have paid the Lenders a facility fee of $150,000. In addition, if we repay all or a portion of either the first tranche or the second tranche prior to maturity, we will pay the Lenders a prepayment fee, based on a percentage of the then outstanding principal balance, equal to: 5.00% if the prepayment occurs prior to or on the first anniversary of the respective funding date, 4.00% if the prepayment occurs after the first anniversary of the respective funding date but prior to or on the second anniversary of the respective funding date, or 2.00% if the prepayment occurs after the second anniversary of the respective funding date.

The Loan Agreement includes customary affirmative and restrictive covenants, but does not include any covenants to attain or maintain certain financial metrics or thresholds, and also includes customary events of default, including payment defaults; breaches of covenants following any applicable cure period; and a material adverse change which is defined as follows: (a) a material impairment in the perfection or priority of Lenders security interest or in the value of the collateral; (b) a material adverse change in our business, operations or financial condition (or otherwise) or (c) a material impairment of the prospect of repayment of any portion of the loans. Upon the occurrence of an event of default and following any applicable cure periods, a default increase in the interest rate by an additional 500 basis points (5.0%) may be applied to the outstanding loan balances, and the Lenders may declare all outstanding obligations immediately due and payable and take such other actions as set forth in the Loan Agreement.

In connection with the Loan Agreement, we issued the Lenders warrants to purchase 132,855 shares of our common stock, or the Warrants, at an exercise price of $11.855 per share. Each Warrant may be exercised on a cashless basis in whole or in part. The exercise period of the Warrants will terminate on the earlier of seven years from March 26, 2012, the issuance date or the closing of certain merger or consolidation transactions in which the consideration is cash or stock of a publicly traded acquiror, or a combination thereof. Using the Black Scholes valuation model, we estimated the fair value of these warrants to be approximately $1.4 million. These warrants are considered to be costs incurred as part of the loan and have been recorded as an other asset, to be amortized over the term life of Loan Agreement on the effective interest method to interest expense.

8. Restructuring Charge

As a result of the May 2010 amendment to our operating lease, we took possession of approximately 16,000 square feet of additional office space adjacent to our corporate headquarters in Palo Alto, California in May 2011. During the year ended December 31, 2011, management concluded that we would not occupy this additional office space, and we have been actively seeking to sublease this space. Given these plans and the fact that this space is adequately separable from our existing facilities, we recorded total restructuring charges of $869,000 during the year ended December 31, 2011, which represents the present value of the estimated future facility costs for which we will obtain no future economic benefit over the term of our lease, net of estimated future sublease income. The $869,000 charge, as well as $72,000 of accretion was recorded during the year ended December 31, 2011 in selling, general and administrative, or SG&A, expenses in the statement of operations.

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

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In March 2012, we entered into a sublease agreement with a third party to sublease approximately 8,000 of the 16,000 square feet of the available office space. The sublease has a twenty-eight month term that begins on May 1, 2012 and ends on August 31, 2014, which is near the end of our lease term of September 30, 2014. In March, management concluded that the remaining excess office space could not effectively be sub-leased due to the sublease of only a portion of the broader space, prevailing market conditions, and our assessment of the marketability of the remaining space given the size and remaining term. As a result of this determination, and due to other developments in our operations, management elected to reconfigure the remaining space to make it available for use by the Company as needed. As a result, we have reversed a net amount of $336,000 relating solely to the new sublease and the related space during the three months ended March 31, 2012.

In August 2011, we initiated a restructuring plan to lower annual operating expenses that included a planned reduction in force of 22 positions.

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

	Facilities Related	Employee Related	Total
Balance as of December 31, 2011	$ 510	265	$ 775
Restructuring charges accrued	77	6	83
Adjustments	(413)	(62)	(475)
Cash payments	(223)	(209)	(432)
Accretion	13		13
Balance at June 30, 2012	(36)		(36)
Less Current Portion	(15)		(15)
Long-term portion as of June 30, 2012	$ (21)	$	$ (21)

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

9. Stock-Based Compensation

During the quarter ended June 30, 2012, we granted 646,200 stock options with a weighted average grant date fair value of $8.56 per share. The options vest over a four year period. No RSUs were granted during the quarter.

We measure and recognize stock-based compensation expense related to employees and directors under the authoritative guidance for share-based payments.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2012	2011	2012	2011
Research and development	$ 1,207	$ 1,289	$ 2,154	$ 2,643
Selling, general and administrative	1,683	1,386	3,028	3,018
Total	$ 2,890	$ 2,675	$ 5,182	$ 5,661

As of June 30, 2012, unrecognized compensation costs related to employee and director stock options and restricted stock units totaled $22.0 million. The cost is expected to be recognized over a weighted-average amortization period of 2.86 years.

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

You should read the following discussion and analysis by our management of our financial condition and results of operations in conjunction with our audited financial statements and related notes thereto included as part of our Annual Report on Form 10-K for the year ended December 31, 2011 and our unaudited condensed financial statements for the three and six month period ended June 30, 2012.

Forward-Looking Statements

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, which are subject to the safe harbor created by those sections. Forward-looking statements are based on our management s beliefs and assumptions and on information currently available to our management. In some cases, you can identify forward-looking statements by terms such as may, will, should, could, would, expect, intend , plan, anticipate, believe, estimate, project, predict, potential, estimate, future and similar expressions intended to identify forward-looking statements. These forward-looking statements include, but are not limited to, statements regarding the commercialization of OMONTYS® (peginesatide) Injection, or OMONTYS, and the continuation and success of our collaboration with Takeda Pharmaceutical Company Limited, or Takeda. 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 related to the factors affecting the commercial potential of OMONTYS, the continued safety and efficacy of OMONTYS, the timing of patient accrual in ongoing and planned clinical trials, regulatory requirements, including the U.S. Food and Drug Administration s, or FDA s, post-marketing requirements and any additional requirements by the FDA or other regulatory authorities, potential regulatory approval outside the U.S., industry and competitive environment, controversy surrounding the class of erythropoiesis stimulating agents, or ESAs, reimbursement coverage, intellectual property rights and disputes and potential costs, disruptions and consequences of any litigation, financing requirements and ability to access capital, and other matters. Given these risks, uncertainties and other factors, you should not place undue reliance on these forward-looking statements. Also, these forward-looking statements represent our estimates and assumptions only as of the date of this filing. You should read this Quarterly Report on Form 10-Q completely and with the understanding that our actual future results may be materially different from what we expect. We hereby qualify our forward-looking statements by these cautionary statements. Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

Overview

We are a biopharmaceutical company committed to developing novel drugs to improve the treatment of serious and often life-threatening conditions. In March 2012, the FDA approved OMONTYS for the treatment of anemia due to chronic kidney disease in adult patients on dialysis. Anemia is a serious condition in which blood is deficient in red blood cells and hemoglobin. It is common in patients with chronic kidney disease, cancer, heart failure, inflammatory diseases and other critical illnesses, as well as in the elderly. If left untreated, anemia may lead to chronic fatigue or increase the risk of other diseases or death. Currently recombinant EPO, or rEPO, is used to manage the anemia of dialysis, non-dialysis and cancer patients. OMONTYS is a synthetic, peptide-based ESA, designed to stimulate production of red blood cells and is the only once-monthly ESA for anemia available to the adult dialysis patient population in the U.S. We are co-commercializing OMONTYS with our collaboration partner, Takeda. In February 2012, Takeda and its wholly owned subsidiary, Takeda Global Research & Development Center (Europe) Ltd., announced the acceptance for assessment from the European Medicines Agency, or EMA, of a Marketing Authorization Application, or MAA, for OMONTYS for the treatment of symptomatic anemia associated with chronic kidney disease in adult patients on dialysis. The application is currently under review by that agency.

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In February 2012, as contemplated under our collaboration, we and Takeda entered into a Co-Promotion Agreement to further specify and formalize terms and conditions relating to the joint U.S. commercialization activities for OMONTYS including a corporate governance structure and division of roles and responsibilities between us and Takeda, including deployment of resources. We will deploy the sales force and the medical affairs field force but share marketing, account management and payer reimbursement related activities with Takeda. In addition, as we and Takeda split profits 50/50 in the U.S., the Co-Promotion Agreement provides further detail relating to the treatment of full time equivalent, or FTE, expenses used to calculate eligible commercial expenses incurred thereunder. Consistent with the terms of the collaboration, Takeda retains final decision making authority with respect to terms related to pricing and contracting and responsibility for distribution activities.

In February 2012, the MAA filed by Takeda in early 2012 was accepted for review by the EMA, which triggered a $5.0 million milestone payment from Takeda which was received in the first quarter of 2012.

In March 2012, we received FDA approval for OMONTYS injection for the treatment of anemia due to chronic kidney disease in adult patients on dialysis which triggered a $50 million milestone payment from Takeda which was received in April 2012.

In March 2012, we entered into a loan and security agreement, or the Loan Agreement, with Oxford Finance Corporation and Silicon Valley Bank, or, collectively, the Lenders, under which we may borrow up to a total of $30.0 million in two tranches. The first tranche of $10.0 million was borrowed in March 2012. In connection with the Loan Agreement, we issued the Lenders warrants to purchase 132,855 shares of our common stock, or the Warrants, which are exercisable at $11.855 per share.

In November 2011, we entered into a settlement and license agreement, or the Settlement and License Agreement, with Janssen Biotech, Inc. (a subsidiary of Johnson & Johnson), and certain of its affiliated companies, or, collectively, Janssen, under which we obtained from Janssen a non-exclusive license to the intellectual property in dispute, a covenant not to sue and a release of all claims associated with the arbitration and dispute. The Settlement and License Agreement also provides for the dismissal of all pending proceedings.

The Settlement and License Agreement provides for fixed payments by us to Janssen of $6.0 million within 30 days of execution thereof, which was paid in December 2011, and $2.0 million which was paid in June 2012. The Settlement and License Agreement also required us to make a $2.5 million milestone payment to Janssen upon FDA regulatory approval of OMONTYS, and requires us to make a $2.5 million milestone payment to Janssen upon regulatory approval of OMONTYS in the first major European country. In addition, Janssen will also be entitled to low, single-digit royalties on sales of OMONTYS in Europe, Japan and certain other countries outside of the United States until mid-2016. Upon execution of the Settlement and License Agreement in the fourth quarter of 2011, we recorded $8.0 million of research and development, or R&D, expense relating to the fixed payments. Upon FDA approval of OMONTYS in March 2012, we capitalized $2.5 million related to the first milestone payment during the first quarter of 2012. The resulting asset will be amortized over the expected life of the related patent family, the last-expiring patent of which expires in June 2016. This $2.5 million milestone payment to Janssen was paid in April 2012.

Concurrent with the execution of the Settlement and License Agreement, we and Takeda entered into an amendment to our collaboration in connection with the above settlement payments to Janssen. Under the terms of this amendment, Takeda has agreed to pay us up to $6.5 million in additional milestones in consideration of the upfront and milestone payments we are required to make to Janssen under the Settlement and License Agreement. $5.25 million of these milestones are earned based on regulatory and commercial events in the U.S. and the remaining $1.25 million is tied to regulatory events in the European Union or E.U. In March 2012, the FDA approval of OMONTYS triggered a $3.0 million milestone payment under this amendment, which we recognized as revenue in the first quarter of 2012 and received in the second quarter of 2012. In July 2012, an additional $2.25 million milestone was earned as a result of commercial progress on the OMONTYS product launch,

which milestone will be recognized in the third quarter of 2012.

We have experienced significant operating losses since inception. We have funded our operations primarily through the sale of equity securities, reimbursement for development expenses and active pharmaceutical ingredient, or API, production, license fees and milestone payments from collaborative partners, issuance of notes payable, operating and capital lease financings, interest earned on investments and limited license fees and royalties from licensing intellectual property. As of June 30, 2012, we had an accumulated deficit of $450.8 million. Due to the

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recognition of revenues from milestone payments from our collaboration with Takeda, or the Arrangement, we were profitable in the three months ended March 31, 2012 and may have profitable quarters from time to time in the future. However, we may incur substantial losses in future periods depending on how successful we are in commercializing OMONTYS.

We believe that our existing cash, cash equivalents, investments and other sources of available capital, together with the interest thereon will enable us to maintain our currently planned operations for at least the next 12 months. Further challenges or delays to commercialization of OMONTYS may require us to draw down on the remaining $20 million available to us under the Loan Agreement executed in March 2012, or to raise additional funding to successfully commercialize OMONTYS. We have experienced volatility in our stock price, which has impaired our ability to access capital on potentially favorable terms, and we expect to experience volatility in our stock price in the future. Our current view of the worldwide capital markets is that they are extremely volatile with limited accessibility and many biotechnology companies have been limited or unsuccessful in obtaining funding in this environment. 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 our stock price, regardless of our operating performance. In addition, various commercialization factors may further harm our stock price or cause volatility in our stock price, including our inability to achieve market acceptance and generate product sales, to comply with requirements of the FDA or other regulatory authorities and to ensure an efficient and consistent product supply chain.

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. Market conditions 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 successfully commercialize OMONTYS, and funding may not be available to us on acceptable terms, or at all. If we are unable to raise additional funds when needed, we could be required to delay, scale back or eliminate some or all of our operations or delay our efforts to discover or develop any product candidates. 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.

Critical Accounting Policies and Significant Judgments and Estimates

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

Our critical accounting policies and the use of estimates are consistent with those noted in our Annual Report on Form 10-K for the year ended December 31, 2011 except as noted below:

Revenue Recognition

Collaboration Revenue

We recognize revenue in accordance with the Securities and Exchange Commission, or SEC, Staff Bulletin No. 101, *Revenue Recognition in Financial Statement*s, as amended by Staff Accounting Bulletin or SAB, No. 104, *Revision of Topic 13* and Accounting Standards Codification, or ASC, 605-25, *Multiple Element Arrangements*. When evaluating multiple element arrangements, we consider whether the components of the arrangement represent separate units of accounting as defined in the authoritative guidance for revenue arrangements with multiple

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deliverables. Application of this guidance requires subjective determinations and requires management to make judgments about the fair value of the individual elements and whether such elements are separable from the other aspects of the contractual relationship. On January 1, 2011, we adopted Accounting Standards Update, or ASU, No. 2009-13, *Multiple Deliverable Revenue Arrangements*. This update amends the guidance on accounting for arrangements with multiple deliverables to require that each deliverable be evaluated to determine whether it qualifies as a separate unit of accounting. This determination is generally based on whether the deliverable has stand-alone value to the customer. This update also establishes a selling price hierarchy for determining how to allocate arrangement consideration to identified units of accounting. The selling price used for each unit of accounting will be based on vendor-specific objective evidence, or VSOE, if available, third-party evidence if VSOE is not available, or estimated selling price if neither VSOE nor third-party evidence is available. We may be required to exercise considerable judgment in determining whether a deliverable is a separate unit of accounting and the estimated selling price of identified units of accounting for new agreements. During the commercialization phase, we have re-evaluated the deliverables to be performed under the Arrangement to determine if the deliverables can be treated as separate units of accounting. We continue to follow the guidance of ASC 605-25 to determine whether the components of the Arrangement represent separate units of accounting. To determine if a delivered item can be treated as a separate unit of accounting, we evaluate (1) if the delivered item has value to Takeda on a standalone basis; (2) there is objective and reliable evidence of fair value of the undelivered item(s) and (3) if a general right of return exists for the delivered item (eg. contingencies), delivery or performance of the undelivered item(s) is considered probable and is substantially within the control of the company.

In June 2011, we moved into the commercialization period as defined under our Arrangement with Takeda. According to the Arrangement, this includes all activities undertaken before and after regulatory approval relating specifically to commercialization services such as pre-marketing, launch, promotions, marketing, sale and distribution of OMONTYS as well as development work that took place after our NDA was filed with the FDA but before OMONTYS received FDA approval. Prior to approval of OMONTYS and commencement of profit sharing payments, our primary source of revenue in the commercialization period has consisted of milestone payments and Takeda s reimbursement of pre-commercialization and development efforts including costs of internal and external activities. On March 27, 2012, we received FDA approval of OMONTYS injection for the treatment of anemia due to chronic kidney disease in adult patients on dialysis, and subsequently launched our product on April 24, 2012 when the product began shipping to wholesalers and distributors.

In addition to the reimbursement of the services described above, the Arrangement provides us the potential to earn substantive at risk milestone payments upon achievement of contractual criteria and profit sharing payments subsequent to product launch. Upon the successful achievement of clinical development and regulatory milestones, we are eligible to receive from Takeda an additional $20 million related to the June 2006 agreement and $33 million related to the February 2006 agreement (see Note 3 of Notes to Condensed Financial Statements), both of which are related to renal indications. In addition, we are eligible to receive up to $150 million of sales-based milestones based on certain aggregate net sales reached during a fiscal year.

During the commercialization period, our obligations include ongoing regulatory work to obtain and maintain FDA approval and commercial efforts related to our product launch and sales and marketing of OMONTYS once launched. Post-marketing development activities incurred during the commercialization period are related to activities to obtain and maintain FDA approval after our NDA was filed, ongoing clinical trial activity on our Phase 3b trial, and activities related to commercial readiness in anticipation of FDA approval and product launch. In addition, as mentioned in our approval action letter, the FDA outlined post-marketing requirements which include an observational study and a randomized controlled trial to evaluate cardiovascular safety and assess safety of long-term use in adult patients on dialysis, in particular in the incident patient population. We expect to start these studies in the near term.

For each source of collaboration revenue, we apply the following revenue recognition model:

- Revenues related to reimbursements by Takeda of third-party development expenses (70/30 split per the Arrangement) and commercial expenses (shared equally 50/50 according to the Arrangement) are recognized as revenue, in the period the related costs are incurred. Revenues related to reimbursement of costs of full time equivalents or FTEs engaged in development related activities such as post-marketing studies, are recognized as revenue in the period the related costs are incurred. Such reimbursement is based on contractually negotiated reimbursement rates for each FTE as specified in

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the Arrangement. Subsequent to the launch of OMONTYS and recognition of product revenue by Takeda, reimbursement of commercial expenses and development costs (both FTE and out of pocket costs) associated with post-marketing development activities, will be incorporated into the profit equalization payment required under the collaboration agreement in order to effect the 50/50 profit split, as described below. As OMONTYS product sales were minimal for the three months ended June 30, 2012, collaboration revenue for this period consisted entirely of expense sharing payments due to us from Takeda.

- Subsequent to the launch of OMONTYS, Takeda will be making quarterly profit equalization payments to us in order to effect the 50/50 profit split called for the Arrangement. The profit equalization payment will be calculated as the payment required to ensure that the profit or loss realized by both Affymax and Takeda on the product equates to 50% of the total product profit or loss. Total product profit or loss on OMONTYS will be calculated as gross product sales recorded by Takeda, less the following deductions: rebates and discounts, cost of goods and other gross-to-net adjustments incurred by Takeda; commercial expenses (FTE related and out of pocket costs) incurred by both Takeda and us, and certain development costs associated with post-marketing development activities (FTE related and out of pocket costs) incurred by us. The profit equalization payment will be recognized as revenue in the period the product sales occur and product revenue is recognized by Takeda and in which the related expenses are incurred. As OMONTYS product sales were minimal for the three months ended June 30, 2012, collaboration revenue for this period consisted entirely of expense sharing payments due to us from Takeda.

- Payments received from Takeda for the shipment of commercial API are recorded as deferred revenue as the earnings process is not complete until either (1) the finished goods produced from each batch of API are sold and utilized for commercial purposes post-approval and charged back to us through the profit sharing each period or (2) the Arrangement has been terminated by Takeda or us.

- Amounts received from Takeda under the launch allowance, which is further described in Note 3 of Notes to Condensed Financial Statements, have been deferred and recorded as a liability under the caption Advance from Takeda as there is no certainty whether those amounts will be recouped by Takeda. The balance will be recognized as revenue as Takeda recoups the amounts paid via reductions in OMONTYS product sales included in the profit sharing each period.

- We account for milestones under ASU No. 2010-17, *Milestone Method of Revenue Recognition*. Under the milestone method, contingent consideration received from the achievement of a substantive milestone is recognized in its entirety in the period in which the milestone is achieved, which we believe is more consistent with the substance of our performance under the collaboration. A milestone is defined as an event (i) that can only be achieved based in whole or in part on either the entity s performance or on the occurrence of a specific outcome resulting from the entity s performance, (ii) for which there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved, and (iii) that would result in additional payments being due to the entity. A milestone is substantive if the consideration earned from the achievement of the milestone is consistent with our performance required to achieve the milestone or the increase in value to the collaboration resulting from our performance, relates solely to our past performance, and is reasonable relative to all of the other deliverables and payments within the collaboration.

Inventory

Upon receiving FDA approval of OMONTYS, we commenced capitalization of manufacturing costs related to the manufacturing of API for OMONTYS. Previously, we expensed manufacturing costs related to the production of inventory as R&D expense in the period incurred. We continue to expense costs associated with clinical trial material as R&D expense.

We value our inventories at the lower of cost or net realizable value. We determine the cost of inventory using the specific identification method on a first-in, first-out basis. We analyze our inventory levels quarterly and write down inventory that has become obsolete or has a cost basis in excess of its expected net realizable value, as well as any inventory quantities in excess of expected requirements. Any expired inventory is disposed of and the related costs are recognized as expense in the statement of comprehensive loss.

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Restructuring Charges

As a result of the May 2010 amendment to our operating lease, we took possession of approximately 16,000 square feet of additional office space adjacent to our corporate headquarters in Palo Alto, California in May 2011. During the year ended December 31, 2011, management concluded that we would not occupy this additional office space, and we have been actively seeking to sublease this space. Given these plans and the fact that this space is adequately separable from our existing facilities, we recorded total restructuring charges of $869,000 during the year ended December 31, 2011, which represents the present value of the estimated future facility costs for which we will obtain no future economic benefit over the term of our lease, net of estimated future sublease income. The $869,000 charge, as well as $72,000 of accretion was recorded during the year ended December 31, 2011 in selling, general and administrative, or SG&A, expenses in the statement of operations.

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

In March 2012, we entered into a sublease agreement with a third party to sublease approximately 8,000 of the 16,000 square feet of the available office space. The sublease has a twenty-eight month term that begins on May 1, 2012 and ends on August 31, 2014 which is near the end of our lease term of September 30, 2014. In March, management concluded that the remaining excess office space could not effectively be sub-leased due to the sublease of only a portion of the broader space, prevailing market conditions, and our assessment of the marketability of the remaining space given the size and remaining term. As a result of this determination, and due to other developments in our operations, management elected to reconfigure the remaining space to make it available for use by the Company as needed. As a result, we have reversed a net amount of $336,000 relating solely to the new sublease and the related space during the three months ended March 31, 2012.

In August 2011, we initiated a restructuring plan to lower annual operating expenses that included a planned reduction in force of 22 positions.

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

	Facilities Related	Employee Related	Total
Balance as of December 31, 2011	$ 510	265	$ 775
Restructuring charges accrued	77	6	83
Adjustments	(413)	(62)	(475)
Cash payments	(223)	(209)	(432)
Accretion	13		13
Balance at June 30, 2012	(36)		(36)
Less Current Portion	(15)		(15)
Long-term portion as of June 30, 2012	$ (21)	$	$ (21)

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Results of Operations

Revenue

	Three Months Ended June 30,			Six Months Ended June 30,		
	2012	2011	% Increase/ (Decrease)	2012	2011	% Increase/ (Decrease)
	($ amounts in thousands)					
Collaboration revenue	$ 2,754	$ 14,146	(81)%	$ 65,959	$ 30,825	114%
License and royalty revenue	1	5	(80)%	5	9	(44)%
Total revenue	$ 2,755	$ 14,151	(81)%	$ 65,964	$ 30,834	114%

We recognized $2.8 million and $14.1 million of collaboration revenue during the three months ended June 30, 2012 and 2011, respectively and $66.0 million and $30.8 million for the six months ended June 30, 2012 and 2011, respectively. The decrease in collaboration revenue for the three months ended June 30, 2012 compared to the three months ended June 30, 2011 was primarily due to significant reductions in R&D expenses reimbursable by the company s partner, Takeda. The increase in collaboration revenue for the six months ended June 30, 2012 compared to the six months ended June 30, 2011 was primarily due to the recognition of $58 million in milestones from Takeda related to FDA approval of OMONTYS and the EMA s acceptance for review of the MAA filed by Takeda partially offset by a decrease in amounts eligible for reimbursement under our collaboration agreement with Takeda. We expect collaboration revenue to be directly affected by milestone payments, profit sharing payments and expenses that are eligible for reimbursement from Takeda under the Arrangement in future periods.

To date, collaboration revenue has consisted of net reimbursement of development and commercial expenses, and milestone payments. Subsequent to the launch of OMONTYS and recognition of product revenue by Takeda, collaboration revenue will consist of a profit equalization payment received from Takeda, net reimbursements of development expenses and milestone payments. As OMONTYS product sales were minimal for the three months ended June 30, 2012, collaboration revenue for this period consisted entirely of expense sharing payments due to us from Takeda. In subsequent periods, as OMONTYS product sales increase, we expect that the quarterly profit equalization payments due to us from Takeda to effect the 50/50 profit split called for in the Arrangement, will become our primary source of revenue.

During the development period under the Arrangement with Takeda, which ended upon the submission of our NDA to the FDA for review, collaboration revenue was recognized using the Contingency Adjusted Performance Model or CAPM. As a result, any payments from Takeda under the Arrangement were recorded as deferred revenue and recognized ratably over the estimated development period. Below is a summary of the components of our collaboration revenue for the three months and six months ended June 30, 2012 and 2011 (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2012	2011	2012	2011
Revenue recognized under CAPM	$	$ 9,926	$	$ 26,606
Net expense reimbursement after CAPM	2,754	4,220	7,959	4,219
Milestone payments			58,000	
Total collaboration revenue	$ 2,754	$ 14,146	$ 65,959	$ 30,825

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Operating expenses incurred by us which have been subject to reimbursement by Takeda under the Arrangement, excluding API manufacturing costs were as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2012	2011	2012	2011
Research & development	$ 1,114	$ 6,254	$ 7,554	$ 10,843
Selling, general & administrative	10,847	1,560	17,399	3,494
Total	$ 11,961	$ 7,814	$ 24,953	$ 14,337

Research and Development Expenses

	Three Months Ended June 30,			Six Months Ended June 30,		
	2012	2011	% Increase/ (Decrease)	2012	2011	% Increase/ (Decrease)
	($ amounts in thousands)					
Research and development expenses	$ 12,963	$ 18,594	(30)%	$ 29,070	$ 36,743	(21)%

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

The decrease in research and development expenses for the three and six months ended June 30, 2012 compared to the three and six months ended June 30, 2011 was primarily due to reduced consulting costs as a result of the completion of our filing of our NDA in May 2011 and reduced personnel related costs related to the reduction in force implemented in the third quarter of 2011. This was partially offset by ongoing clinical trial activity on our Phase 3b trial, and a Phase 2 study in Pure Red Cell Aplasia, or PRCA patients.

Selling, General and Administrative Expenses

	Three Months Ended June 30,			Six Months Ended June 30,		
	2012	2011	% Increase/ (Decrease)	2012	2011	% Increase/ (Decrease)
	($ amounts in thousands)					
Selling, general and administrative expenses	$ 21,173	$ 8,088	162%	$ 36,755	$ 16,254	126%

Selling, general and administrative, or SG&A, expenses consist principally of salaries and related costs for personnel in executive, finance, accounting, business development, commercial operations, information technology, legal and human resources functions. Other SG&A expenses include facility costs not otherwise included in R&D expense, patent filing, prosecution and defense costs and professional fees for legal, consulting, auditing and tax services.

The increase in selling, general and administrative expenses for the three and six months ended June 30, 2012 compared to the three and six months ended June 30, 2011 was primarily due to higher commercial expenses related to expansion of our commercial capabilities, including the establishment of a field sales force and other activities to support our commercialization efforts. In addition, as a result of our FDA approval, we also expensed a one-time milestone payment of $2.0 million to be made to Nektar Therapeutics AL Corporation during the three months ended March 31, 2012.

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Interest Income (Expense), Net

	Three Months Ended June 30,			Six Months Ended June 30,		
	2012	2011	% Increase/ (Decrease)	2012	2011	% Increase/ (Decrease)
	($ amounts in thousands)					
Interest income (expense), net	$ (571)	$ 10	(5810)%	$ (615)	$ 18	(3517)%

The decrease in interest income (expense), net, was due primarily to interest expense related to our notes payable with the Lenders and our launch allowance with Takeda and lower interest rates and lower average cash balance during the three and six months ended June 30, 2012 compared to the same period in 2011.

Other Income (Expense), Net

	Three Months Ended June 30,			Six Months Ended June 30,		
	2012	2011	% Increase/ (Decrease)	2012	2011	% Increase/ (Decrease)
	($ amounts in thousands)					
Other income (expense), net	$ (4)	$ 2	(300)%	$ (26)	$ 36	(172)%

Other expense, net, for the six months ended June 30, 2012 includes a $30,000 loss on disposal of fixed assets. Other income, net, for the six months ended June 30, 2011 includes a $26,000 gain on disposal of fixed assets.

Provision for Income Taxes

	Three Months Ended June 30,			Six Months Ended June 30,		
	2012	2011	% Increase/ (Decrease)	2012	2011	% Increase/ (Decrease)
	($ amounts in thousands)					
Provision for income taxes	$	$	%	$ 1	$ 1	Calculation not meaningful

We are subject to federal and state income taxes. While we did generate net income during the first quarter of 2012 due to significant milestone payments received in the period, we anticipate being in a net operating loss position for 2012 and therefore have not recorded any federal or state taxes, other than the minimum statutory California tax, for the six months ended June 30, 2012. We also did not record any tax liability for the six months ended June 30, 2011 other than the minimum statutory California tax due to the anticipated tax loss position for the year ended December 31, 2011.

Liquidity and Capital Resources

Our cash, cash equivalents, and investments at June 30, 2012 and December 31, 2011 were as follows (in thousands):

	June 30, 2012	December 31, 2011
Cash and cash equivalents	$ 88,734	$ 54,339
Short-term investments	29,342	44,165

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, issuance of notes payable, operating and capital lease financing, interest earned on investments and limited license fees and royalties from licensing intellectual property. From inception through June 30, 2012, we have received net proceeds of $447.4 million from the issuance of equity securities, including $53.6 million in net proceeds from the sale of 9,745,762 shares of our common stock in a secondary public offering in March 2011.

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In March 2012, we entered into the Loan Agreement, with the Lenders, under which we may borrow up to a total of $30.0 million in two tranches. The first tranche of $10.0 million was borrowed in March 2012. Subject to our continued compliance with the terms and conditions under the Loan Agreement, the second tranche of $20.0 million will be available for drawdown at our option during the period commencing on the later of (i) October 31, 2012 and (ii) the date our revenues from the sale of OMONTYS in the U.S. reach at least $5.0 million, and ending on the earlier of (i) March 31, 2013 or (ii) the occurrence of an event of default, as defined in the Loan Agreement. The interest rate for each tranche will be fixed upon drawdown of the respective tranche at a per annum rate equal to the greater of 8.95% or 8.57% plus the then effective U.S. Treasury note yield to maturity for a 36 month term determined three (3) business days prior to the funding date of the tranche (but in any event not less than thirty-eight basis points (0.38%)). The interest rate related to the drawdown of the first tranche is 9.11%. Payments under the Loan Agreement for the first tranche are interest-only through February 1, 2013, followed by equal monthly payments of principal and interest through the scheduled maturity date on July 1, 2015. If the second tranche is utilized, payments under the Loan Agreement for the second tranche are interest-only from the funding date through the first day of the next calendar month plus an additional 12 months, followed by 30 equal monthly payments of principal and interest. In addition, a final payment equal to 5% of the aggregate amount drawn will be due with the last amortized payment, or such earlier date as specified in the Loan Agreement.

We have also received $122 million of upfront license fees, $113 million in milestone payments and $264.0 million for the reimbursement of development and commercial expenses and purchase of API under our Arrangement with Takeda. In the first quarter of 2012, we earned a $5 million milestone in February 2012 upon acceptance of the MAA filing for OMONTYS by the EMA, and a $50 million milestone in March 2012 upon FDA approval of OMONTYS in the dialysis indication. Upon the successful achievement of as yet unmet clinical development and regulatory milestones, we are eligible to receive from Takeda an additional aggregate of $20 million related to the June 2006 agreement and $33 million related to the February 2006 agreement, both of which are related to the renal program. In addition, we are eligible to receive up to $150 million of sales-based milestones based on certain aggregate net sales reached during a fiscal year. We and Takeda will share equally in the net profits and losses of OMONTYS in the U.S., which include certain expenses related to the marketing and launch of OMONTYS and other joint costs related to commercialization. Takeda controls the sales of OMONTYS and will provide us a profit sharing payment each period. As product sales were minimal for the three months ended June 30, 2012, collaboration revenue for this period consisted entirely of expense sharing payments due us from Takeda.

During the commercialization period under the Arrangement, which commenced in June 2011, Takeda bears responsibility for 70% of all third-party expenses related to U.S. development and 50% of all third party expenses related to the commercialization of OMONTYS in the U.S. Certain employee-related expenses supporting preparation for commercialization of OMONTYS in the U.S. are also shared equally. Such employee-related costs include the cost of certain employees that would be required to commercialize OMONTYS such as field sales representatives, sales operations, medical science liaisons, nurse educators, conversion specialists, national accounts managers and reimbursement specialists. In addition, costs of certain employees in clinical, regulatory and other development functions supporting any post-marketing development activities such as additional clinical trials required by the FDA as a condition of the approval of OMONTYS in March 2012 or other activities separately agreed to by the parties in the U.S. are shared equally.

We have also received a launch allowance from Takeda to help fund the initial costs associated with preparing to launch OMONTYS in the U.S. Under the allowance, Takeda funded the first $20 million of U.S. commercial expenses. This launch allowance is non-refundable; however, upon FDA approval of OMONTYS and product profits being earned, Takeda is entitled to deduct up to 8% of net sales from the profit share amounts which would have otherwise been due to us each period until they have recouped an amount equal to $11 million. As a result of the potential reductions in payments from the profit sharing arrangements from the launch allowance, we have reflected amounts received under the terms of the launch allowance as a deferred liability under the caption Advance from Takeda on our balance sheet. We will recognize the amount as collaboration revenue proportionate to the deductions that Takeda will take from product sales in recouping the balance. We have fully utilized and received the $10.0 million allowable under the launch allowance.

In February 2012, the MAA filed by Takeda in early 2012 was accepted for review by the EMA, which triggered a $5.0 million milestone payment from Takeda which was received in the first quarter of 2012.

In March 2012, we received FDA approval for OMONTYS which triggered a $50 million milestone payment from Takeda which we received in the second quarter of 2012.

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In November 2011, as contemplated under the Arrangement, we and Takeda executed a Commercial API Supply Agreement which formalizes our respective responsibilities as they relate to the manufacture of OMONTYS API by Affymax and the purchase of that API by Takeda for commercial manufacturing and sales of OMONTYS. We are also responsible for the manufacture and supply of all quantities of API to be used in the development and commercialization of OMONTYS worldwide. Takeda remains responsible for the fill and finish steps in the manufacture of OMONTYS worldwide under the Arrangement. Under the terms of the Commercial API Supply Agreement, Takeda agreed to pay an aggregate of $10.8 million in deposits for commercial API manufactured by us, all of which had been received as of June 30, 2012. In addition, during the six months ended June, 30, 2012, Takeda also paid us another deposit of $0.5 million to be applied to future purchases of commercial API. Through June 30, 2012, we have received $11.3 million and shipped $5.2 million of API against the prepayments, leaving a remaining prepaid balance of $6.1 million as of June 30, 2012. The value of the API shipped to Takeda has been recorded as deferred revenue. The remainder of the amount paid by Takeda has been recorded as a liability on our balance sheet.

In November 2011, we entered into the Settlement and License Agreement with Janssen, which requires us to make two fixed payments to Janssen of $6.0 million, which was paid in December 2011, and $2.0 million which was paid in June 2012. The Settlement and License Agreement required us to make a $2.5 million milestone payment to Janssen upon FDA regulatory approval of OMONTYS, and requires us to make a $2.5 million milestone payment to Janssen upon regulatory approval of OMONTYS in the first major European country. In addition, Janssen will be entitled to royalties on sales of OMONTYS in Europe, Japan and certain other countries outside of the United States until mid-2016. Upon execution of the Settlement and License Agreement in the fourth quarter of 2011, we recorded $8.0 million of R&D, expense relating to the fixed payments. Upon FDA approval of OMONTYS in March 2012, we capitalized $2.5 million related to the first milestone payment during the first quarter of 2012. The resulting asset will be amortized over the expected life of the related patent family, the last-expiring patent of which expires in June 2016. This $2.5 million milestone payment to Janssen was paid in April 2012.

Concurrent with the execution of the Settlement and License Agreement, we and Takeda entered into an amendment to the Arrangement. Under the terms of this amendment, Takeda has agreed to pay up to $6.5 million in additional milestones to us in consideration of the upfront and milestone payments we are required to make to Janssen under the Settlement and License Agreement (see Note 4 of Notes to Condensed Financial Statements). $5.25 million of these milestones are earned based on regulatory and commercial events in the U.S. and the remaining $1.25 million is tied to regulatory events in the E.U. As of June 30, 2012, $3.0 million of these milestones had been earned as a result of FDA approval of OMONTYS, which we received payment in the second quarter of 2012. In July 2012, we earned an additional $2.25 million milestone as a result of commercial progress on the OMONTYS product launch, which will be recognized as revenue in the third quarter of 2012. There are no royalties to Janssen on U.S. sales of OMONTYS, but we are solely responsible for the royalty payment to Janssen on sales of OMONTYS in certain regions outside the U.S. when it is approved in those regions.

In February 2012, as contemplated under the Arrangement, we and Takeda entered into a Co-Promotion Agreement to further specify and formalize terms and conditions relating to the joint U.S. commercialization activities for OMONTYS including a corporate governance structure and division of roles and responsibilities between us and Takeda, including deployment of resources. We will deploy the sales force and the medical affairs field force but share marketing, account management and payer reimbursement related activities with Takeda. In addition, as we and Takeda split profits 50/50 in the U.S., the Co-Promotion Agreement provides further detail relating to the treatment of FTE expenses used to calculate eligible commercial expenses incurred by us and Takeda thereunder. Consistent with the terms of the Arrangement, Takeda retains final decision making authority with respect to terms related to pricing and contracting and responsibility for distribution activities.

Net cash provided by operating activities for the six months ended June 30, 2012 was primarily due to an increase in our Advance from Takeda related to our launch allowance, an increase in our Deposit from Takeda related to future API purchases, and noncash expenses associated with depreciation and stock compensation expense. These were partially offset by changes in other assets related to OMONTYS intellectual property rights and payments made to third party vendors related to the manufacturing of our API, accrued clinical trials and accrued liabilities. Net cash used in operating activities for the six months ended June 30, 2011 was primarily the result of our net loss generated primarily by the development of OMONTYS and payments to Takeda related to our outstanding payable as well as payments to third party vendors related to our accrued clinical trial expenses and accrued liabilities. The impact of this loss was reduced in part by non-cash activities including stock-based

compensation and depreciation.

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Net cash provided by investing activities for the six months ended June 30, 2012 was primarily due to maturities of investments. Net cash provided by investing activities for the six months ended June 30, 2011 was primarily a result of maturities of investments offset by purchases of investments.

Net cash provided by financing activities for the six months ended June 30, 2012 was primarily attributable to proceeds of $10.0 million received from the issuance of a notes payable and $2.0 million received from the issuance of common stock upon exercise of stock options and our employee stock purchase plan. Net cash provided by financing activities for the six months ended June 30, 2011 was primarily attributable to net proceeds of $53.6 million received from our March 2011 public offering and proceeds received from the issuance of common stock upon exercise of stock options and our employee stock purchase plan.

In September 2009 we obtained an equity line of credit arrangement, with Azimuth Opportunity, Ltd, or 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. In September 2010, we entered into an amendment, or the Amendment, to the Purchase Agreement with Azimuth which extends the term of the equity facility to September 2012 and reduces the minimum threshold price we may establish at which, upon presentation to Azimuth of a draw down notice, Azimuth is required to purchase shares of our common stock. The Amendment further provides that 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 of common stock on the effective date of the Amendment. We do not plan to extend this facility when it expires in September 2012.

Our equity facility is subject to a number of conditions that limit our ability to draw against such facility. For example, Azimuth is not required to purchase our common stock when the price of our common stock is below $4.00 per share. In addition, Azimuth is not obligated to purchase shares of our common stock which, when aggregated with all other shares of our common stock then owned beneficially by Azimuth, would result in the beneficial ownership by Azimuth of more than 9.9% of the then issued and outstanding shares of our common stock. At June 30, 2012, this represents 3,578,489 shares. After deducting 999,061 shares purchased by Azimuth in October 2010, assuming that all remaining 2,579,428 shares were sold at the $12.88 closing price of our common stock at June 30, 2012 at the largest possible discount and assuming that Azimuth still owns these shares, the maximum aggregate net proceeds we could receive under the agreement with Azimuth would be approximately $31.0 million.

As of June 30, 2012, we had $119.2 million in cash, cash equivalents, restricted cash and investments. Our cash and investment balances are held in a variety of interest bearing instruments, including obligations of U.S. government agencies, certificates of deposit, and money market funds. Cash in excess of immediate requirements is invested in accordance with our investment policy primarily with a view to liquidity and capital preservation.

We believe that our existing cash, cash equivalents, investments and other sources of available capital together with the interest thereon will enable us to maintain our currently planned operations for at least the next 12 months. Further challenges to successfully commercialize OMONTYS may require us to draw down on the remaining $20 million available to us under the Loan Agreement executed in March 2012, or to raise additional funding to complete the commercialization of OMONTYS. We have experienced volatility in our stock price, which has impaired our ability to access capital on potentially favorable terms, and we expect to experience volatility in our stock price in the future. Our current view of the worldwide capital markets is that they are extremely volatile with limited accessibility and many biotechnology companies have been limited or unsuccessful in obtaining funding in this environment. 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 our stock price, regardless of our operating performance. In addition, various commercialization factors may further harm our stock price or cause volatility in our stock price, including our inability to achieve market acceptance and generate product sales, to comply with requirements of the FDA or

other regulatory authorities and to ensure an efficient and consistent product supply chain.

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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. Market conditions 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 successfully commercialize OMONTYS, and funding may not be available to us on acceptable terms, or at all. If we are unable to raise additional funds when needed, we could be required to delay, scale back or eliminate some or all of our operations or delay our efforts to discover or develop any product candidates. We may seek to raise additional funds through public or private financing, strategic partnerships or other arrangements. Any additional equity financing would be dilutive to stockholders and debt financing, if available, may involve restrictive covenants. Further, any strategic or licensing arrangements, if available, may require us to relinquish product rights that we would otherwise seek to develop or commercialize ourselves. Our failure to raise capital when needed may harm our business and operating results.

Our future capital requirements will depend on many forward-looking factors, and we expect to continue to spend substantial amounts in order to:

- commercialize OMONTYS, including building our own commercial organization, sales force and infrastructure to address renal markets;
- prepare for the manufacturing process for OMONTYS at our contract manufacturers;
- complete the post-marketing requirements established by the FDA.

Contractual Obligations and Significant Commitments

Our future contractual obligations, including financing costs, at June 30, 2012, were as follows (in thousands):

		Payments Due by Period			
Contractual Obligations	**Total**	**Less Than 1 Year**	**1-3 Years**	**3-5 Years**	**More than 5 Years**
Operating lease obligations (1)	$ 9,567	$ 2,094	$ 7,473	$	$
Notes payable (2)	10,000		7,814	2,186	
Long-term income tax liability (3)	10,479				
Total fixed contractual obligations	$ 30,046	$ 2,094	$ 15,287	$ 2,186	$

(1) Relates primarily to minimum lease payments for lease of our facilities, consisting of approximately 113,000 square feet which expire in September 2014.

(2) Relates to Loan Agreement with the Lenders.

(3) With respect to our long-term income tax liability as of June 30, 2012, we are unable to make a reasonably reliable estimate of the period of cash settlement, if any, with the respective taxing authorities.

Item 3. Quantitative and Qualitative Disclosure About Market Risk

Interest Rate Risk

Our exposure to market risk is confined to our cash, cash equivalents and investments. We do not use derivative financial instruments in our investment portfolio. The goals of our investment policy are preservation of capital, fulfillment of liquidity needs and fiduciary control of cash and investments. We also seek to maximize income from our investments without assuming significant risk. To achieve our goals, we maintain a portfolio of cash equivalents and investments in a variety of securities of high credit quality. The securities in our investment portfolio are not leveraged, are classified as available for sale and are subject to minimal interest rate risk. We currently do not hedge interest rate exposure. We do not believe that a decrease in interest rates would have a material negative impact on the value of our investment portfolio. During the three and six months ended June 30, 2012, there were no material changes to our interest rate disclosures as set forth in Part II, Item 7A, *Quantitative and Qualitative Disclosure About Market Risk*, of our Annual Report on Form 10-K for the year ended December 31, 2011.

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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. An evaluation was performed by our Chief Executive Officer and Chief Financial Officer of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act as of June 30, 2012. Disclosure controls and procedures are those controls and procedures designed to provide reasonable assurance that the information required to be disclosed in our Exchange Act filings is (1) recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission s rules and forms, and (2) accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of June 30, 2012, our disclosure controls and procedures were effective at the reasonable assurance level.

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

Changes in Internal Control over Financial Reporting. Our management, including our Chief Executive Officer and Chief Financial Officer, has evaluated any changes in our internal control over financial reporting that occurred during the quarter ended June 30, 2012, and has concluded that there were no changes during such quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. We completed the implementation of a new Enterprise Resource Planning system during the second quarter of 2012. This implementation was not undertaken in response to any identified deficiency or weakness to our internal controls over financial reporting. It was undertaken to establish a scalable foundation for our core business processes.

PART II OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we are involved in legal proceedings arising in the ordinary course of business. We believe there is no 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

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

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Risks Related to Our Business

Our success will depend on our ability to effectively and profitably commercialize OMONTYS® (peginesatide) Injection, or OMONTYS, our only product.

Our success will depend on our ability to effectively and profitably commercialize OMONTYS, our only product, which was approved by the U.S. Food and Drug Administration, or FDA, in March 2012 for the treatment of anemia due to chronic kidney disease in adult patients on dialysis, which will include our ability to:

- create market demand for OMONTYS through our education, marketing and sales activities, as well as through our co-promotion agreement with Takeda Pharmaceutical Company Limited, or Takeda, including our ability to establish or demonstrate the safety of OMONTYS;

- build, train, support and maintain a qualified commercial and medical affairs organization and field force;

- achieve market acceptance and generate product sales through Takeda s execution of agreements with the major operators of dialysis clinics on commercially reasonable terms;

- support the efforts of dialysis clinics to safely and effectively administer OMONTYS to dialysis patients on a different treatment plan than for the other approved erythropoiesis stimulating agents, or ESAs;

- receive adequate levels of reimbursement from third-party payors, including government healthcare programs such as Medicare and Medicaid and private insurance programs;

- comply with the post-marketing requirements established by the FDA, including the Risk Evaluation and Mitigation Strategy, or REMS, and any other requirements established by the FDA in the future;

- comply with other healthcare regulatory requirements;

- ensure that the Active Pharmaceutical Ingredient, or API, for OMONTYS and the finished product are manufactured in sufficient quantities and in compliance with requirements of the FDA and similar foreign regulatory agencies and with an acceptable quality and pricing level in order to meet commercial demand; and

- ensure that the entire supply chain for OMONTYS from API to finished product efficiently and consistently delivers OMONTYS to our customers.

If we are unable to successfully commercialize OMONTYS, then we will not be able to generate product sales, which will have a material adverse impact on our business and our prospects.

If we are unable to build effective commercial, medical affairs and distribution capabilities, or enter into agreements with third parties to perform these functions, then we will be unable to commercialize OMONTYS successfully.

Prior to the launch of our first product OMONTYS in the second quarter of 2012, we had no experience commercializing a pharmaceutical product. To commercialize OMONTYS successfully, we must further develop internal sales, marketing, medical affairs, contracting, reimbursement, and distribution capabilities, or make arrangements with third parties to perform some or all of these services. We market OMONTYS directly with Takeda, and we must commit significant time and financial and managerial resources to build, train, support and maintain a commercial and medical affairs force with technical and market expertise and distribution support capabilities for our principal customer, dialysis clinics. Factors that may inhibit our efforts to build, train, support and maintain an effective commercial and medical affairs organization with Takeda include:

- our inability to recruit, hire, train, support and maintain adequate numbers of effective commercial and medical affairs personnel;

- the inability of our sales personnel to obtain access to adequate numbers of physicians who would prescribe OMONTYS;

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- the inability of our sales and medical affairs personnel, who have no prior experience with our company or OMONTYS, to deliver a consistent and appropriate message regarding the product and to provide appropriate information and education to physicians and other healthcare providers regarding the product and its proper administration;

- 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;

- our inability to effectively manage the substantial growth of our company, including the significant increase in our number of full-time employees in a matter of months and the introduction and implementation of a variety of new systems and processes; and

- unforeseen costs and expenses associated with creating and sustaining independent commercial and medical affairs organizations and coordinating our efforts with Takeda.

If we, or Takeda through our collaboration, are not successful in building, training, supporting and maintaining a commercial and medical affairs organization, then we will have difficulty commercializing OMONTYS, which would adversely affect our business and financial condition. If we are unable to successfully address these responsibilities ourselves, then we may need to identify third-party providers to support these efforts, which may lead to delays and additional costs as well as potential confusion to our customers. To the extent that we enter into additional 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.

Our commercial success depends upon attaining significant market acceptance of OMONTYS among physicians, patients, health care payors, and the major operators of dialysis clinics, and upon reaching a long-term agreement with either or both of the largest operators of dialysis clinics.

Until the approval of OMONTYS, only EPOGEN and Aranesp, the ESAs of our competitor Amgen, Inc., or Amgen, have been used for the treatment of anemia due to chronic kidney disease in adult patients on dialysis in the U.S. This dialysis market, which OMONTYS will attempt to penetrate, is highly established and concentrated, with EPOGEN and Aranesp serving a significant majority of all dialysis patients on Medicare. These two products are the current standard of care, and it may be difficult to encourage healthcare providers to consider OMONTYS as an alternative to these products with which they and their patients have a longstanding relationship. Physicians, who make the ultimate decision to prescribe a product, may not prescribe OMONTYS, in which case our ability to sell the product would be adversely impacted. Similarly, dialysis clinics using EPOGEN or Aranesp could incur substantial expense in administration and training if they were to convert to OMONTYS. Finally, healthcare providers may not receive adequate levels of reimbursement for OMONTYS from third-party payors, including government healthcare programs such as Medicare and Medicaid and private insurance programs. Some or all of these factors may hinder our efforts to attain significant market acceptance of OMONTYS, which would pose a risk to our ability to obtain revenues or favorable margins for the product.

Even if we are able to achieve market acceptance of OMONTYS, if we are unable to reach a long-term supply agreement with either or both of the largest operators of dialysis clinics in the U.S, DaVita Inc. and Fresenius Medical Care North America, or DaVita and Fresenius,

respectively, on favorable terms or on a timely basis, then the revenue opportunity for OMONTYS could be significantly reduced. We may not be able to reach a long-term supply agreement with either DaVita or Fresenius because both entered into a long-term supply agreement with Amgen that began in January 2012. In particular, DaVita entered into a seven-year agreement with Amgen whereby Amgen would supply EPOGEN to meet at least 90% of DaVita s requirements for ESAs used in providing dialysis services in the U.S., and Fresenius entered into a multi-year agreement with Amgen whereby Amgen would supply EPOGEN on a non-exclusive basis to Fresenius. The specific terms of the Amgen-DaVita agreement and the Amgen-Fresenius agreement have not been publicly disclosed, and we cannot predict how these agreements may impact the commercial opportunity for OMONTYS. But these agreements may limit the market opportunity for the product and adversely impact our ability to generate product sales.

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In July 2012, Fresenius entered into an agreement with Takeda Pharmaceuticals America, Inc., or TPA, a subsidiary of Takeda, whereby TPA will supply OMONTYS to Fresenius through the end of April 2013 for use in certain U.S. dialysis clinics within its organization. Fresenius is not obligated to utilize OMONTYS under the terms of this agreement, and we cannot be certain that Fresenius will utilize a significant quantity, or any quantity, of the product on a long-term basis. Further, we cannot predict how Fresenius will evaluate its initial commercial experience with OMONTYS even if it utilizes the product. Fresenius initial commercial experience with OMONTYS may be affected by many factors including, but not limited to, healthcare provider and patient satisfaction with the product, ease of conversion and other operational considerations, competitive pricing and reimbursement. We cannot predict whether Fresenius initial commercial experience with OMONTYS will lead to a long-term supply agreement, and even if Fresenius enters into such an agreement, the terms of the agreement may not be favorable to us. Our failure to attain significant market acceptance of OMONTYS and enter into a long-term supply agreement with DaVita or Fresenius on a timely basis would have a material adverse effect on our business.

The market opportunity for OMONTYS may be significantly reduced as a result of the increasing concerns surrounding the safety of ESAs as a class, and as a result of any negative perception of the safety of OMONTYS relative to other ESAs.

In recent years, safety concerns have significantly reduced the market opportunity for ESAs as a class, which may significantly reduce the market opportunity for OMONTYS. For example:

- In March 2007, as a result of concerns associated with administering ESAs to target higher hemoglobin levels, the FDA required that revised warnings, including boxed warnings, be added to the 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.

- In late 2009, Amgen announced the results from the Trial to Reduce Cardiovascular Endpoints with Aranesp Therapy, or TREAT, its large, randomized, double-blind, placebo-controlled Phase 3 study of patients with chronic kidney disease (not requiring dialysis), anemia and type-2 diabetes. In this study, Aranesp was used to treat anemia to a target hemoglobin of 13 g/dL, which was higher than the 10 g/dL 12 g/dL range previously approved by the FDA in the label. Study results reportedly failed to show benefit compared to the control group with regard to composite of time to all-cause mortality or cardiovascular morbidity (including heart failure, heart attack, stroke, or hospitalization for myocardial ischemia) and a composite of time to all-cause mortality or chronic renal replacement. In addition, higher rates of stroke were reported among patients treated with Aranesp compared to the control group. Finally, 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.

- In January 2010, FDA officials published an editorial in the New England Journal of Medicine noting that a number of randomized trials, including TREAT, had attempted to show that using ESAs to raise hemoglobin concentrations to higher targets improves clinical outcomes but rather suggested the opposite. Accordingly, the article indicated that more conservative hemoglobin targets (well below 12 g/dL), more frequent hemoglobin monitoring, and more cautious dosing, should be evaluated.

- In February 2010, the FDA announced that ESAs must be prescribed and used under a REMS to ensure the safe use of the drugs. As part of the REMS, a medication guide explaining the risks and benefits of ESAs must be provided to all patients receiving ESAs for all indications, and the manufacturer has reporting and monitoring obligations to ensure compliance.

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

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The increasing controversy surrounding ESAs, the TREAT results and recent and future FDA actions represent additional challenges to the market for ESAs as a class and increase the uncertainty associated with the successful commercialization of OMONTYS. We cannot predict what additional actions, if any, the FDA may take, which may include additional label restrictions, the use of informed consents, further lowering or removal of target hemoglobin levels, or even the removal of indications from the label. Further, regardless of whether or not the FDA takes additional action, the Centers for Medicare and Medicaid Services, or CMS, and other third-party payors may still decide separately to discontinue or limit coverage or lower reimbursement as CMS has recently adopted changes and continues to evaluate coverage and reimbursement policy for ESAs as class.

In addition, any negative perception of the safety of OMONTYS relative to other ESAs as a result of our Phase 3 clinical results could significantly reduce the market opportunity for our product. Specifically, in June 2010, we announced preliminary top-line results from the OMONTYS Phase 3 clinical program for the treatment of patients with anemia associated with chronic kidney disease. Our Phase 3 clinical program included four open-label, randomized controlled clinical trials: PEARL 1 and PEARL 2 conducted in non-dialysis patients and EMERALD 1 and EMERALD 2 conducted in dialysis patients. Analysis of efficacy and safety for all of the Phase 3 trials were based primarily on assessments of non-inferiority to the comparator drugs. While OMONTYS met the statistical criterion for non-inferiority for the assessment of safety for the cardiovascular composite safety endpoint, or CSE, which was composed of death, stroke, myocardial infarction, congestive heart failure, unstable angina and arrhythmia from a pooled safety database across the four Phase 3 trials, some differences were observed when secondary analyses were conducted, including a difference in a subgroup analysis conducted in the PEARL trials where the frequency of CSE events was higher in the OMONTYS group relative to the comparator in non-dialysis patients. Any negative perception of OMONTYS safety relative to other ESAs as a result of the differences observed in the Phase 3 secondary analyses could significantly limit the market opportunity for the product.

Finally, any negative perception of the safety of OMONTYS relative to other ESAs as a result of any new medical data or product quality issues that suggest new risks or side effects, or increase concern over previously identified risks or side effects, could reduce the market opportunity for the product.

Coverage and reimbursement may not be available for OMONTYS, or may not be available to a sufficient extent, which would materially diminish our ability to successfully commercialize the product.

Market acceptance and sales of OMONTYS will depend on reimbursement policies and may be affected by future health care reform measures. Government agencies and other third-party payors decide which drugs they will cover and establish reimbursement levels. We cannot be sure that reimbursement will be available for OMONTYS by all payors, or that future reimbursement amounts or policies will not reduce the access to, or demand for, the product. In addition, we continue to seek coverage and reimbursement from third-party payors for OMONTYS. Despite receiving a product-specific Q-code from CMS that became effective in July 2012, we cannot be sure that reimbursement from third-party payors will be available or processed in a timely manner. If reimbursement is not available, or is not available in a timely manner, then it will have a negative impact on our ability to commercialize the product.

CMS, the government agency that manages Medicare and is responsible for coverage and reimbursement of OMONTYS for Medicare beneficiaries, has significantly restricted coverage of ESAs in response to the FDA s boxed warning and public health advisories, including coverage for non-dialysis indications. 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 due to cancer not related to cancer treatment, among others. The National Coverage Decision also established the ESA reimbursement policy for Medicare and other government beneficiaries who are treated for chemotherapy-induced anemia and contains a coverage restriction for hemoglobin levels greater than 10g/dL, which has had a material adverse effect on the use of ESAs. In July 2007, CMS also issued revisions to its reimbursement policies for the use of ESAs for end-stage renal

disease in cases where hemoglobin levels exceed 13 g/dL and also decreased the monthly dosing limits. In July 2008, CMS announced that ESAs are a potential topic for another National Coverage Decision citing adverse effects in cancer and chronic kidney disease patients, including dialysis patients, while noting the large costs but uncertain benefits. In March 2010, CMS convened a Medicare Evidence Development & Coverage Advisory Committee meeting to review the available evidence on the use of ESAs to manage anemia in patients who have chronic kidney disease, and in January 2011 to review the role of ESAs in successful kidney transplantation. In November 2011, pursuant to

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the FDA label changes, CMS through rulemaking, modified its performance incentive program for dialysis providers by removing a performance measure focused on maintaining hemoglobin level above 10g/dL in dialysis patients, which created incentives for lower overall ESA utilization. Independent of any additional action the FDA may take as to ESAs, CMS may further decrease coverage, reimbursement or create disincentives which could have a materially negative impact on the size of the ESA market in the U.S. and reduce the overall size of the market in which OMONTYS competes.

As the costs of the Medicare program continue to grow, CMS may also 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 a share of the Medicare budget, ESAs, including OMONTYS, 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 safety concerns relating to ESAs, CMS has implemented policies limiting coverage of ESAs in the past and may consider further changes that could negatively affect coverage or reimbursement of ESAs in the future. Further, prior to January 1, 2011, CMS reimbursed healthcare providers for use of ESAs at average selling price plus 6%. However, under the 2008 Medicare Legislation a new bundled payment system commenced in January 2011 for facilities that furnish renal dialysis services to Medicare beneficiaries with end-stage renal disease. Under the new bundled payment system, providers are expected to be reimbursed a fixed amount per patient, including for ESAs such as OMONTYS. This new capitated reimbursement payment methodology has created incentives for significantly lower utilization or dosing of ESAs, including OMONTYS, and has reduced the commercial potential for the product.

Finally, as a result of CMS coverage and reimbursement changes, third-party payors are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement of new drugs. Third-party payors have begun to follow CMS 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 ESAs like OMONTYS, which in turn will put pressure on the pricing and utilization of the product. We expect to experience pricing pressures in connection with the sale of OMONTYS due to the trend toward managed health care and the adoption of government coverage and reimbursement policies.

The FDA approved OMONTYS subject to certain post-marketing requirements, which could significantly increase costs or delay or limit our ability to successfully commercialize the product.

The FDA approved OMONTYS subject to certain post-marketing requirements. First, we are required to conduct an observational study and a randomized controlled trial to be completed with final reports submitted in 2018 and 2019, respectively, to evaluate cardiovascular safety and assess safety of long-term use in adult patients on dialysis. Second, we are required to initiate pediatric studies with target dates for completion between 2016 and 2027. Third, we are required to comply with a REMS, which includes a requirement to send Dear Healthcare Provider letters to nephrology healthcare providers informing them that OMONTYS is not indicated in patients with chronic kidney disease not on dialysis. These post-marketing requirements, and any other post-marketing requirements the FDA may require, will result in additional costs to the company and could significantly delay, limit, or prevent, successful commercialization of OMONTYS or otherwise severely harm our business and financial condition.

In addition, obtaining and maintaining regulatory approval has been, and will continue to be, increasingly difficult. If we are unable to fulfill the requirements of regulatory authorities or our post-marketing requirements or to the extent there are unfavorable results or data arising therefrom, then there may be limitations imposed on our product label or we may be required to withdraw the product from the market.

We have relied on numerous third parties to conduct and complete our development program for OMONTYS, and we will continue to rely on third parties to maintain approval of the product.

Due to the size and limited experience of our organization, we have relied heavily on third parties to assist us in managing, monitoring and otherwise conducting our clinical trials. Even though we have completed our Phase 3 clinical program and OMONTYS was approved by the FDA, we will continue to require the assistance of third parties in the future, particularly with respect to completing our post-marketing requirements. For example, FDA and foreign regulatory agencies require us to comply with regulations and standards, commonly referred to as good

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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 in connection with conducting our post-marketing trials does not relieve us of these responsibilities and requirements, and regulatory authorities may find remediation efforts by us or such third parties insufficient. In addition, we have had significant difficulties obtaining necessary and quality third-party assistance. We continue to compete with larger and other companies for the attention and assistance of these third parties. If we are unsuccessful in obtaining the needed assistance on acceptable terms, we will have difficulty commercializing OMONTYS and completing our post-marketing requirements.

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

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

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 OMONTYS, our commercial opportunity will be reduced or eliminated.

We face competition from established pharmaceutical and biotechnology companies, in particular companies that have an approved ESA on the market. 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 OMONTYS or any other future products we may develop and commercialize. 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 OMONTYS in order to compete effectively, resulting in lower revenues and reduced margins on the sales of OMONTYS.

We anticipate that OMONTYS will compete with EPOGEN and potentially Aranesp, which are both marketed by Amgen, and NeoRecormon and Mircera, which are currently marketed outside the U.S. by Roche. Mircera reportedly has greater plasma stability and is longer acting than any rEPO product that was on the market in the U.S. prior to OMONTYS. As a result of the patent litigation between Roche and Amgen, Mircera was found to infringe several U.S. patents owned by Amgen and was enjoined from being sold in the U.S. until the expiration of these patents in mid-2014 under a limited license. If Mircera enters the U.S. market, we believe that it will be in direct competition with OMONTYS, and therefore could potentially limit the market for the product, because of its ability to be longer acting. Other potential competitors are developing small molecules designed to promote the production of greater levels of naturally-occurring EPO in patients. The introduction of biosimilars into the ESA market, or new market entrants, could also prove to be a significant threat to us as it could not only limit the market for OMONTYS, but could also drive down the price of ESAs.

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Most of these competitors have substantially greater financial resources and expertise in research and development, manufacturing, pre-clinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Current marketers of ESAs also have the ability to bundle sales of existing ESA products with their other products, potentially disadvantaging OMONTYS, which we 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 OMONTYS 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 or discovering, developing and commercializing products before we do.

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

In March 2010, federal legislation gave the FDA authority to create an abbreviated approval path for biological products that are demonstrated to be biosimilar to, or interchangeable with, an FDA-approved biological product. In February 2012, the FDA released three draft guidance documents regarding this abbreviated approval path for biosimilar products, and the FDA is accepting public comments on these documents. A biosimilar product would be a subsequent version of an existing, branded FDA-approved biologic product. The patent for the existing branded product must expire in a given market before biosimilars may enter that market.

The patents for epoetin alfa, a version of recombinant human erythropoietin, or rEPO, expired in 2004 in the European Union, or E.U., and the remaining patents expire from 2012 through 2015 in the U.S. Biosimilars of rEPO are currently being developed or sold in the E.U., and in various other markets outside the U.S. And in January 2012, Hospira Inc. announced the beginning of its U.S. Phase 3 clinical program for its biosimilar of rEPO with results anticipated in 2013.

We expect that biosimilars, including rEPO, will be sold at a discount to existing branded products when they are launched in the U.S. as in the E.U. The introduction of biosimilars into the rEPO market in the U.S. could prove to be a significant threat to OMONTYS if they are able to demonstrate biosimilarity to existing rEPO. Biosimilars will constitute additional competition for OMONTYS, and are expected to drive its price and sales volume down, which would adversely affect our revenues.

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

We have experienced significant operating losses since our inception in 2001. At June 30, 2012, we had an accumulated deficit of $450.8 million. Due to the recognition of revenues from milestone payments from our collaboration with Takeda, we were profitable in the three months ended March 31, 2012 and may have profitable quarters from time to time in the future. However, we continue to expect to incur substantial losses in order to complete the commercialization of OMONTYS. Our operations have consumed substantial amounts of cash since our inception. We expect to continue to spend substantial amounts in order to:

- commercialize OMONTYS, including building our own commercial and medical affairs organizations and infrastructure to address renal markets;

- prepare for the manufacturing process for OMONTYS at our contract manufacturers;

- complete the post-marketing requirements established by the FDA.

We believe that our existing cash, cash equivalents, investments and other sources of available capital, together with the interest thereon, will enable us to maintain our currently planned operations for at least the next 12 months. Further challenges or delays to commercialization of OMONTYS may require us to draw down on the remaining $20 million available to us under the loan and security agreement executed in March 2012, or to raise additional funding to successfully commercialize OMONTYS.

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The current capital markets have been extremely volatile, and biotechnology companies have been limited or unsuccessful in obtaining funding on favorable terms in this environment. Securing funding has been particularly difficult for companies of our size with limited capital resources. Our failure to raise capital when needed may harm our business and operating results.

To date, our sources of cash have been limited primarily to the proceeds from the sale of our securities to private and public investors and payments by Takeda under our collaboration agreements. We cannot be certain that additional funding will be available on acceptable terms, or at all. To the extent that we raise additional funds by issuing equity securities, if available, our stockholders may experience significant dilution. Our current debt financing involves security interests on our assets and 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 commercialization of OMONTYS;
- relinquish some or all of our existing rights to OMONTYS;
- eliminate or defer manufacturing efforts that may negatively impact OMONTYS; or
- pursue merger and acquisition alternatives.

We expect to continue to incur substantial operating losses as we add infrastructure and operations to support commercialization of OMONTYS, and potentially begin new research and development programs. Our ability to generate product sales and become profitable depends heavily on our ability to successfully commercialize OMONTYS. OMONTYS will require significant marketing efforts and substantial investment before it can provide us or our partners with any meaningful revenue. We expect to incur substantial expenses associated with our commercialization efforts, as well as share in those of Takeda s, as we attempt to penetrate a highly competitive market. Accordingly, we may never generate significant revenues and, even if we do generate product sales, we may never achieve or sustain profitability.

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

The maintenance and successful performance of our strategic collaboration with Takeda for commercialization of OMONTYS is an important part of our business model. Our collaboration with Takeda is extremely complex, particularly in the context of our U.S. commercialization of OMONTYS with respect to financial provisions, allocations of responsibilities, and the respective rights of the parties in decision making. Accordingly, significant aspects of the commercialization of OMONTYS require Takeda to execute its responsibilities under the co-promotion arrangement, or require Takeda s agreement or approval, prior to implementation, which could cause significant delays that may materially impact the potential success of OMONTYS in the U.S. Further, if we are not able to reach agreement with Takeda or maintain our existing collaboration with Takeda on plans and efforts to commercialize OMONTYS, our business could be severely and adversely affected. Takeda has the ability to terminate each of the collaboration agreements upon an uncured material breach by us or even in the absence of a material breach with six months notice. Currently, Takeda could terminate either or both of our collaboration agreements, which would likely have a material adverse effect on the advancement of our OMONTYS program and our business. Events such as the suspension of the OMONTYS oncology program, the impact of the Phase 3 results on the renal program particularly on the non-dialysis indication, and the decreased market opportunity for ESAs may increase the possibility that Takeda may elect to terminate the collaboration or limit the resources Takeda is willing to commit to the product on a worldwide basis. In December 2011, Takeda notified us of its decision not to commercialize the product in Japan, which may negatively impact Takeda s overall commitment in the U.S. or elsewhere, in particular if the commercial opportunity becomes less promising.

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Under our collaboration, Takeda currently provides commercialization funding and performs important functions, including contracting, setting price, accounting for the collaboration revenue and profit share and conducting manufacturing activities, and is expected to pay us milestone payments upon the completion of certain events, all of which would be unavailable to us and would require significant and costly transition in the event of an early termination of the collaboration. Even in the absence of termination by Takeda, the significant resources and commitment that may be required to successfully commercialize OMONTYS in the U.S. may result in limited penetration in the market for ESAs, and Takeda s failure to provide funding or perform its co-promotion obligations necessary for successful commercialization of OMONTYS on a timely basis may have a material adverse effect on the success of the product, particularly in the U.S.

The commercial success of OMONTYS in the U.S. depends in significant part on the commercialization efforts of Takeda, over which we have limited control in the U.S. The corporate governance structure and division of roles and responsibilities with Takeda under our co-promotion agreement is complex and requires substantial coordination and focus on the part of Takeda to successfully execute our plans. Outside of the U.S. in the Takeda territory, we are solely dependent on the efforts and commitments of Takeda, either directly or through third parties, to further commercialize OMONTYS. If our collaborations are unsuccessful, our ability to commercialize products through our collaborations, and to generate future product sales, would be significantly reduced.

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

Under our collaboration with Takeda in the U.S., we co-commercialize OMONTYS in the U.S. Because we share responsibility with Takeda for commercialization activities in the U.S., which involves a complex corporate governance structure and division of roles and responsibilities, the conduct and success of the OMONTYS program is substantially dependent on the efforts of Takeda over which we have limited or no control. Further, as Takeda has significant rights, responsibilities and decision-making authority over commercialization of OMONTYS in the U.S., including final decision-making authority with respect to pricing, contracting and distribution activities, any failure of Takeda to act in a timely manner or make adequate investments of funds or resources may delay commercialization of OMONTYS,which may result in a negative impact on our planned timelines, require us to contribute more resources to successfully commercialize OMONTYS and decrease the likelihood of commercial success for OMONTYS in the U.S.

Outside of the U.S., Takeda holds an exclusive license to develop and commercialize OMONTYS and has primary responsibility for filing regulatory submissions and obtaining product approvals in those territories, including in Europe and Japan. As a consequence, any progress and commercial success in those territories is dependent solely on Takeda s efforts and commitment to the program. Takeda s recent decision not to commercialize the product in Japan and the delay or failure to secure a third party to commercialize the product in a timely manner may significantly reduce the commercial opportunity in that territory. In addition, Takeda may delay, reduce or terminate development efforts relating to the product elsewhere, independently develop products that compete with the product, or fail to commit sufficient resources to the marketing and distribution of the product. 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 the product.

In the event that Takeda fails to diligently commercialize OMONTYS, our collaboration and co-promotion agreements provide us the right to allege breach and if successfully asserted, terminate our partner s rights in certain instances. However, our ability to enforce the diligence provisions and establish breach of Takeda s diligence or other obligations so as to obtain meaningful recourse within a reasonable timeframe is uncertain. Further, any decision to pursue available remedies including termination would impact the potential success of OMONTYS, and we may choose not to terminate as we may not be able to find another partner and any new collaboration likely will not provide comparable financial terms to those in our arrangement with Takeda. In the event of our termination, this may require us to commercialize the product on our own, which is likely to result in significant additional expense and delay. Significant changes in Takeda s business strategy, resource

commitment and the willingness or ability of Takeda to complete its obligations under our arrangement could materially affect the potential success of the product.

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

Significant challenges remain with us and Takeda to manufacture OMONTYS on a commercial scale. Our dependence upon third parties for manufacture and supply may cause delays in, or prevent us from, successfully commercializing OMONTYS. 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. Manufacturing difficulties, disruptions or delays could limit supply of our product sales and have a material adverse effect on our business.

The OMONTYS manufacturing process is complicated and time consuming. Manufacture of OMONTYS API involves long lead times with our contract manufacturers and suppliers. Manufacturing difficulties, disruptions or delays could limit supply of our product. We do not currently have the infrastructure or capability internally to manufacture the OMONTYS needed to conduct our clinical trials or to commercialize the product. We have relied, and will continue to rely, upon contract manufacturers to produce our clinical trial materials for the foreseeable future and we expect to continue to rely on contract manufacturers, partners and other third parties to produce sufficient quantities of OMONTYS for all our uses, including commercialization. If our contract manufacturers or other third parties fail to deliver materials for the manufacture of OMONTYS, or OMONTYS itself, 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 future clinical trials or otherwise delay or discontinue commercialization or production.

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

- product quality issues;
- 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.

While we continue to be responsible for the manufacture of API, we have transferred responsibility for the manufacture of OMONTYS 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 our, and Takeda s, operations, suppliers and manufacturers are currently, and planned to be, single-sourced, leaving us at greater risk of supply interruptions, potential delays and failure to successfully commercialize.

We, Takeda, and our third-party manufacturers are required to comply with applicable FDA manufacturing practice and other applicable 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 OMONTYS could be interrupted, resulting in delays and additional costs. If for any reason these third parties are unable or unwilling to perform under our agreements or enter into new agreements with us, we may not be able to locate alternative manufacturers or enter into favorable agreements with them in an expeditious manner. We could also experience manufacturing delays if our third-party manufacturers, Takeda or suppliers give greater priority to the production of other products over OMONTYS. If new medical data or product quality issues suggest unacceptable safety risk or previously unidentified side effects, we and Takeda may withdraw or recall some or all of the affected product. Any inability to acquire sufficient quantities of OMONTYS or components thereof in a timely manner from third parties could delay clinical trials or result in product shortages and prevent us from commercializing OMONTYS 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 switching to, OMONTYS from our competitors products or from continuing to use OMONTYS.

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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 OMONTYS 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 OMONTYS from unauthorized making, using, selling, offering to sell or importation by third parties is dependent upon the extent to which we have rights under valid and enforceable patents, or have trade secrets that cover these activities.

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

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

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.

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

We may 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 the ability of our commercial partners, to commercialize OMONTYS 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 OMONTYS and other programs as well as underlying platform technologies and may file additional U.S. and foreign patent applications related thereto. There can be no assurance that any issued patents we own or control will provide sufficient protection to conduct our business as presently conducted or as proposed to be conducted, that any patents will issue from the patent applications owned by us, or that we will remain free from infringement claims by third parties.

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

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

Any future patent litigation, interference or other administrative proceedings will result in additional expense and distraction of our personnel. An adverse outcome in such litigation or proceedings may expose us or our collaborators to loss of our proprietary position or to significant liabilities, or require us to seek licenses that may not be available from third parties on commercially acceptable terms or at all. In addition, we may be restricted or prevented from manufacturing or commercializing OMONTYS 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.

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If we fail to attract and retain senior management and key commercial, medical affairs, clinical and scientific personnel, we may be unable to successfully commercialize OMONTYS, conduct post-marketing studies and trials or develop and commercialize any future product candidates.

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management, commercial, medical affairs, 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, commercial, medical affairs, clinical and scientific staff, particularly John Orwin, our Chief Executive Officer, Jeffrey Knapp, our Chief Commercial Officer and Dr. Anne-Marie Duliege, our Chief Medical Officer. The loss of services of Mr. Orwin, Mr. Knapp or Dr. Duliege, or one or more of our other members of senior management,could delay or prevent the successful commercialization of OMONTYS.

We will need to hire additional personnel as we expand our commercial activities and conduct post-marketing studies and trials, and as we develop and commercialize any future product candidates. Competition for qualified personnel in the biotechnology and pharmaceuticals field is intense. We may not be able to attract and retain quality personnel on acceptable terms. In addition, 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 as a commercial company, we may encounter difficulties in managing our growth and expanding our operations successfully.

As we advance through commercialization, we will need to expand our organization, including our commercial and medical affairs 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 successfully commercialize OMONTYS and to compete effectively will depend, in part, on our ability to manage our current and future growth effectively. To that end, we must be able to hire, train, integrate and retain additional management, administrative, commercial and medical affairs personnel. We may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successfully growing our company.

Risks Related to Our Industry

Even though OMONTYS has been approved by the FDA, we are subject to continued FDA review, which may result in significant additional expense and limit our ability to successfully commercialize OMONTYS.

The FDA approval of OMONTYS is subject to various post-marketing requirements, and 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 product, including adverse events of unanticipated severity or frequency, may result in restrictions on the marketing of the product, and could include withdrawal of the product from the market. In addition, the FDA s policies may change and additional government regulations may be enacted that could prevent or delay successful commercialization of OMONTYS. 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 OMONTYS, or any future product, and we may not achieve or sustain profitability.

If we fail to comply with federal and state healthcare laws, including fraud and abuse and healthcare privacy and security laws, we could face substantial penalties that could adversely affect our business, financial condition and results of operations.

We are subject to federal and state healthcare laws, including fraud and abuse and healthcare privacy and security laws. The healthcare laws that may affect our ability to operate include:

- federal sunshine laws that require transparency regarding financial arrangements with healthcare providers, such as the reporting and disclosure requirements imposed on drug manufacturers by the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively, PPACA, regarding any transfer of value made or distributed to prescribers and other health care providers;

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- the federal healthcare programs Anti-Kickback Law, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;

- federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent; the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created federal criminal laws that prohibit executing a scheme to defraud any health care benefit program or making false statements relating to health care matters; and

- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers.

In addition, California, and other states such as Massachusetts and Vermont, mandate implementation of comprehensive compliance programs to ensure compliance with these laws.

Many of these laws have not been fully interpreted by applicable regulatory authorities or the courts and their provisions are subject to a variety of interpretations, which increases the risk that we may be found in violation of these laws. Violations of these laws are punishable by criminal and civil sanctions, including, in some instances, exclusion from participation in federal and state healthcare programs, including Medicare and Medicaid, and the curtailment or restructuring of operations. We believe that our operations are in material compliance with these laws, and we have enacted a compliance program to ensure such compliance. However, because of the far-reaching nature of these laws, there can be no assurance that we would not be required to alter one or more of our practices to be in compliance, or that the occurrence of one or more violations would not result in a material adverse effect on our financial condition and results of operations.

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

We intend to co-market OMONTYS in the U.S., and have exclusively licensed Takeda to market the product in foreign jurisdictions. In order to market the product in the E.U. and other foreign jurisdictions, Takeda or a sublicensee 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. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. In addition, there are a number of ESAs available in the E.U. and other foreign markets, and therefore it may be more challenging to obtain regulatory approval in such markets because the risk/benefit analysis for approval may be different than in the U.S. Foreign regulatory approvals may not be obtained on a timely basis, if at all. If we or Takeda, as part of our collaboration, are not able to obtain regulatory approval in any foreign market, then we will not be able to commercialize OMONTYS in any foreign market, and we will not obtain certain regulatory milestones from Takeda.

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

We intend to seek approval to market the product, 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

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

We face an inherent risk of product liability as a result of conducting clinical trials and will face an even greater risk as we commercialize OMONTYS. We may be held liable if OMONTYS, or any other product we may develop in the future, 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 OMONTYS. Even successful defense would require significant financial and management resources. Regardless of the merit or eventual outcome, liability claims may result in:

- decreased demand for OMONTYS;
- 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 OMONTYS.

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 OMONTYS, or any other product we may develop in the future. We currently carry product liability insurance covering our clinical trials and commercial sales of OMONTYS in the amount of $15 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.

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Risks Related to the Ownership of Our Common Stock

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

The trading price of our common stock has been highly volatile. For the 52 weeks ended June 30, 2012 the closing price of our common stock ranged between a high of $14.50 per share and a low of $4.04 per share. Our stock is expected to be subject to wide fluctuations in price in response to various factors, many of which are beyond our control, including:

- actual or anticipated results from, and any delays in, commercialization of OMONTYS;
- actual or anticipated contractual arrangements for OMONTYS or competing products;
- actual or anticipated changes in our funding requirements, capital resources and our ability to obtain financing and the terms thereof;
- actual or anticipated actions taken by regulatory agencies including CMS with respect to ESAs generally or OMONTYS specifically;
- new products or services introduced or announced by us or our collaboration partners, or our competitors, including Roche s Mircera or biosimilars, and the timing of these introductions or announcements;
- actions taken by regulatory agencies with respect to clinical trials, manufacturing process or sales and marketing activities;
- changes in laws or regulations applicable to OMONTYS;
- 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 management or other personnel;
- developments relating to proprietary rights held by us or our competitors;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies; and
- trading volume of our common stock.

In addition, the stock market in general and the market for biotechnology and biopharmaceutical companies in particular have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies.

These broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance. In the past, following periods of volatility in the market, securities class-action litigation or regulatory investigations have often been instituted against companies. Such litigation or investigations, if instituted against us, could result in substantial costs and diversion of management s attention and resources, which could materially and adversely affect our business and financial condition.

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Raising funds through our current credit arrangement may restrict our operations or place further restrictions on our operations.

In March 2012, we entered into a $30 million loan and security agreement with Oxford Finance LLC and Silicon Valley Bank. We initially drew $10.0 million under this agreement and are subject to a variety of affirmative and negative covenants, including required financial reporting, limitations on certain dispositions of assets, limitations on the incurrence of additional debt and other requirements. To secure our performance of our obligations under this loan and security agreement, we granted a security interest in substantially all of our assets, other than intellectual property assets, to the lenders. Our failure to comply with the terms of the loan and security agreement, the occurrence of a material impairment in our prospect of repayment or in the perfection or priority of the lender s lien on our assets, as determined by the lenders, or the occurrence of certain other specified events could result in an event of default that, if not cured or waived, could result in the acceleration of all or a substantial portion of our debt, potential foreclosure on our assets, and other adverse results.

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

The Sarbanes-Oxley Act of 2002 requires, among other things, that we maintain effective internal control over financial reporting and disclosure controls and procedures. We currently have not had any material weaknesses for the years ended December 31, 2011, 2010 or 2009. We did identify a material weakness in the operation of our internal controls over financial reporting that occurred during the second quarter of 2008 which has been fully remediated. We cannot assure you that material weaknesses will not be identified in future periods. There can be no assurance that we will successfully and timely report on the effectiveness of our internal control over financial reporting in future periods. If we do experience a material weakness in future periods, then investor confidence, our stock price and our ability to obtain additional financing on favorable terms could be adversely affected.

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

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

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

Our ability to use net operating loss carryforwards and tax credit carryforwards to offset future taxable income or future tax will be limited and may be further limited in the future due to ownership changes that have occurred or may occur in the future.

In general, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, a corporation that undergoes an ownership change is subject to limitations on its ability to utilize its pre-change net operating losses, or NOLs, and certain other tax assets to offset future taxable income. In general, an ownership change occurs if the aggregate stock ownership of certain stockholders increases by more than 50 percentage points over such stockholders lowest percentage ownership during the testing period (generally three years). An ownership change could limit our ability to utilize our NOL and tax credit carryforwards for taxable years including or following such ownership change . The issuance of shares of our common stock in our March 2011 public offering resulted in an ownership change and further ownership changes may occur in the future, including as a result of transactions outside of our control, such as sales by existing stockholders, and as a consequence, our ability to utilize our NOL and tax credit carryforwards will be limited. Limitations imposed on the ability to use NOLs and tax credits to offset future taxable income could require us to pay U.S. federal income taxes earlier than would otherwise be required if such limitations were not in effect and could cause such NOLs and tax credits to expire unused, in each case reducing or eliminating the benefit of such NOLs and tax credits. Similar rules and limitations may apply for state income tax purposes.

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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. Our stock price may continue to experience extreme price volatility as has been experienced by biotechnology and biopharmaceutical companies in recent years. If we were to face such litigation, it could result in substantial costs and a diversion of management s attention and resources, which could harm our business.

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

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

These provisions include:

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

- limiting the removal of directors by the stockholders;

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

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

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

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

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

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

Unregistered Sales of Equity Securities

There were no unregistered sales of our equity securities during the quarter ended June 30, 2012.

Issuer Purchases of Equity Securities

We did not repurchase any of our equity securities during the three months ended June 30, 2012.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

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Item 6. Exhibits

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

10.5	Amended and Restated 2006 Equity Incentive Plan, as amended June 13, 2012
31.1	Certification required by Rule 13a-14(a) or Rule 15d-14(a)
31.2	Certification required by Rule 13a-14(a) or Rule 15d-14(a)
32.1	Certification required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. 1350)
101.INS*	XBRL Instance
101.SCH*	XBRL Taxonomy Extension Schema
101.CAL*	XBRL Taxonomy Extension Calculation
101.LAB*	XBRL Taxonomy Extension Labels
101.PRE*	XBRL Taxonomy Extension Presentation
101.DEF*	XBRL Taxonomy Extension Definition

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

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SIGNATURES

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

AFFYMAX, INC.

Dated: August 8, 2012	By:	/s/ JOHN A. ORWIN *Chief Executive Officer and Member of the Board of Directors*
Dated: August 8, 2012	By:	/s/ HERB CROSS *Chief Financial Officer (Principal Financial Officer)*

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EXHIBIT INDEX

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