AFFYMAX INC
Form 10-Q
May 09, 2013
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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 fiscal year ended March 31, 2013

or

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

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)

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Name of Each Exchange on Which Registered
Common stock, par value $0.001 per share	The NASDAQ Stock Market LLC

Securities registered pursuant to Section 12(g) of the Act:
None

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 April 30, 2013, 37,489,637 shares of the registrant's common stock, $0.001 par value, were outstanding.

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PART I—FINANCIAL INFORMATION

Item 1. Financial Statements
AFFYMAX, INC.
CONDENSED BALANCE SHEETS
(in thousands, except share data)

	March 31, 2013 (unaudited)	December 31, 2012
Assets		
Current assets		
Cash and cash equivalents	$46,615	$68,265
Short-term investments	7,221	9,717
Receivable from Takeda	881	18,365
Deferred tax assets	363	363
Prepaid expenses	1,657	2,731
Other current assets	60	3,069
Total current assets	56,797	102,510
Property and equipment, net	647	2,981
Restricted cash	1,135	1,135
Long-term investments	1,213	2,323
Deferred tax assets, net of current	6,876	6,876
Other assets	50	2,392
Total assets	$66,718	$118,217
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities		
Accounts payable	$9,307	$6,591
Accrued liabilities	43,224	52,522
Accrued clinical trial expenses	2,234	2,844
Deposit from Takeda	—	559
Advance from Takeda, current	8,069	27,715
Notes payable, current	8,020	8,844
Total current liabilities	70,854	99,075
Long-term income tax liability	10,097	10,062
Other long-term liabilities	543	799
Total liabilities	81,494	109,936
Commitments and contingencies (Note 9)		
Stockholders' equity		
Preferred Stock, $0.001 par value, 10,000,000 shares authorized, none issued and outstanding	—	—
Common stock: $0.001 par value, 100,000,000 shares authorized, 37,489,637 and 37,369,717 shares issued and outstanding at March 31 2013 and December 31, 2012, respectively	37	37
Additional paid-in capital	555,576	551,959
Accumulated deficit	(570,387)	(543,713)
Accumulated other comprehensive income (loss)	(2)	(2)

Total stockholders' equity (deficit)	(14,776	) 8,281
Total liabilities and stockholders' equity (deficit)	$66,718	$118,217

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

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AFFYMAX, INC.
CONDENSED STATEMENTS OF COMPREHENSIVE (LOSS) INCOME
(in thousands, except per share data)
(Unaudited)

	Three Months Ended March 31,	
	2013	2012
Revenue:		
Collaboration revenue	$839	$63,205
License and royalty revenue	5	4
Total revenue	844	63,209
Operating expenses:		
Research and development	9,736	16,107
Selling, general and administrative	24,326	15,582
Collaboration cost reimbursement	(20,378)	—
Impairment of prepaid expenses, fixed assets and intangible assets	5,140	—
Restructuring charge	8,216	—
Total operating expenses	27,040	31,689
(Loss) income from operations	(26,196)	31,520
Interest income	15	13
Interest expense	(492)	(57)
Other income (expense), net	—	(22)
(Loss) income before provision for income taxes	(26,673)	31,454
Provision for income taxes	1	1
Net (loss) income	(26,674)	$31,453
Net (loss) income per share:		
Basic	$(0.71)	$0.88
Weighted-average number of shares used in computing basic net (loss) income per share	37,469	35,772
Diluted	$(0.71)	$0.87
Weighted-average number of shares used in computing diluted net (loss) income per share	37,469	36,338
Total comprehensive (loss) income	$(26,674)	$31,444

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)

	Three Months Ended March 31,	
	2013	2012
Cash flows from operating activities		
Net (loss) income	$(26,674)	$31,453
Adjustments to reconcile net (loss) income to net cash used in operating activities:		
Collaboration cost reimbursement	(19,767)	—
Impairment of prepaid expenses, fixed assets and intangible assets	5,140	—
Noncash restructuring charge	274	—
Depreciation and amortization	386	449
Amortization of premium on investments	6	(43)
Stock-based compensation expense	3,346	2,292
Loss on disposal of property and equipment	—	30
Noncash interest expense	271	34
Changes in operating assets and liabilities:		
Receivable from Takeda	17,485	(52,082)
Prepaid expenses and other current assets	(228)	(885)
Other current assets	2,968	(57)
Other assets	220	(2,592)
Accounts payable	2,715	(413)
Accrued liabilities	(9,337)	1,668
Accrued clinical trial expenses	(610)	(1,209)
Deposit from Takeda	(559)	559
Advance from Takeda	—	3,892
Other long-term liabilities	(256)	(95)
Net cash used in operating activities	(24,620)	(16,999)
Cash flows from investing activities		
Purchases of property and equipment	—	(478)
Proceeds from maturities of investments	3,600	11,580
Proceeds from sale of property and equipment	—	25
Net cash provided by investing activities	3,600	11,127
Cash flows from financing activities		
Proceeds from issuance of common stock upon exercise of stock options	271	1,310
Proceeds from note payable	—	10,000
Repayment of note payable	(901)	—
Net cash (used in) provided by financing activities	(630)	11,310
Net (decrease) increase in cash and cash equivalents	(21,650)	5,438
Cash and cash equivalents at beginning of the period	68,265	54,339
Cash and cash equivalents at end of the period	$46,615	$59,777
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

1. The Company

Affymax, Inc., a Delaware corporation, was incorporated in July 2001. We are a biopharmaceutical company in the process of restructuring operations. In March 2012, the U.S. Food and Drug Administration, or FDA, approved our first and only 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 has been the only once-monthly ESA available to the adult dialysis patient population in the U.S. We co-commercialized OMONTYS with our collaboration partner, Takeda Pharmaceutical Company Limited, or Takeda during 2012 until February 2013, when we and Takeda announced a nationwide voluntary recall of OMONTYS as a result of safety concerns. Effective April 1, 2013, we entered into an amendment of our collaboration with Takeda pursuant to which Takeda assumed full responsibility for OMONTYS, including responsibility for the ongoing recall and investigation with the FDA, and we granted them an exclusive worldwide license to OMONTYS in consideration for potential milestones and royalties.

We have experienced significant operating losses since inception. The recall of OMONTYS has severely harmed our business, financial condition, and prospects as a going concern and even with the transition of responsibilities effectuated by the Takeda amendment and the reductions in force, these planned cost reductions may not be sufficient to continue as a going concern. We continue to take steps to reduce our outstanding obligations to third parties, and are dependent on those efforts to continue operations even in the near term, which may not be successful. The recall has also limited our access to funds. We may be unable to continue our operations or to succeed in the existing and potential future litigation, particularly with the reductions in force and in view of our limited resources and funds. We may explore various strategic alternatives, including a sale of the Company or our assets or a corporate merger. We are considering all possible alternatives, including further restructuring activities, wind-down of operations or bankruptcy proceedings. As of March 31, 2013, we had an accumulated deficit of $570.4 million.

Product Recall

On February 23, 2013, we and Takeda announced a nationwide voluntary recall of OMONTYS as a result of postmarketing reports regarding safety concerns, including anaphylaxis, which can be life-threatening or fatal. As a result of the voluntary recall of OMONTYS, all marketing activities were suspended and we have also suspended or terminated manufacturing activities.

Restructuring and Impairment

In March 2013, we commenced a restructuring plan to reduce operating costs, which included an initial reduction in force of approximately 230 employees (75% of our workforce). We incurred approximately $8.2 million in restructuring charges, all of which are related to expenditures for one-time employee termination benefits (see Note 11 of the Notes to Condensed Financial Statements). We recorded all of the charges during the first quarter of 2013. As a result of this restructuring and the recall, we also recorded impairment changes with respect to our property and equipment and intangible assets related to our license from Janssen Biotech, Inc. (a subsidiary of Johnson & Johnson) and certain of its affiliated companies, collectively referred to as Janssen, in the first quarter of 2013 (see Note 4 of the Notes to Condensed Financial Statements).

Subsequent Events

Effective April 1, 2013, we and Takeda, collectively the Parties, entered into the Fourth Amendment, or the Amendment, to the February 13, 2006 and June 27, 2006 Collaboration and License Agreements to amend and restate the ongoing respective roles and responsibilities and related commitments and financial terms between the Parties, including the termination of the Collaboration and License Agreement dated as of February 13, 2006, under which we

granted Takeda a certain right and license for the development and commercialization in Japan of OMONTYS, as amended by the First Amendment, dated April 1, 2007, the Second Amendment, dated January 1, 2008 and the Third Amendment, dated November 7, 2011, as well as the related manufacturing supply, safety, quality and co-promotion agreements between the Parties. The Amendment revised the economics from a profit-sharing arrangement to a milestone and royalty-based compensation structure to us effective as of April 1, 2013. This Amendment is part of our ongoing restructuring efforts resulting from the voluntary recall announced on February 23, 2013 related to OMONTYS, the suspension of U.S. marketing and promotional activities, and the ongoing investigation with the FDA. The arrangement with Takeda including the Amendment is referred to as the Arrangement.

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The Amendment effectuated a transfer of product and regulatory responsibilities, including the OMONTYS New Drug Application, or NDA, and all manufacturing, and development responsibilities from us to Takeda prior to April 30, 2013 with related transition services and support, which has been completed. Takeda agreed to reimburse us for certain personnel costs to assist in the transition and investigation activities for the month of April in order to support the planned transition. Takeda received a worldwide, exclusive royalty-bearing license under our and joint Takeda-Affymax patents to develop, manufacture and commercialize OMONTYS.

As a result of the Amendment, Takeda assumed full responsibility for OMONTYS, including the ongoing recall and investigation of OMONTYS as well as any subsequent decisions as to whether the product may be subject to reintroduction if Takeda is able to complete the investigation and address the safety concerns to the satisfaction of the FDA. If Takeda decides to reintroduce OMONTYS, which is highly uncertain, we are eligible to receive royalties and (i) potential commercial milestone payments totaling up to $180.0 million which consists of the following: (a) $10.0 million is payable upon the first commercial sale after reintroduction of OMONTYS in the U.S.; (b) $10.0 million and another $10.0 million relates to U.S. sales-based milestones, and (c) $150.0 million relates to sales-based milestones in amounts as previously disclosed outside of the U.S. but now including Japan as a result of the Amendment and (ii) a potential development milestone payment of $5.0 million payable either upon regulatory approval in the E.U. or Japan. The royalties are tiered in the range of 13% to 17% with respect to net sales in the U.S. and in the range of 13% to 24% depending on the level of net sales by Takeda worldwide outside of the U.S. As of March 31, 2013, we have retained a liability for an advance from Takeda on our condensed balance sheet of approximately $8.1 million, which Takeda may offset a percentage of future royalty and milestone payments due to us, if any against the advance recorded (see Note 3 of the Notes to Condensed Financial Statements).

On April 3, 2013, we entered into a letter agreement, or Letter Agreement, relating to the loan and security agreement dated March 26, 2012, or the Loan Agreement, with Oxford Finance Corporation and Silicon Valley Bank, or, collectively, the Lenders. Pursuant to the terms of the Letter Agreement: (i) we paid all amounts due and owing so as to discharge our obligations thereunder totaling $9.8 million including principal, interest, final payment and prepayment fees, (ii) we waived any rights to seek additional credit extensions or unfunded commitments under the Loan Agreement, and (iii) the security interest granted to Lenders relating to substantially all of our assets, other than our intellectual property, was terminated.

In April 2013, as part of our ongoing efforts to restructure our operations in order to further reduce costs, we commenced a process to notify substantially all of the remaining 25% of our workforce of estimated dates of separation and we engaged an experienced restructuring firm. With the engagement of the restructuring firm, we announced our plan to terminate the employment of our remaining executive officers, including our Chief Executive Officer and Chief Financial Officer, by June 15, 2013.

Going Concern

Because we have not made an irrevocable decision to liquidate, the accompanying condensed financial statements have been prepared under the assumption of a going concern basis that contemplates the realization of assets and liabilities in the ordinary course of business. Operating losses have been incurred each year since inception, resulting in an accumulated deficit of $570.4 million as of March 31, 2013. Nearly all of our revenues to date have come from our collaboration with Takeda. As a result of the February 23, 2013 nationwide voluntary recall of OMONTYS and the suspension of all marketing activities, there is significant uncertainty as to whether we will have sufficient existing cash, cash equivalents and investments to fund our operations for the next 12 months. Our liabilities exceed our assets. Even with the recent reorganization, further reductions in our workforce and cash flows, there is no assurance that we will be able to reduce our operating expenses enough to meet our existing obligations and conduct ongoing operations. If we do not have sufficient funds to continue operations, we could be required to liquidate our assets, seek bankruptcy protection or other alternatives. Any failure to dispel any continuing doubts about our ability to continue as a going concern could adversely affect our ability to enter into collaborative relationships with business partners. These matters raise substantial doubt about our ability to continue as a going concern. Our financial statements do not include any adjustments that may result from the outcome of this uncertainty.

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

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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, 2012, which includes our audited financial statements and the notes thereto.

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

Concentration of Risk

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.

As of March 31, 2013 and December 31, 2012, our accounts receivable balance with Takeda was $0.9 million and $18.4 million, respectively. The receivable is comprised of the amounts due from Takeda under our Arrangement with them. We have not experienced any credit losses from our receivables with Takeda and none are expected. We do not require collateral on our receivable. The receivable balance as of March 31, 2013 has been collected in full subsequent to quarter end.

Our future is based on only one source of product-related revenue, OMONTYS. If Takeda is not successful in identifying a cause and is unable or unwilling to reintroduce OMONTYS, we have no prospects for other sources of revenue.

Use of Estimates

The preparation of financial statements in conformity with U.S. 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 for contracts entered into prior to 2011 in accordance with the SEC Staff Bulletin No. 101, Revenue Recognition in Financial Statements, 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(s) 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 (e.g. contingencies), delivery or performance of the undelivered item(s) is considered probable and is substantially within the control of the Company. We recognize revenue for contracts entered into or materially modified after January 1, 2011, in accordance with 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 or modified agreements.

We account for our Arrangement with Takeda under ASC 605-25 and through the date of the recall, had been operating in the commercialization period as defined in the Arrangement. Before the recall, we were performing commercialization

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services such as promotions and marketing as well as development work related to OMONTYS post approval. In return for these services, we received a 50/50 share of operating profit from the sale and distribution of OMONTYS (as described below), certain milestone payments and contingent payments due under the Arrangement. We also received reimbursement of costs for commercial and development costs as described in the Arrangement. Prior to approval of OMONTYS, our primary source of revenue consisted of milestone payments and Takeda's reimbursement of commercialization and development costs.

In addition to the profit sharing and reimbursement of the costs described above, the Arrangement provides us the potential to earn substantive at risk milestone payments upon achievement of contractual criteria (see Note 3 of Notes to Financial Statements). However, timing and amounts of these milestones are highly uncertain due to the recall.

During the commercialization period, our obligations included ongoing regulatory work to obtain and maintain FDA approval and commercialization efforts related to our product launch and promotion and marketing of OMONTYS.

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

- Expense reimbursement revenue. Revenues related to reimbursements by Takeda of third-party development expenses (70/30 split per the Arrangement) and commercialization expenses (shared 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 commercialization expenses and development costs (both FTE and out of pocket costs) associated with post-marketing development activities, is incorporated into the profit equalization revenue as required under the Arrangement in order to effect the 50/50 profit split, as described below. As part of the Amendment with Takeda, both Parties agreed that they will no longer share expenses related to third-party development (70/30 split) and commercialization (50/50 split) as of April 1, 2013. Any expenses incurred by either us or Takeda after April 1, 2013 shall be the responsibility of the respective party and neither us or Takeda has the obligation to share expenses with each other.

- Profit equalization revenue/loss. Subsequent to the launch of OMONTYS and prior to the Amendment, as to the recognition of product revenue by Takeda, Takeda allocates the quarterly profit equalization revenue/loss to us in order to effect the 50/50 profit/loss split from the sale of OMONTYS, as called for by the Arrangement. Profit equalization revenue/loss is calculated as the amount required so that the profit or loss realized by both us and Takeda on the product equates to 50% of the total product profit or loss. Total product profit or loss on OMONTYS is calculated on a quarterly basis as gross product sales recorded by Takeda less the following deductions also recorded by Takeda: rebates and discounts, cost of goods, and other gross-to-net adjustments incurred by Takeda; royalty expenses incurred by us, commercialization 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 both Takeda and us. Profit equalization revenue is recognized as revenue in the period product revenue is recognized by Takeda. As a result of the voluntary recall of OMONTYS in February 2013, all marketing activities were suspended. As part of the Amendment with Takeda, the profit equalization revenue for the three months ended March 31, 2013 will be the final profit equalization payment under the Arrangement. Upon signing the Amendment with Takeda, the economics of the collaboration changed from a profit sharing arrangement to a milestone and royalty-based compensation structure to us, effective April 1, 2013.

- Milestone revenue. 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. Although we are eligible to receive future milestones from Takeda, timing and amounts of future milestone payments, if any are highly uncertain due to the recall.

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Below is a summary of the components of our collaboration revenue for the three months ended March 31, 2013, and 2012 (in thousands):

	Three months ended March 31,	
	2013	2012
Profit equalization payment	$—	$—
Milestone payments	—	58,000
Net expense reimbursement	839	5,205
Total collaboration revenue	$839	$63,205

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.

If Takeda decides to reintroduce OMONTYS, which is highly uncertain, we are eligible to receive potential milestones and royalties. The royalties are tiered in the range of 13% to 17% with respect to net sales in the U.S. and in the range of 13% to 24% depending on the level of net sales by Takeda worldwide outside of the U.S.

Fair Value of Financial Instruments

For financial instruments consisting of cash and cash equivalents, receivable from Takeda, advance from Takeda, accounts payable, deposit from Takeda and accrued liabilities included in our condensed financial statements, the carrying amounts are reasonable estimates of fair value due to their short maturities. Estimated fair values for short-term and long-term investments are based on quoted market prices for the same or similar instruments. Based on borrowing rates currently available to us for loans with similar terms, the carrying value of lease obligations approximates fair value.

Inventory

We value our inventories at the lower of cost or net realizable value which is contractually determined in our collaboration with Takeda to be our cost plus a markup. We determine the cost of inventory using the specific identification method. We record active pharmaceutical ingredient, or API, as inventory when the title transfers to us from the contract manufacturing organization, or CMO, until the point of acceptance by Takeda. We initiate orders for API with our CMOs based on forecasts from Takeda. To date, all orders have generally commenced once there was a contractual commitment for the API from Takeda.

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. The voluntary recall of OMONTYS in February 2013 impacted the recoverability of our inventories based on assumptions about expected demand and net realizable value. In the December 31, 2012 balance sheet, given the significant uncertainty of demand following the recall, we had written down our API inventory and prepayments made to our CMOs to the net realizable value of zero. We also established an accrual for estimated losses on firm inventory purchase commitments by applying the same lower of cost or market approach that is used to value inventory. As of March 31, 2013, the balance of this accrual was $32.9 million. If we are able to settle these obligations for less than the contractual amounts, we may have favorable adjustments to our operating results in the future.

We expense costs relating to the production of API as research and development or R&D expense in the period incurred until we receive FDA approval for a new product or product configuration and began to capitalize the subsequent inventory costs relating to that product or product configuration. Prior to approval of OMONTYS for commercial sale in March 2012 by the FDA, we had expensed all costs associated with the production of API as R&D expense. Subsequent to receiving FDA approval of OMONTYS, we commenced capitalization of third party costs which are incurred to manufacture the API used in the production of OMONTYS.

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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 component of accumulated other comprehensive income (loss) in stockholders' equity until realized. Debt securities are adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization as well as realized gains and losses are included in interest income. We assess our investments for potential other-than-temporary impairment based on factors including the length of time and extent to which the fair 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.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation and amortization. Depreciation and amortization of property and equipment are calculated using the straight-line method over the estimated useful lives of the assets, generally three to five years. Assets under capital lease and leasehold improvements are amortized over the lesser of their estimated useful lives or the term of the related lease. Maintenance and repairs are charged to operations as incurred.

Valuation of Long-Lived Assets

We assess the impairment of long-lived assets when events or changes in circumstances indicate that the carrying value of the assets or the asset grouping may not be recoverable. Factors that we consider in deciding when to perform an impairment review include significant negative industry or economic trends, and significant changes or planned changes in our use of the assets. We measure the recoverability of assets that will continue to be used in our operations by comparing the carrying value of the asset grouping to our estimate of the related total future undiscounted net cash flows. If an asset grouping's carrying value is not recoverable through the related undiscounted cash flows, the asset grouping is considered to be impaired. The impairment is measured by comparing the difference between the asset grouping's carrying value and its fair value. Fair value is the price that would be received from selling an asset in an orderly transaction between market participants at the measurement date. Long-lived assets such as intangible assets and property, plant and equipment are considered non-financial assets, and are recorded at fair value only when an impairment charge is recognized. The recall of OMONTYS was considered to be an impairment indicator for certain assets. We evaluated the recoverability of our assets and determined that certain assets were impaired. We recorded impairment charges for the quarter ended March 31, 2013 of $5.1 million. These charges are reflected in the statement of comprehensive (loss) income under the caption "Impairment of prepaid expenses, fixed assets, and intangible assets."

Net (Loss) Income Per Common Share

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

Diluted net (loss) income per share is computed similarly to basic net (loss) income per share, except that the denominator is increased to include all dilutive potential common shares using the treasury stock method. For purposes of this calculation, options to purchase common stock, common stock issuable pursuant to the 2006 Employee Stock Purchase Plan, restricted stock units, or RSUs, and warrants are considered to be potential common shares and are only included in the calculation of diluted (loss) income per share when their effect is dilutive. The computations for basic and diluted net (loss) income per share were as follows (in thousands):

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	Three Months Ended March 31,	
	2013	2012
Numerator:		
Net (loss) income	$(26,674)	$31,453
Denominator:		
Weighted-average number of common shares used in computing basic and diluted net (loss) income per common share	37,469	35,772
Dilutive effect of:		
Options to purchase common stock	$—	219
Common stock issuable pursuant to the 2006 Employee Stock Purchase Plan	$—	104
Restricted stock units	$—	243
Weighted-average shares used in computing diluted net (loss) income per share	37,469	36,338
Basic net (loss) income per share	$(0.71)	$0.88
Diluted net (loss) income per common share	$(0.71)	$0.87

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

	Three Months Ended March 31,	
	2013	2012
Options to purchase common stock	4,803	3,559
Common stock issuable pursuant to the 2006 Employee Stock Purchase Plan	125	—
Restricted stock units	437	—
Warrant to purchase common stock	424	433

Stock-Based Compensation

We account for equity instruments issued to employees and directors under the authoritative guidance for share-based payments.

The equity instruments we most typically grant are stock options and RSUs. Stock options are valued using the Black-Scholes valuation model while the fair value of RSUs is equivalent to the market value of the equivalent number of shares of common stock on the date of grant. The measurement of stock-based compensation is subject to periodic adjustments as the underlying equity instruments vest or do not vest as a result of employee terminations prior to vest.

We have issued stock options to nonemployees. We account for equity instruments issued to nonemployees in accordance with the authoritative guidance for equity-based payments to nonemployees, using a fair value approach.

3. Development and Commercialization Agreements with Takeda

We entered into two separate collaboration agreements with Takeda in February 2006 and June 2006 related to the co-development and co-commercialization of OMONTYS, which have been combined for accounting purposes due to their proximity of negotiation. We previously amended these arrangements in November 2011 concurrent with the settlement and license agreement, or Settlement and License Agreement, with Janssen (see further discussion below and Note 4 of Notes to Condensed Financial Statements).

On February 23, 2013, we and Takeda announced a nationwide voluntary recall of OMONTYS as a result of postmarketing reports regarding safety concerns, including anaphylaxis. As a result of the voluntary recall of OMONTYS, all marketing activities were suspended. Effective April 1, 2013, we and Takeda entered into the

Amendment to the February 2006 and June 2006 agreements to amend and restate the ongoing respective roles and responsibilities and related commitments and financial terms between the Parties, including the termination of the Collaboration and License Agreement dated as of February 13, 2006, under which we had granted Takeda a certain right and license for the development and commercialization in Japan

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of OMONTYS, as amended by the First Amendment, dated April 1, 2007, the Second Amendment, dated January 1, 2008 and the Third Amendment, dated November 7, 2011, as well as the related manufacturing supply, safety, quality and co-promotion agreements between the parties. The Amendment revised the economics from a profit-sharing arrangement to a milestone and royalty-based compensation structure to us effective as of April 1, 2013. The Amendment is part of our ongoing restructuring efforts resulting from the voluntary recall announced on February 23, 2013 related to OMONTYS, the suspension of U.S. marketing and promotional activities, and the ongoing investigation with the FDA.

The Amendment effectuated a transfer of regulatory responsibilities, including the OMONTYS NDA, and all manufacturing, and development responsibilities from us to Takeda as prior to April 30, 2013 with related transition services and support, which has been completed. Takeda agreed to reimburse us for certain personnel costs to assist in the transition and investigation activities for the month of April in order to support the planned transition. Takeda received a worldwide, exclusive royalty-bearing license under our and joint Takeda-Affymax patents to develop, manufacture and commercialize OMONTYS.

As a result of the Amendment, Takeda assumed full responsibility for OMONTYS, including the ongoing recall and investigation of OMONTYS as well as any subsequent decisions as to whether the product may be subject to reintroduction if Takeda is able to complete the investigation and address the safety concerns to the satisfaction of the FDA. With the transfer of responsibilities and the NDA, Takeda is responsible for continuing the investigation but there can be no assurance as to when and if a solution will be identified.

Collaboration revenue reported on our statement of comprehensive (loss) income consists of the nonrefundable upfront license fees, reimbursement for the sale of API net of costs incurred, net reimbursement of certain development and commercial expenses, revenues from product profit sharing, and milestone payments. We recognized $0.8 million and $63.2 million of collaboration revenue during the three months ended March 31, 2013 and 2012, respectively. The amount receivable from Takeda as of March 31, 2013 and December 31, 2012 was $0.9 million and $18.4 million, respectively.

Development and Commercialization of OMONTYS in the U.S. Prior to the April 2013 Amendment

Prior to the Amendment, Takeda bore responsibility for 70% of all third-party expenses related to U.S. development and 50% of all third party expenses related to U.S. commercialization. Certain employee-related expenses supporting the commercialization of OMONTYS in the U.S. were also shared equally. 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. were shared equally. As part of the Amendment between us and Takeda, both Parties agreed that they will no longer share expenses related to third-party development (70/30 split) and commercialization (50/50 split) as of April 1, 2013. Any expenses incurred by either us or Takeda after April 1, 2013 shall be the responsibility of the respective party and neither us or Takeda has the right to share expenses with each other.

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. Prior to the Amendment, we were responsible for deployment of the sales force and the medical affairs field force but shared marketing, account management and payor reimbursement related activities with Takeda. Takeda was responsible for manufacturing and distribution of the finished drug product to the customer and recorded product sales of OMONTYS. Specifically, Takeda had sole responsibility for handling all returns, order processing, invoicing and collection of receivables with regard to sales of OMONTYS. Takeda also had the rights and responsibility for establishing and modifying terms and conditions with respect to the sale of OMONTYS in the U.S., including pricing discounts available to third party payers, price adjustments and other allowable discounts and allowances. In addition, as we and Takeda split profits 50/50 in the U.S., the Co-Promotion

Agreement provided 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 retained final decision making authority with respect to terms related to pricing and contracting and responsibility for distribution activities.

Prior to the Amendment, while Takeda was responsible for the sale of OMONTYS and accordingly Takeda recorded product revenue, we and Takeda shared equally in the net profits and losses of those sales of OMONTYS in the U.S. In determining the OMONTYS net profit or loss, OMONTYS product revenue was reduced by rebates and discounts, cost of goods, and other gross-to-net adjustments incurred by Takeda; royalty expense incurred by us, commercialization expenses (FTE related and out of pocket costs) incurred by both Takeda and us, and certain development costs associated with post-

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marketing development activities (FTE related and out of pocket costs) incurred by both Takeda and us. We reviewed the revenue, related deductions and expenses provided by Takeda and prepared an invoice to Takeda for our portion of the OMONTYS net profit after factoring in applicable costs incurred by us and Takeda at the end of each quarter. The profit equalization amount was recognized as revenue in the period the product sales occurred and product revenue was recognized by Takeda.

As a result of the voluntary recall of OMONTYS in February 2013, all marketing activities were suspended. As part of the Amendment with Takeda, the profit equalization revenue for the three months ended March 31, 2013 will be the final profit equalization payment under the Arrangement. Upon signing the Amendment with Takeda, the economics of the collaboration changed from a profit sharing arrangement to a milestone and royalty-based compensation structure to us, effective April 1, 2013.

Development and Commercialization of OMONTYS outside of the U.S.

In February 2006, we granted an exclusive license to Takeda for development and commercialization of OMONTYS in Japan. In December 2011, Takeda announced that it had decided not to commercialize OMONTYS in Japan. We and Takeda have explored other options for the commercialization rights for OMONTYS in the Japanese market, including potentially licensing it to a third party. If Takeda or its licensee is successful in clinical development and regulatory milestones, we are eligible to receive contingent payments from Takeda which aggregate up to $33.0 million relating to the Japan renal program and $5 million for a third indication that neither we or Takeda is pursuing. Per the terms of the Amendment, the Japan agreement was terminated.

In June 2006, Takeda subsequently received an exclusive license to develop and commercialize the product outside of the U.S. 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 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.

Launch Allowance

As noted above, Takeda bore responsibility for 50% of all third party expenses related to the commercialization of OMONTYS in the U.S. Takeda also provided a launch allowance to help fund the initial costs associated with preparing to launch under which it committed to fund the first $20.0 million of U.S. commercial expenses incurred in total by us and Takeda. Amounts received under the launch allowance are non-refundable; under the Amendment, however, Takeda is entitled to deduct up to 8% from any future payments made to us under the royalty or milestone provisions until they have recouped an amount equal to $11.0 million ($10.0 million plus a $1.0 million fixed amount that represents interest). During the three months ended March 31, 2013, amounts less than $0.1 million were deducted by Takeda under this arrangement. As of March 31, 2013, our liability balance under the launch allowance is $8.1 million.

Milestones

During 2012, we earned the following milestone payments from Takeda: a $50.0 million milestone upon FDA approval of OMONTYS in the dialysis indication, a $5.0 million milestone upon acceptance for review of the MAA, filing for OMONTYS by the EMA, and a $3.0 million and $2.25 million milestone related to an amendment to the Arrangement or the November 2011 Amendment, described below.

As a result of the Amendment, Takeda assumed full responsibility for OMONTYS, including the ongoing recall and investigation of OMONTYS as well as any subsequent decisions as to whether the product may be subject to reintroduction if Takeda is able to complete the investigation and address the safety concerns to the satisfaction of the FDA. We provided transition support to Takeda through April 30, 2013. After April 30, 2013 we have no performance obligations under our agreement with Takeda. If Takeda decides to reintroduce OMONTYS, all of which is highly uncertain, we are eligible to receive royalties and (i) potential contingent payments in the form of commercial milestone payments totaling up to $180.0 million, which consist of the following: (a) $10.0 million is payable upon the first commercial sale after reintroduction of OMONTYS in the U.S.: (b) $10.0 million and another $10.0 million relates to U.S. sales-based milestones, and (c) $150.0 million relates to sales-based milestones outside of the U.S. as disclosed below but now including Japan as a result of the Amendment and (ii) a potential development milestone payment of $5 million payable either upon regulatory approval in the E.U. or Japan. The royalties are tiered in the range of 13% to 17% with respect to net sales in the U.S. and in the range of 13%

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to 24% depending on the level of net sales by Takeda worldwide outside of the U.S. The $150.0 million of sales-based milestones consists of milestones of $10.0 million, $20.0 million, $30.0 million, $40.0 million and $50.0 million for worldwide net sales reached and recorded by Takeda during a fiscal year of the arrangement of $0.5 billion, $1.0 billion, $1.5 billion, $2.0 billion and $3.0 billion, respectively. Although we are eligible to receive future milestones from Takeda, timing and amounts of future milestone payments, if any, are highly uncertain due to the recall.

API Supply Agreement

In November 2011, as contemplated under the Arrangement, we and Takeda executed a Commercial API Supply Agreement. Under the terms of the API Supply Agreement, we were responsible for the manufacture and supply of all quantities of API to be used in the development and commercialization of OMONTYS worldwide. Takeda reimbursed us for our cost of API plus 20%. Takeda was responsible for the fill and finish steps in the manufacture of OMONTYS worldwide under the Arrangement. As of December 31, 2012 we had a balance of $19.8 million recorded as an Advance from Takeda which was related to deferred revenue on API shipped to Takeda. As a result of the recall and the impairment charges recorded on the OMONTYS inventory during 2012, the remaining balance of deferred revenue has been reversed as of March 31, 2013.

Impairment of Inventory and Firm Purchase Commitments

Prior to the voluntary recall, we initiated orders for API with our CMOs based on forecasts from Takeda, which were based on expected demand for OMONTYS. Orders generally have commenced once there was a contractual commitment for the API from Takeda. As of March 31, 2013, we have recognized future purchase commitments amounting to $32.9 million. These future commitments are comprised of $5.4 million for firm purchase commitments of PEG, and the remaining $27.5 million of manufacturing obligations relate to API, and were based on firm demand forecasts from Takeda.

In the December 31, 2012 balance sheet, given the significant uncertainty of demand following the recall, we had written down our API inventory and prepayments made to our CMOs to the net realizable value of zero. We also established an accrual for estimated losses on firm inventory purchase commitments by applying the same lower of cost or market approach that is used to value inventory. As of March 31, 2013, the balance of this accrual was $32.9 million. If we are able to settle these obligations for less than the contractual amounts, we may have favorable adjustments to our operating results in the future.

In addition to the binding CMO purchase commitments, we also had $10.4 million in inventory and prepayments made to our CMOs on our balance sheet as of December 31, 2012. As a result of the inability to sell OMONTYS and the uncertainty of future revenues, we have written down our API inventory and prepayments for API being produced by our CMOs to a net realizable value of zero and recorded a $10.4 million impairment charge related to this writedown during the year ended December 31, 2012. We had also recorded a $34.6 million loss on firm purchase commitments by applying the same lower of cost or market approach that is used to value inventory during the same period. Of the total $45.0 million charge for impairment of inventory and loss on CMO purchase commitments recorded in 2012, we recorded a benefit of $20.4 million in the first quarter of 2013, primarily related to the collaboration cost reimburement under the Takeda Q1 profit equalization payment.

Cost of Recall

As a result of the Amendment, Takeda assumed full responsibility for OMONTYS, including the ongoing recall and investigation of OMONTYS as well as any subsequent decisions as to whether the product may be subject to reintroduction if Takeda is able to complete the investigation and address the safety concerns to the satisfaction of the FDA.

The total costs of recalling the product were primarily composed of costs to a third-party to gather, store, and return the product to Takeda, of which $1.1 million was incurred in the first quarter of 2013. Our portion of the expense was $0.6 million which we were charged as a part of the Q1 profit equalization payment in the first quarter of 2013. Takeda capitalizes inventory costs associated with the production of OMONTYS and enters into purchase commitments for goods associated with this manufacturing. The write down or write off of such inventory and any

charges for purchase commitments by Takeda was subject to the profit equalization revenue or loss calculation of the Arrangement. Takeda included inventory write down charges of $31.8 million for the cost of inventory on hand at Takeda as of March 31, 2013 in the Q1 profit equalization payment. Our portion of this write down was $15.9 million and was previously reserved for as of December 31, 2012 as a part of our Advance from Takeda liability. With respect to purchase commitments, Takeda requested reimbursement for a portion of the costs associated with Takeda's firm purchase commitment of $9.3 million with Baxter for pre-filled syringes. Our exposure was limited to the portion of the Baxter agreement that relates to the U.S. We had no liability related to the E.U. or Japan because in those countries we receive only a royalty on product sales and the collaboration profit split did not apply to operations in those countries. The amount of our exposure was $0.7 million which was included in the Q1 profit equalization payment in the first quarter of 2013.

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In the first quarter of 2013, Takeda recorded an impairment charge for certain long lived assets associated with OMONTYS. Under the profit/loss equalization we were responsible for half of these charges. Our exposure related to this impairment was $6.2 million. This amount was charged to us as a part of the Q1 profit equalization payment in the first quarter of 2013.

November 2011 Amendment

In November 2011, concurrent with the execution of the Settlement and License Agreement with Janssen, we and Takeda entered into an amendment to the Arrangement. Under the terms of this amendment, Takeda 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 were earned based on regulatory and commercial events in the U.S. and the remaining $1.25 million tied to regulatory events in the E.U, which was eliminated as part of the Amendment. 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.

4. Contractual Arrangements

Our License, Manufacturing and Supply Agreement with Nektar

In April 2004, we entered into a License, Manufacturing and Supply Agreement with Nektar Therapeutics AL Corporation, or Nektar, under which we obtained from Nektar a worldwide, non-exclusive license, with limited rights to grant sublicenses, under certain intellectual property covering pegylation technology to manufacture, develop and commercialize OMONTYS. The license we obtained consists of a license under intellectual property owned by Nektar and a sublicense under intellectual property owned by Enzon Pharmaceuticals, Inc., or Enzon, licensed to Nektar pursuant to a cross-license agreement between Nektar, Inhale Therapeutic Systems, Inc. and Enzon.

In consideration of the license grant, we agreed to pay royalties on the sales of OMONTYS, which began with the launch of the product in the U.S. in 2012; sales of the product were suspended on February 26, 2013. We also agreed to pay base milestones plus possible additional milestones in connection with our partnering activities relating to OMONTYS or merger and acquisition activities. As of March 31, 2013, no further milestone obligations remain.

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 required 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 as another asset. 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. During the three months ended March 31, 2013, as a result of the recall, we recorded a $1.9 million impairment charge related to this asset, bringing the asset value to zero.

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. This royalty payment is not reimbursable under our Arrangement with Takeda.

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5. Balance Sheet Components

Property and Equipment, Net

Property and equipment consist of the following (in thousands):

	March 31, 2013	December 31, 2012
Leasehold improvements	$2,501	$2,501
Equipment	9,565	9,794
Software	3,064	3,064
Construction in progress	—	9
	15,130	15,368
Less: Accumulated depreciation and amortization	(14,483)	(12,387)
	$647	$2,981

Depreciation and amortization expense for the three months ended March 31, 2013 and 2012 was $0.4 million and $0.4 million, respectively. In addition to the expense noted above, we also incurred $1.9 million in impairment charges for the three months ended March 31, 2013.

Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	March 31 2013	December 31, 2012
Accrued potential losses related to firm purchase commitments [1]	$32,944	$34,599
Restructuring accrual [2]	3,235	—
Compensation-related expenses	5,178	12,837
SG&A related costs [3]	1,097	3,633
R&D related costs	26	830
Other	744	623
	$43,224	$52,522

(1) See Note 3 of Notes to Condensed Financial Statements.

(2) See Note 11 of Notes to Condensed Financial Statements.

(3) Includes accruals relating to FDA fee, legal and accounting fees, commercial and medical affairs, IT related and other miscellaneous accruals.

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6. Investments

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

	As of March 31, 2013				
	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Other-Than Temporary Impairment	Fair Value
Short-term investments:					
Certificates of deposit	$1,300	$—	$—	$—	$1,300
Corporate debt securities	5,920	1	—	—	5,921
Total short-term investments	$7,220	$1	$—	$—	$7,221
Long-term investments:					
Corporate debt securities	$1,215	$—	$(2)	$—	$1,213
Total long-term investments	$1,215	$—	$(2)	$—	$1,213

	As of December 31, 2012				
	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Other-Than Temporary Impairment	Fair Value
Short-term investments:					
Certificates of deposit	$1,300	$—	$—	$—	$1,300
Corporate debt securities	8,416	1	—	—	8,417
Total short-term investments	$9,716	$1	$—	$—	$9,717
Long-term investments:					
Corporate debt securities	$2,326	$—	$(3)	$—	$2,323
Total long-term investments	$2,326	$—	$(3)	$—	$2,323

The investments held as of March 31, 2013 mature between April 2013 and July 2014. No other-than-temporary impairments were identified for the investment securities held by us as of March 31, 2013.

7. Fair Value Measurements

We measure certain financial assets and liabilities 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.

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, under which we review trading activity and pricing for these investments as of the measurement date. When

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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.

Financial instruments that are not recorded at fair value are measured at fair value on a quarterly basis for disclosure purposes. The fair value of the notes payable are based on the present value of expected future cash flows, assumptions about current interest rates and the creditworthiness of Affymax. Market risk associated with our fixed rate debt relates to the potential reduction in fair value. The carrying amounts of our notes payable approximate fair value.

The carrying amounts of certain financial instruments, such as cash equivalents, accounts receivable, accounts payable and accrued liabilities, approximates fair value due to their relatively short maturities, and low market interest rates if applicable.

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 March 31, 2013			
		Fair Value Measurements Using		
	Total	Level 1	Level 2	Level 3
Money market funds	$11,597	$11,597	$—	$—
Short-term investments:				
Certificates of deposit	$1,300	$—	$1,300	$—
Corporate debt securities	5,921	—	5,921	—
Total short-term investments	$7,221	$—	$7,221	$—
Long term investments:				
Corporate debt securities	$1,213	$—	$1,213	$—
Total long-term investments	$1,213	$—	$1,213	$—

	As of December 31, 2012			
		Fair Value Measurements Using		
	Total	Level 1	Level 2	Level 3
Money market funds	$45,999	$45,999	$—	$—
Short-term investments:				
Certificates of deposit	$1,300	$—	$1,300	$—
Corporate debt securities	8,417	—	8,417	—
Total short-term investments	$9,717	$—	$9,717	$—
Long term investments:				
Corporate debt securities	$2,323	$—	$2,323	$—
Total long-term investments	$2,323	$—	$2,323	$—

In conjunction with the product recall and related restructuring activities, we have evaluated our property and equipment. Equipment and leasehold improvements categorized as held for use on the condensed balance sheet at March 31, 2013 totaled $0.6 million. The fair value of the equipment and leasehold improvements was determined using Level 3 valuation inputs including broker estimates for similar assets plus estimated normal use charge based on depreciation for the remaining period of use.

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8. Loan and Security Agreement and Repayment

As of March 31, 2013, we had approximately $8.0 million of notes payable outstanding under the Loan Agreement with the Lenders. On April 3, 2013, we entered into a Letter Agreement, under which (i) we paid all amounts due and owing so as to discharge our obligations thereunder which totaled $9.8 million including principal, interest, final payment and prepayment fees, (ii) we waived any rights to seek additional credit extensions or unfunded commitments under the Loan Agreement, and (iii) the security interest granted to Lenders relating to substantially all of our assets, other than our intellectual property, was terminated.

9. Commitments and Contingencies

Legal Proceedings

On February 27, 2013, a securities class action complaint was filed in the United States District Court for the Northern District of California, naming as defendants Affymax, Inc. or the Company, certain of its officers, Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals U.S.A., Inc. and Takeda Global Research & Development Center, Inc. A second complaint naming the same defendants was filed on March 6, 2013. The complaints, filed on behalf of purported stockholders of the Company, allege violations of Section 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder, in connection with allegedly false and misleading statements made by the defendants regarding the Company's business practices, financial projections and other disclosures between December 8, 2011 and February 22, 2013, or the Class Period. The plaintiff seeks to represent a class comprised of purchasers of the Company's common stock during the Class Period and seeks damages, costs and expenses and such other relief as determined by the Court.

On March 19, 2013, and March 29, 2013, respectively, two derivative lawsuit were filed purportedly on behalf of the Company in California Superior Court for the County of Santa Clara naming certain of our officers and directors as defendants. The lawsuits allege that the certain of the Company's officers and directors breached their fiduciary duties related to the clinical trials for OMONTYS and for representations regarding the Company's business health which was tied to the success of OMONTYS. The lawsuits also assert claims for unjust enrichment and corporate waste.

We believe that we have meritorious defenses and intend to defend these lawsuits vigorously. However, these lawsuits are subject to inherent uncertainties, the actual cost may be significant, and we may not prevail. We believe we are entitled to coverage under our relevant insurance policies, subject to a retention, but coverage could be denied or prove to be insufficient.

Additionally, in light of the recall, a product liability claim could potentially arise, although no claim has been filed to date.

We assess litigation to determine if an unfavorable outcome would lead to a probable loss or reasonable possible loss, which could be estimated. We accrue for losses that are both probable and reasonably estimable. If the estimate of a probable loss is a range and no amount within the range is more likely, we accrue the minimum amount of the range. In the cases where we believe that a reasonable possible loss exists, we disclose the facts and circumstances of the litigation, including an estimable range, if possible. Substantially all of these contingencies are subject to significant uncertainties and, therefore, determining the likelihood of a loss and/or the measurement of any loss can be complex. Consequently, we are unable to estimate the range of reasonable possible loss. Accordingly, no loss accrual has been established for the above. While it is not possible to accurately predict or determine the eventual outcome of these matters, an adverse determination in one or more of these matters currently pending could have a material adverse effect on our financial condition, results of operations or cash flows.

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10. Stock-Based Compensation

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

	Three Months Ended March 31,	
	2013	2012
Research and development	$1,191	$947
Selling, general and administrative	2,155	1,345
Total	$3,346	$2,292

We granted the following stock options, RSUs and performance RSUs, or PRSUs to employees as follows:

	Three Months Ended March 31, 2013	
	Number of Shares	Weighted-Average Grant Date Fair Value Per Share
Stock options	888,778	$15.79
Restricted stock units	331,195	$19.42
Performance restricted stock units	62,000	$19.43

The options vest over a four year period and the RSUs vest annually over a three year period. The PRSUs vest, if at all, as follows: 50% of PRSUs vest upon achievement of OMONTYS cumulative net sales targets and 50% of PRSUs vest upon achievement of 110% of the Board-approved OMONTYS annual net sales targets for fiscal year 2013, 2014 and 2015.

Stock Option and Restricted Stock Unit Activity

The following tables summarize information about stock option and RSU activity for the three months ended March 31, 2013:

	Number of Shares	Weighted-Average Exercise Price (Per Share)(1)	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)(2)
Stock Options:				
Balances at December 31, 2012	4,857,536	$13.49		
Granted	888,778	18.83		
Exercised	(30,418)	8.90		
Forfeited	(870,849)	13.15		
Cancelled	(42,100)	16.09		
Balances at March 31, 2013	4,802,947	$14.55	5.76	$12
Options exercisable at March 31, 2013	2,210,438	$16.18	4.76	$12

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	Number of Shares	Weighted-Average Grant Date Fair Value (Per Share)(1)	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)(2)
Restricted Stock Units:				
Balances at December 31, 2012	296,723	$7.54		
Granted (time-based)	393,195	19.42		
Vested	(89,502)	7.58		
Forfeited	(163,596)	15.19		
Balances at March 31, 2013	436,820	$21.73	1.52	$726

(1) The weighted average price per share is determined using exercise price per share for stock options and fair value per share on grant date for restricted stock units.

(2) The aggregate intrinsic value is calculated as:

- For options: the difference between the exercise price of the option and the fair value of our common stock for in-the-money options at March 31, 2013.
- For restricted stock units: the difference between the grant date fair value of the unit and the fair value of our common stock for in-the-money units at March 31, 2013.

11. Restructuring Charge

March 2013 Restructuring

On February 23, 2013, we and Takeda announced a nationwide voluntary recall of OMONTYS as a result of postmarketing reports regarding safety concerns, including anaphylaxis, which can be life-threatening or fatal. As a result of the voluntary recall of OMONTYS, all marketing activities were suspended and we have also suspended or terminated manufacturing activities.

In March 2013, we commenced a re-organization plan to reduce operating costs and focus on the OMONTYS safety and other related FDA issues associated with the recall of the product. The reorganization plan included an initial reduction in force of approximately 230 employees (75% of our workforce), which included our commercial and medical affairs field organizations as well as other officers and employees. We incurred $8.2 million in restructuring charges, all of which are related to expenditures for one-time employee termination benefits. We recorded all of these charges during the first quarter of 2013.

In April 2013, as part of our ongoing efforts to restructure our operations in order to further reduce costs, we commenced a process to notify substantially all of the remaining 25% of our workforce of estimated dates of separation and we engaged an experienced restructuring firm. With the engagement of the restructuring firm, we plan to terminate the employment of our remaining executive officers, including our Chief Executive Officer and Chief Financial Officer, by June 15, 2013.

2011 Restructuring

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. 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 expected 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 SG&A expenses in the statement of operations.

The estimates underlying the fair value of the lease-related restructuring liability involved significant assumptions regarding the time required to contract with a subtenant, the amount of space we would be able to sublease, the range of potential sublease rates and the level of leasehold improvement expenditures that would be incurred to sublease the property.

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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 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 at December 31, 2012	$(29)	$—	$(29)
Restructuring charges accrued	—	8,216	8,216
Adjustments	—	(274)	(274)
Cash payments	4	(4,690)	(4,686)
Accretion	(1)	—	(1)
Balance at March 31, 2013	(26)	3,252	3,226
Less Current Portion	(17)	3,252	3,235
Long-term portion as of March 31, 2013	$(9)	$—	$(9)

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 condensed balance sheet.

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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, 2012 and our unaudited condensed financial statements for the three month period ended March 31, 2013.

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 "estimate," "project," "predict," "potential," "estimate," "future" and similar expressions intended to identify 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," and in "Management's Discussion and Analysis of Financial Conditions and Results of Operations" in Part I, Item 2 of this Form 10-Q. 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

Affymax, Inc., a Delaware corporation, was incorporated in July 2001. We are a biopharmaceutical company in the process of restructuring operations. In March 2012, the U.S. Food and Drug Administration, or FDA, approved the Company's first and only 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 has been the only once-monthly ESA available to the adult dialysis patient population in the U.S. We co-commercialized OMONTYS with our collaboration partner, Takeda Pharmaceutical Company Limited, or Takeda during 2012 until February 2013, when we and Takeda announced a nationwide voluntary recall of OMONTYS as a result of safety concerns. Effective April 1, 2013, we entered into an amendment of our collaboration with Takeda pursuant to which Takeda assumed full responsibility for OMONTYS, including responsibility for the ongoing recall and investigation with the FDA, and we granted them an exclusive license to OMONTYS in consideration for potential royalties and milestones.

Restructuring

In March 2013, we undertook plans to restructure our operations in order to reduce operating costs and focus on the OMONTYS safety and other related FDA issues associated with the recall of the product. In addition to transitioning many of the ongoing activities to our collaborator, Takeda, our plans included a significant reduction in force of approximately 230 employees (75% of our workforce), including our commercial and medical affairs field forces as well as other employees throughout the organization. We have recorded $8.2 million in restructuring charges related to the workforce reduction during the first quarter of 2013. As a result of this restructuring and the recall, we also recorded impairment changes of $5.1 million with respect to our property and equipment and intangible assets related

to our license from Janssen Biotech, Inc. (a subsidiary of Johnson & Johnson) and certain of its affiliated companies, collectively referred to as Janssen, in the first quarter of 2013.

In April 2013, as part of our ongoing efforts to restructure our operations in order to further reduce costs, we commenced a process to notify substantially all of the remaining 25% of our workforce of estimated dates of separation and we engaged an experienced restructuring firm. With the engagement of the restructuring firm, we announced our plan to terminate the employment of our remaining executive officers, including our Chief Executive Officer and Chief Financial Officer, by June 15, 2013.

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Takeda Amendment

Effective April 1, 2013, we and Takeda, collectively the Parties, entered into the Fourth Amendment, or the Amendment, to the February 13, 2006 and June 27, 2006 Collaboration and License Agreements to amend and restate the ongoing respective roles and responsibilities and related commitments and financial terms between the Parties, including the termination of the Collaboration and License Agreement dated as of February 13, 2006, under which we have granted Takeda a certain right and license for the development and commercialization in Japan of OMONTYS, as amended by the First Amendment, dated April 1, 2007, the Second Amendment, dated January 1, 2008 and the Third Amendment, dated November 7, 2011, as well as the related manufacturing supply, safety, quality and co-promotion agreements between the parties. The Amendment revised the economics from a profit-sharing arrangement to a milestone and royalty-based compensation structure to us effective as of April 1, 2013. This Amendment is part of our ongoing restructuring efforts resulting from the voluntary recall announced on February 23, 2013 related to OMONTYS, the suspension of U.S. marketing and promotional activities, and the ongoing investigation with the FDA. The arrangement with Takeda including the Amendment is referred to as the Arrangement.

The Amendment effectuated a transfer of regulatory responsibilities, including the OMONTYS New Drug Application, or NDA, and all manufacturing, and development responsibilities from us to Takeda prior to April 30, 2013 with related transition services and support which has been completed. Takeda agreed to reimburse us for certain personnel costs to assist in the transition and investigation activities for the month of April in order to support the planned transition. Takeda received a worldwide, exclusive royalty-bearing license under our and joint Takeda-Affymax patents to develop, manufacture and commercialize OMONTYS.

As a result of the Amendment, Takeda assumed full responsibility for OMONTYS, including the ongoing recall and investigation of OMONTYS as well as any subsequent decisions as to whether the product may be subject to reintroduction if Takeda is able to complete the investigation and address the safety concerns to the satisfaction of the FDA. If Takeda decides to reintroduce OMONTYS, all of which is highly uncertain, we are eligible to receive royalties and (i) potential commercial milestone payments totaling up to $180.0 million which consists of the following: (a) $10.0 million is payable upon the first commercial sale after reintroduction of OMONTYS in the U.S.; (b) $10.0 million and another $10.0 million relates to U.S. sales-based milestones, and (c) $150.0 million relates to sales-based milestones in amounts as previously disclosed outside of the U.S. but now including Japan as a result of the Amendment and (ii) a potential development milestone payment of $5.0 million payable either upon regulatory approval in the E.U. or Japan. The royalties are tiered in the range of 13% to 17% with respect to net sales in the U.S. and in the range of 13% to 24% depending on the level of net sales by Takeda worldwide outside of the U.S.

In 2012, we co-commercialized OMONTYS with Takeda. The commercial launch of the product occurred in April 2012. To commercialize OMONTYS, we established commercial and medical affairs infrastructures in 2012. The functions of our commercial and medical affairs infrastructures included marketing and sales, medical education, coverage and reimbursement and account management.

In 2012, we marketed our product primarily to dialysis organizations. Associated costs are included in selling, general and administrative costs or SG&A, in our accompanying financial statements.

In 2012, Takeda was responsible for account management, pricing and contracting. Specifically, Takeda had sole responsibility for invoicing and collection of receivables with regard to sales of OMONTYS. Takeda also had the rights and responsibility for establishing and modifying terms and conditions with customers with respect to the sale of OMONTYS in the U.S., including pricing discounts available to third-party payors, price adjustments and other allowable discounts and allowances. Both parties also had shared responsibilities such as joint marketing activities, business analytics and account management allocated by customer segments.

Prior to the Amendment, 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.

Loan Agreement

In March 2012, we entered into a loan and security agreement, or the Loan Agreement, with Oxford Finance LLC and Silicon Valley Bank, or, collectively, the Lenders, under which we borrowed $10.0 million. As of March 31, 2013, we had outstanding borrowings under the Loan Agreement with the Lenders of approximately $8.0 million. On April 3, 2013, we entered into a letter agreement, or Letter Agreement, relating to the Loan Agreement with the Lenders. Pursuant to the terms of the Letter Agreement: (i) we paid all amounts due and owing so as to discharge our obligations thereunder which totaled $9.8 million including principal, interest, final payment and prepayment fees, (ii) we waived any rights to seek additional credit

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extensions or unfunded commitments under the Loan Agreement, and (iii) the security interest granted to Lenders relating to substantially all of our assets, other than our intellectual property, was terminated.

Litigation

On February 27, 2013, a securities class action complaint was filed in the United States District Court for the Northern District of California, naming as defendants Affymax, Inc. or the Company, certain of its officers, Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals U.S.A., Inc. and Takeda Global Research & Development Center, Inc. A second complaint naming the same defendants was filed on March 6, 2013. The complaints, filed on behalf of purported stockholders of the Company, allege violations of Section 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder, in connection with allegedly false and misleading statements made by the defendants regarding the Company's business practices, financial projections and other disclosures between December 8, 2011 and February 22, 2013, or the Class Period. The plaintiff seeks to represent a class comprised of purchasers of the Company's common stock during the Class Period and seeks damages, costs and expenses and such other relief as determined by the Court. On March 19, 2013 and March 29, 2013, respectively, two derivative lawsuits were filed purportedly on behalf of the Company in California Superior Court for the County of Santa Clara naming certain of our officers and directors as defendants. The lawsuits allege that certain of the Company's officers and directors breached their fiduciary duties related to the clinical trials for OMONTYS and for representations regarding the Company's business health, which was tied to the success of OMONTYS. The lawsuits also asserts claims for unjust enrichment and corporate waste. Additional complaints may be filed against us and our directors and officers related to our recall of OMONTYS. Our management believes that we have meritorious defenses and intends to defend these lawsuits vigorously. However, these lawsuits are subject to inherent uncertainties, the actual cost may be significant, and we may not prevail. We believe we are entitled to coverage under our relevant insurance policies, subject to a retention, but coverage could be denied or prove to be insufficient.

Financial Outlook

We have experienced significant operating losses since inception. We expect to continue to incur substantial operating losses. We may never generate significant revenues and, even if we do generate revenue in the future, we may never achieve or sustain profitability. 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, milestone payments and profit equalization revenue from Takeda, issuance of notes payable, capital lease financings, interest earned on investments and limited license fees and royalties from licensing intellectual property. As of March 31, 2013, we had an accumulated deficit of $570.4 million. All of our revenue has been derived almost exclusively from collaboration revenue from Takeda. Collaboration revenue consists of milestone payments, profit equalization revenue related to our share of product profit or loss on OMONTYS, reimbursement of development and commercialization expenses, and revenue for API under our agreements with Takeda or collectively, the Arrangement. We derived most of our collaboration revenue in 2012 from milestone payments and profit equalization revenue. From inception to March 31, 2013, we have received $122.0 million of upfront license fees, $115.3 million in milestone payments and $300.2 million related to the profit equalization revenue, the reimbursement of development and commercialization expenses and purchase of API under our Arrangement with Takeda.

Our operations have consumed substantial amounts of cash since our inception. As a result of the February 23, 2013 nationwide voluntary recall of OMONTYS and the suspension of all marketing activities, there is significant uncertainty as to whether we will have sufficient existing cash, cash equivalents and investments to fund our operations for the next 12 months. Our liabilities exceed our assets. While we continue to reduce cash outflows, there is no assurance that we will be able to reduce our operating expenses enough to meet our existing obligations in a timely manner. If Takeda is unable to reintroduce the product or we are unable to obtain additional funding in the near future, our cash resources will rapidly be depleted and we will be required to materially reduce or suspend operations,

which would likely have a material adverse effect on our business, stock price and our relationships with third parties with whom we have business relationships, at least until additional funding is obtained. If we do not have sufficient funds to continue operations, we could be required to liquidate our assets, seek bankruptcy protection or other alternatives that would likely result in our receiving less than the value at which those assets are carried on our financial statements, and it is likely that investors will lose all or some of their investment in us. Any failure to dispel any continuing doubts about our ability to continue as a going concern make it more difficult to obtain required financing on favorable terms or at all, negatively affect the market price of our common stock and could otherwise have a material adverse effect on our business, financial condition and results of operations.

If Takeda is unable to rapidly identify and rectify the causes of the safety concerns to the satisfaction of the FDA, which is highly uncertain, OMONTYS may be permanently withdrawn from the market. As a result, we may be unable to continue our operations. In order to reintroduce OMONTYS, Takeda would have to complete their ongoing thorough investigation, identify the causes of the safety concerns and provide a suitable plan to the FDA for approval. Accordingly, there can be no assurance

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that Takeda can address the safety concerns and meet the requirements of the FDA for reintroduction. Moreover, even if OMONTYS could be reintroduced, the commercial prospects for this product may be permanently diminished and the product may no longer be commercially viable.

If Takeda is unable to identify quickly the causes of the OMONTYS safety concerns or raise additional funds when required or on acceptable terms, we may have to:

- discontinue operations;
- relinquish some or all of our existing rights to OMONTYS milestones, royalties or other existing rights; or
- pursue alternatives such as sale of the Company or its assets, a corporate merger, winddown of operations or even bankruptcy proceedings.

The recall of OMONTYS has severely harmed our business, financial condition and prospects as a going concern. The recall has also limited our access to funds and the resources that may be required in order to address the safety concerns. If Takeda is not able to reintroduce OMONTYS, this will result in elimination of revenue in future periods. Even if Takeda is successful in reintroducing and commercializing OMONTYS in the future, there can be no assurance that revenues will ramp up rapidly enough to offset operating losses and repayment of debts. Further challenges or delays to potential reintroduction and commercialization of OMONTYS may require us to raise additional funding to continue operations. We may seek to raise additional funds through public or private financing, strategic partnerships or other arrangements, however, such sources of funds may not be available to us at all. Even if available, any additional equity financing would be dilutive to stockholders and debt financing, if available, may involve restrictive covenants that may limit our ability to conduct our business and increase our risk of defaults. 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 funding may not be available to us on acceptable terms, or at all.

Results of Operations

Revenue

During the commercialization period, which commenced in June 2011 through March 31, 2013 we received reimbursement for certain collaboration expenses. Takeda bore responsibility for 70% of third-party expenses related to U.S. development and 50% of third party expenses related to the commercialization of OMONTYS in the U.S. incurred by us and we were responsible for the reciprocal amount of development and commercialization expenses. Certain employee-related expenses supporting preparation for commercialization of OMONTYS in the U.S. were also shared equally. Such employee-related costs included the cost of certain employees that are 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 employees in clinical, regulatory and other development functions supporting any post-marketing development activity required by the FDA or separately agreed to by the parties in the U.S. were generally shared equally.

OMONTYS sales by Takeda commenced in September 2012. Subsequent to the launch of OMONTYS and recognition of product revenue by Takeda, our collaboration revenue consisted of profit equalization revenue generated from our Arrangement with Takeda, milestone payments, reimbursements of certain eligible development and commercial expenses, net of Takeda's own eligible expenses, and revenue previously deferred related to payments we received associated with previously expensed API, which have been sold by Takeda. Revenue from profit

equalization is calculated on a quarterly basis as the amount required so that the profit or loss realized by both Affymax and Takeda on OMONTYS equates to 50% of the total product profit or loss. Total product profit or loss on OMONTYS is calculated as gross product sales recorded by Takeda, less the following deductions recorded by Takeda: rebates and discounts, cost of goods and other gross-to-net adjustments incurred by Takeda, royalty expense incurred by us, commercialization expenses (full-time equivalents or 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 both Takeda and us.

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Revenue as compared to the prior year is as follows (in thousands):

	Three Months Ended March 31,		Percent Change
	2013	2012	2013/2012
Collaboration revenue	$839	$63,205	(99)%
License and royalty revenue	5	4	25 %
Total revenue	$844	$63,209	(99)%

Revenue decreased $62.4 million from $63.2 million for the three months ended March 31, 2012 to $0.8 million for the three months ended March 31, 2013. The decrease in collaboration revenue for the three months ended March 31, 2013 compared to the three months ended March 31, 2012 was primarily due to suspension of all marketing activities, as a result of the product recall of OMONTYS. During the three months ended March 31, 2012, we recognized $58.0 million in milestone payments from Takeda related to FDA approval of OMONTYS, the European Medicines Agency, or EMA's acceptance for review of the Marketing Authorization Application or MAA submitted by Takeda.

The following table presents our collaboration revenue, by revenue type, for the periods presented (in thousands):

	Three Months Ended March 31,	
	2013	2012
Profit equalization revenue [1]	$—	$—
Milestone payments	—	58,000
Net expense reimbursement after CAPM	839	5,205
Total collaboration revenue	$839	$63,205

[1] The final Q1 profit equalization amount was reflected under collaboration cost reimbursement; see table below for details regarding the Q1 final profit equalization payment.

On February 23, 2013, we and Takeda announced a nationwide voluntary recall of OMONTYS as a result of postmarketing reports regarding safety concerns, including anaphylaxis, which can be life-threatening or fatal. As a result of the voluntary recall of OMONTYS, all marketing activities were suspended.

Effective April 1, 2013, we and Takeda or the Parties, entered into the Amendment, to the February 13, 2006 and June 27, 2006 Collaboration and License Agreements to amend and restate the ongoing respective roles and responsibilities and related commitments and financial terms between the Parties, including the termination of the Collaboration and License Agreement dated as of February 13, 2006, under which we have granted Takeda a certain right and license for the development and commercialization in Japan of OMONTYS, as amended by the First Amendment, dated April 1, 2007, the Second Amendment, dated January 1, 2008 and the Third Amendment, dated November 7, 2011, as well as the related manufacturing supply, safety, quality and co-promotion agreements between the parties. The Amendment revised the economics from a profit-sharing arrangement to a milestone and royalty-based compensation structure to us effective as of April 1, 2013. This Amendment is part of our ongoing restructuring efforts resulting from the voluntary recall announced on February 23, 2013 related to OMONTYS, the suspension of U.S. marketing and promotional activities, and the ongoing investigation with the FDA.

The Amendment effectuated a transfer of regulatory responsibilities, including the OMONTYS NDA, and all manufacturing, and development responsibilities from us to Takeda as soon as practicable but in any event prior to April 30, 2013 with related transition services and support, which has been completed. As of April 30, 2013, all transition activities have been completed. Takeda agreed to reimburse us for certain personnel costs to assist in the transition and investigation activities for the month of April in order to support the planned transition. Takeda received a worldwide, exclusive royalty-bearing license under our and joint Takeda-Affymax patents to develop, manufacture and commercialize OMONTYS.

As a result of the Amendment, Takeda assumed full responsibility for OMONTYS, including the ongoing recall and investigation of OMONTYS as well as any subsequent decisions as to whether the product may be subject to reintroduction if Takeda is able to complete the investigation and address the safety concerns to the satisfaction of the FDA. If Takeda decides to reintroduce OMONTYS, all of which is highly uncertain, we are eligible to receive royalties and (i) potential commercial milestone payments totaling up to $180.0 million which consists of the following: (a) $10.0 million is payable upon the first commercial sale after reintroduction of OMONTYS in the U.S.; (b) $10.0 million and another $10.0 million relates to U.S. sales-based milestones, and (c) $150.0 million relates to sales-based milestones in amounts as previously disclosed outside of the U.S.

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but now including Japan as a result of the Amendment and (ii) a potential development milestone payment of $5 million payable either upon regulatory approval in the E.U. or Japan. The royalties are tiered in the range of 13% to 17% with respect to net sales in the U.S. and in the range of 13% to 24% depending on the level of net sales by Takeda worldwide outside of the U.S.

The following table presents the net impact of our portion of the Takeda Q1 expenses and reimbursements from Takeda associated with the Q1 profit equalization payment (in thousands):

	Three Months Ended March 31, 2013
Takeda cost incurred:	
Net loss for OMONTYS	$(793)
Write off of inventory on hand at Takeda	(15,881)
Recall related costs [1]	(529)
Loss on firm purchase commitments	(653)
Asset impairment	(6,171)
Commercial and development expense reimbursement	(3,202)
Affymax cost incurred:	
Loss on firm purchase commitments and inventory impairment	13,922
Commercial expense reimbursement	10,295
Development expense reimbursement	1,689
API reimbursement	2,182
Other	21
Total Amount Due to Affymax from Takeda for Q1 Profit Equalization[2]	$880

(1) Per the Arrangement, the allocation of expenses incurred in connection with a recall is based on the source of the defect if determinable. The total costs of recalling the product, which is primarily composed of costs to a third-party to gather, store, and return the product to Takeda was $1.1 million, all incurred by Takeda of which we were charged half as a part of the Q1 profit equalization payment in the first quarter of 2013. The Arrangement provides that the allocation of expenses incurred in connection with a recall is to be based on the source of the defect, if determinable. If the recall is determined to be due to manufacturing defect of bulk API, then we are required to bear all such recall expenses. If the recall is determined to be due to manufacturing defect of finished product, then Takeda is required to bear all such recall expenses. If the recall is determined to be due to both manufacturing defects of the API and the manufacturing of the final drug product, then we and Takeda are required to share recall expenses proportionally. Given the ongoing nature of the investigation, the cause of the recall is not yet known and the range of recall costs that we may ultimately be responsible for may be up to the full amount of the costs incurred.

(2) The profit equalization payment relating to the quarter ended March 31, 2013 is the last profit equalization payment under the Arrangement. Effective with the Amendment, there will be no more profit equalization payments. We and Takeda agreed that the Q1 profit equalization payment includes all commercial and US development expenses that the parties agreed to share equally in accordance to the terms of the Arrangement. We and Takeda acknowledged that the $0.9 million payment paid to us by Takeda settles all obligations between us with respect to commercial expenses to be shared under the Arrangement including all expenses owed by either of us to third parties, including contract manufacturing.

Cost of Manufacturing API for the Collaboration

The cost of manufacturing API is not reflected in our statement of comprehensive (loss) income as we were reimbursed by Takeda for all costs we incurred with third parties. At the time of FDA approval in March 2012, we had produced approximately $20.5 million of commercial grade API that had been expensed previously as R&D expenses.

As of December 31, 2012, we had a remaining balance of $19.8 million in deferred revenue related to previously expensed API shipped to Takeda. As a result of the recall, the remaining balance of deferred revenue has been reversed during the three months ended March 31, 2013.

Research and Development Expenses

The major components of R&D expenses include clinical trial expenses, consulting and other third-party costs, API manufacturing costs incurred prior to FDA approval, salaries and employee benefits, license fees paid to third parties for use of their intellectual property, supplies and allocations of various overhead and occupancy costs. Clinical trial expenses include, but are not limited to, contract research organization, or CRO, and investigator fees, site costs, comparator drug costs and clinical research organization costs. All R&D expenses are expensed as incurred. R&D expenses, as compared to the prior year are as follows (in thousands):

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	Three Months Ended March 31,		Percent Change
	2013	2012	2013/2012
Research and development expenses	$9,736	$16,107	(40)%

R&D expenses declined $6.4 million from 2012 to 2013. The decrease in R&D expenses in 2013 compared to 2012 was primarily due to reduced costs resulting from the reduction of development activities related to OMONTYS. 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.

The Amendment with Takeda effectuated a transfer of regulatory responsibilities, including the OMONTYS NDA, and all manufacturing, and development responsibilities from us to Takeda as soon as practicable but in any event prior to April 30, 2013 with related transition services and support which has been completed. Takeda has agreed to reimburse us for certain personnel costs to assist in the transition and investigation activities for the month of April in order to support the planned transition. As a result of the Amendment, Takeda assumed full responsibility for OMONTYS, including the ongoing recall and investigation of OMONTYS as well as any subsequent decisions as to whether the product may be subject to reintroduction if Takeda is able to complete the investigation and address the safety concerns to the satisfaction of the FDA.

Selling, General and Administrative Expenses

SG&A expenses consist principally of salaries, employee benefits, consulting, professional fees for legal, auditing and tax services, marketing and commercial support for OMONTYS, allocation for overhead and occupancy costs and royalty expense. SG&A, expenses as compared to the prior year are as follows (in thousands):

	Three Months Ended March 31,		Percent Change
	2013	2012	2013/2012
Selling, general and administrative expenses	$24,326	$15,582	56%

SG&A expenses increased $8.7 million from 2012 to 2013. The increase in SG&A expenses in 2013 compared to 2012 was primarily due to higher commercialization expenses related to our field sales force and other activities to support our commercialization efforts.

As a result of the voluntary recall of OMONTYS, all product was recalled and all marketing activities were suspended. As a result of the Amendment, Takeda assumed full responsibility for OMONTYS, including the ongoing recall and investigation of OMONTYS as well as any subsequent decisions as to whether the product may be subject to reintroduction if Takeda is able to complete the investigation and address the safety concerns to the satisfaction of the FDA.

Collaboration Cost Reimbursement

Collaboration cost reimbursement as compared to the prior year are as follows (in thousands):

	Three Months Ended March 31,		Percent Change
	2013	2012	2013/2012
Collaboration cost reimbursement	$(20,378)	$—	N/A

Prior to the Amendment, we initiated orders for API with our contract manufacturing organizations, or CMOs based on forecasts from Takeda, which were based on expected demand for OMONTYS. Orders generally have commenced once there was a contractual commitment for the API from Takeda. As a result of the inability to sell OMONTYS and the uncertainty of future revenues, we have written down our API inventory and prepayments for API being produced by our CMOs to a net realizable value of zero and recorded a $10.4 million impairment charge related to this writedown during the year ended December 31, 2012. We have also recorded a $34.6 million loss on firm purchase commitments by applying the same lower of cost or market approach that is used to value inventory during the same period. Of the total $45.0 million charge for impairment of inventory and loss on CMO purchase commitments

recorded at year end, we recorded a benefit of $20.4 million, primarily related to the Takeda Q1 profit equalization payment. Related to the $45.0 million charge for impairment of inventory and loss on CMO purchase commitments in 2012, we had the right under the Arrangement to submit to Takeda for reimbursement for a portion of such expenses. However because we had not presented such amounts to Takeda for reimbursement, and such reimbursements would be subject to Takeda's approval, we had not recorded a receivable for such amounts as of December 31, 2012.

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As of March 31, 2013, we recognized future purchase commitments amounting to $32.9 million. These future commitments are comprised of $5.4 million for firm purchase commitments of PEG, and the remaining $27.5 million of manufacturing obligations relate to API. If we are able to settle these obligations for less than the contractual amounts, we may have favorable adjustments to our operating results in the future.

As a result of the Amendment, Takeda assumed full responsibility for OMONTYS, including the ongoing recall and investigation of OMONTYS as well as any subsequent decisions as to whether the product may be subject to reintroduction if Takeda is able to complete the investigation and address the safety concerns to the satisfaction of the FDA.

Impairment of Prepaid Expenses, Fixed Assets and Intangible Assets

Impairment of prepaid expenses, fixed assets and intangible assets and percentage changes as compared to the prior year are as follows (in thousands):

	Three Months Ended March 31,		Percent Change
	2013	2012	2013/2012
Impairment of prepaid expenses, fixed assets and intangible assets	$5,140	—	N/A

As a result of the product recall and related restructuring activities that occurred in the quarter ended March 31, 2013, we incurred impairment charges of $5.1 million. The impairment related to our prepaid expenses, fixed assets and our intangible assets related to our license with Janssen was $1.3 million, $1.9 million and $1.9 million respectively during the first quarter of 2013.

Restructuring Charges

Restructuring charges and percentage changes as compared to the prior year are as follows (in thousands):

	Three Months Ended March 31,		Percent Change
	2013	2012	2013/2012
Restructuring charges	$8,216	—	N/A

In March 2013, we undertook plans to reorganize our operations in order to reduce operating costs and focus on the OMONTYS safety and other related FDA issues associated with the recall of the product. In addition to transitioning many of the ongoing activities to our collaborator, Takeda, our plans included a significant reduction in force of approximately 230 employees (75% of our workforce), including our commercial and medical affairs field forces as well as other employees throughout the organization. We have incurred $8.2 million in restructuring charges related to the workforce reduction during the first quarter of 2013.

In April 2013, as part of our ongoing efforts to restructure our operations in order to further reduce costs, we commenced a process to notify substantially all of the remaining 25% of our workforce of estimated dates of separation and we engaged an experienced restructuring firm. With the engagement of the restructuring firm, we announced our plan to terminate the employment of our remaining executive officers, including our Chief Executive Officer and Chief Financial Officer, by June 15, 2013.

Interest Income (Expense), Net

Interest income (expense), net as compared to prior years are as follows (in thousands):

	Three Months Ended March 31,		Percent Change	
	2013	2012	2013/2012	
Interest income	$15	$13	15	%
Interest expense	$(492)	$(57)	763	%
Interest income (expense), net	$(477)	$(44)	984	%

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The increase in interest expense, net was due primarily to interest expense related to our notes payable with the Lenders and our launch allowance with Takeda for the three months ended March 31, 2013 as compared to the same period in 2012.

On April 3, 2013, we entered into a Letter Agreement, relating to the Loan Agreement, with the Lenders. Pursuant to the terms of the Letter Agreement: (i) we paid all amounts due and owing so as to discharge our obligations thereunder which totaled $9.8 million including principal, interest, final payment and prepayment fees, (ii) we waived any rights to seek additional credit extensions or unfunded commitments under the Loan Agreement, and (iii) the security interest granted to Lenders relating to substantially all of our assets, other than our intellectual property, was terminated. As a result of the April loan payoff we expect to incur $1.6 million in interest expense in the quarter ended June 30, 2013.

Other Income (Expense), Net

Other income (expense), net as compared to prior years are as follows (in thousands):

	Three Months Ended March 31,		Percent Change
	2013	2012	2013/2012
Other income (expense), net	$—	$(22)	(100)%

Other expense, net, for the three months ended March 31, 2012 includes a $30,000 loss on disposal of fixed assets.

Provision for Income Taxes

We are subject to federal and state income taxes. We did not record any income tax expense for three months ended March 31, 2013 other than the minimum statutory California tax due to the anticipated tax loss position for the year ended December 31, 2013. While we did generate net income during the first quarter of 2012 due to significant milestone payments received in the period, we were in a net operating loss position for 2012 and therefore did not recorded any federal or state taxes, other than a benefit of federal statute of limitations lapsing on a previously reserved tax benefit and the minimum statutory California tax, for the three months ended March 31, 2012.

Liquidity and Capital Resources

Our cash, cash equivalents, and investments at March 31, 2013 and December 31, 2012 are as follows (in thousands):

	March 31, 2013	December 31 2012
Cash and cash equivalents	$46,615	$68,265
Short-term investments	$7,221	$9,717
Long-term investments	$1,213	2,323

As of March 31, 2013, we had $56.2 million in cash, cash equivalents, restricted cash and marketable securities. Our cash and investment balances are held in a variety of interest bearing instruments, including corporate debt securities, and money market funds. Cash in excess of immediate requirements is invested in accordance with our investment policy primarily with a view to liquidity and capital preservation. As of March 31, 2013, we had total debt of $8.0 million, which consists of the face value of the notes payable less the net debt discount associated with the issuance of warrants to our Lenders.

Working Capital (Deficit). Working capital (deficit) was $(14.1) million at March 31, 2013, a decrease of $17.5 million from working capital as of December 31, 2012.

As a result of the February 23, 2013 nationwide voluntary recall of OMONTYS and the suspension of all marketing activities, there is significant uncertainty as to whether we will have sufficient existing cash, cash equivalents and

investments to fund our operations for the next 12 months. Our liabilities exceed our assets. If we were to reduce cash outflows, there is no assurance that we will be able to reduce our operating expenses enough to meet our existing obligations. If Takeda is not able to reintroduce the product or we are not able to obtain additional funding in the near future, our cash resources will rapidly be depleted and we will be required to materially reduce or suspend operations, which would likely have a material adverse effect on our business, stock price and our relationships with third parties with whom we have business relationships. If we do not have sufficient funds to continue operations, we could be required to liquidate our assets, including relinquish some or all of our existing rights to OMONTYS, seek bankruptcy protection or other alternatives that would likely result in receiving less than the

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value at which those assets are carried on our financial statements, and it is likely that investors will lose all or some of their investment in us. Any failure to dispel any continuing doubts about our ability to continue as a going concern could adversely affect our ability to enter into collaborative relationships with business partners, make it more difficult to obtain required financing on favorable terms or at all, negatively affect the market price of our common stock and could otherwise have a material adverse effect on our business, financial condition and results of operations.

In March 2013, we undertook plans to reorganize our operations in order to reduce operating costs and focus on the OMONTYS safety and other related FDA issues associated with the recall of the product. In addition to transitioning many of the ongoing activities to our collaborator, Takeda, our plans included a significant reduction in force of approximately 230 employees (75% of our workforce), including our commercial and medical affairs field forces as well as other employees throughout the organization. We incurred approximately $8.2 million of restructuring charges related to the workforce reduction during the first quarter of 2013. As a result of this restructuring and the recall, we also recorded impairment changes of $5.1 million with respect to our prepaid expenses, property and equipment and intangible assets related to our license from Janssen in the first quarter of 2013.

In April 2013, as part of our ongoing efforts to restructure our operations in order to further reduce costs, we commenced a process to notify substantially all of the remaining 25% of our workforce of estimated dates of separation and we engaged an experienced restructuring firm. With the engagement of the restructuring firm, we announced our plan to terminate the employment of our remaining executive officers, including our Chief Executive Officer and Chief Financial Officer, by June 15, 2013.

Effective April 1, 2013, we and Takeda, collectively the Parties, entered into the Amendment to the February 13, 2006 and June 27, 2006 Collaboration and License Agreements to amend and restate the ongoing respective roles and responsibilities and related commitments and financial terms between the Parties, including the termination of the Collaboration and License Agreement dated as of February 13, 2006, under which we have granted Takeda a certain right and license for the development and commercialization in Japan of OMONTYS, as amended by the First Amendment, dated April 1, 2007, the Second Amendment, dated January 1, 2008 and the Third Amendment, dated November 7, 2011, as well as the related manufacturing supply, safety, quality and co-promotion agreements between the parties. The Amendment revised the economics from a profit-sharing arrangement to a milestone and royalty-based compensation structure to us effective as of April 1, 2013. The Amendment is part of our ongoing restructuring efforts resulting from the voluntary recall announced on February 23, 2013 related to OMONTYS, the suspension of U.S. marketing and promotional activities, and the ongoing investigation with the FDA.
The Amendment effectuated a transfer of regulatory responsibilities, including the OMONTYS NDA, and all manufacturing, and development responsibilities from us to Takeda prior to April 30, 2013 with related transition services and support, which has been completed. Takeda agreed to reimburse us for certain personnel costs to assist in the transition and investigation activities for the month of April in order to support the planned transition. Takeda received a worldwide, exclusive royalty-bearing license under our and joint Takeda-Affymax patents to develop, manufacture and commercialize OMONTYS.
As a result of the Amendment, Takeda assumed full responsibility for OMONTYS, including the ongoing recall and investigation of OMONTYS as well as any subsequent decisions as to whether the product may be subject to reintroduction if Takeda is able to complete the investigation and address the safety concerns to the satisfaction of the FDA. If Takeda decides to reintroduce OMONTYS, all of which is highly uncertain, we are eligible to receive royalties and (i) potential commercial milestone payments totaling up to $180.0 million which consists of the following: (a) $10.0 million is payable upon the first commercial sale after reintroduction of OMONTYS in the U.S.; (b) $10.0 million and another $10.0 million relates to U.S. sales-based milestones, and (c) $150.0 million relates to sales-based milestones in amounts as previously disclosed outside of the U.S. but now including Japan as a result of the Amendment and (ii) a potential development milestone payment of $5 million payable either upon regulatory approval in the E.U. or Japan. The royalties are tiered in the range of 13% to 17% with respect to net sales in the U.S. and in the range of 13% to 24% depending on the level of net sales by Takeda worldwide outside of the U.S.

In view of our limited resources and funds, we plan to explore various strategic alternatives, including a sale of the Company or our assets or a corporate merger. We are considering all possible alternatives, including further restructuring activities, wind-down of operations or even bankruptcy proceedings. If the recall is not lifted and Takeda is not able to reintroduce OMONTYS, this will result in a severe decrease to our revenue in future periods. Even if Takeda is successful in reintroducing and commercializing OMONTYS in the future, there can be no assurance that revenues will ramp up rapidly enough to offset operating losses and repayment of debts. Further challenges or delays to potential reintroduction and commercialization of OMONTYS may require us to raise additional funding to successfully reintroduce and commercialize OMONTYS. We may seek to raise additional funds through public or private financing, strategic partnerships or other

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arrangements. Any additional equity financing would be dilutive to stockholders and debt financing, if available, may involve restrictive covenants that may limit our ability to conduct our business and increase our risk of defaults. The market may take into consideration of the recent recall of OMONTYS, which recall is described under the caption "OMONTYS Voluntary Recall" in "Item 1. Business" of our Annual Report on Form 10-K which may negatively affect our ability to obtain additional funding. 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 reintroduce and commercialize OMONTYS, and funding may not be available to us on acceptable terms, or at all.

Our independent registered public accounting firm, in their most recent audit report, expressed substantial doubt about our ability to continue as a going concern.

Since our inception, we have financed our operations through sale of capital stock, license fees, milestone payments, reimbursement for development and commercial expenses, profit equalization revenue for OMONTYS, and manufacturing costs from collaborative partners, issuance of notes payable, capital lease financing, interest earned on investments and limited license fees and royalties from licensing intellectual property. From inception through March 31, 2013, we have received net proceeds of $458.8 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.

Due to our announcement of our voluntary recall of OMONTYS in February 2013, there has been an extremely high volume of trading of our stock, which has caused a significant drop in the value of our stock. As a result of the large trading volume, there may be a shift of ownership amongst our 5% stockholders that could result in an ownership change, under Section 382 of the Internal Revenue Code of 1986, as amended. Under Section 382, a corporation that undergoes an ownership change, as defined by the Internal Revenue Code, may be subject to significant limitations on its ability to utilize its net operating losses or NOLs, and tax credits accumulated prior to the ownership change to offset future taxable income or tax liabilities. We are currently in the process of assessing the impact. At March 31, 2013, deferred tax assets were offset by a valuation allowance except to the extent of possible taxable income in an earlier period.

Financing Agreements

Loan Agreement. In March 2012, we entered into the Loan Agreement, with the Lenders, under which we borrowed $10.0 million. As of March 31, 2013, we had outstanding borrowings under the Loan Agreement with the Lenders of approximately $8.0 million. On April 3, 2013, we entered into a Letter Agreement, relating to the Loan Agreement dated March 26, 2012, with the Lenders. Pursuant to the terms of the Letter Agreement: (i) we paid all amounts due and owing so as to discharge our obligations thereunder totaling $9.8 million including principal, interest, final payment and prepayment fees, (ii) we waived any rights to seek additional credit extensions or unfunded commitments under the Loan Agreement, and (iii) the security interest granted to Lenders relating to substantially all of our assets, other than our intellectual property, was terminated.

Funding from our Collaboration Partner

We have received cumulative amounts of $122.0 million of upfront license fees, $115.3 million in milestone payments and $300.2 million related to profit equalization revenue, the reimbursement of development and commercialization expenses and purchase of API under our Arrangement with Takeda.

In early 2013 and in consultation with the FDA, we and Takeda voluntarily recalled OMONTYS nationwide from the market as a result of post-marketing reports regarding safety concerns, including anaphylaxis, which can be life-threatening or fatal. In connection with the recall, we and Takeda suspended all promotional and marketing activities for OMONTYS. Effective April 1, 2013, we and Takeda, and collectively the Parties, entered into the Amendment, to the February 13, 2006 and June 27, 2006 Collaboration and License Agreements to amend and restate the ongoing respective roles and responsibilities and related commitments and financial terms between the Parties, including the termination of the Collaboration and License Agreement dated as of February 13, 2006, under which we

have granted Takeda a certain right and license for the development and commercialization in Japan of OMONTYS, as amended by the First Amendment, dated April 1, 2007, the Second Amendment, dated January 1, 2008 and the Third Amendment, dated November 7, 2011, as well as the related manufacturing supply, safety, quality and co-promotion agreements between the parties. The Amendment revised the economics from a profit-sharing arrangement to a milestone and royalty-based compensation structure to us effective as of April 1, 2013, and is part of our ongoing restructuring efforts resulting from the voluntary recall announced on February 23, 2013 related to OMONTYS, the suspension of U.S. marketing and promotional activities, and the ongoing investigation with the FDA.

The Amendment effectuated a transfer of regulatory responsibilities, including the OMONTYS NDA, and all manufacturing, and development responsibilities from us to Takeda prior to April 30, 2013 with related transition services and support which has been completed. Takeda agreed to reimburse us for certain personnel costs to assist in the transition and

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investigation activities for the month of April in order to support the planned transition. Takeda received a worldwide, exclusive royalty-bearing license under our and joint Takeda-Affymax patents to develop, manufacture and commercialize OMONTYS.
As a result of the Amendment, Takeda assumed full responsibility for OMONTYS, including the ongoing recall and investigation of OMONTYS as well as any subsequent decisions as to whether the product may be subject to reintroduction if Takeda is able to complete the investigation and address the safety concerns to the satisfaction of the FDA.

Eligible Profit Equalization Profit and Loss from our Collaboration Partner.
As part of the Amendment between us and Takeda, both Parties agreed that they will no longer share expenses related to third-party development (70/30 split) and commercialization (50/50 split) as of April 1, 2013. Any expenses incurred by either us or Takeda after April 1, 2013 shall be the responsibility of the respective party and neither us or Takeda has the right to share expenses with each other.
As a result of the voluntary recall of OMONTYS in February 2013, all marketing activities were suspended. As part of the Amendment with Takeda, the profit equalization revenue for the three months ended March 31, 2013 will be the final profit equalization payment under the Arrangement. Upon signing the Amendment with Takeda, the economics of the collaboration changed from a profit sharing arrangement to a milestone and royalty-based compensation structure to us, effective April 1, 2013.
As a result of the Amendment, Takeda assumed full responsibility for OMONTYS, including the ongoing recall and investigation of OMONTYS as well as any subsequent decisions as to whether the product may be subject to reintroduction if Takeda is able to complete the investigation and address the safety concerns to the satisfaction of the FDA.
Profit Equalization Revenue/Loss. As part of the Amendment with Takeda, the profit equalization revenue for the three months ended March 31, 2013 will be the final profit equalization payment under the Arrangement. Upon signing the Amendment with Takeda, the economics of the collaboration changed from a profit sharing arrangement to a milestone and royalty-based compensation structure to us, effective April 1, 2013.

Launch Allowance. Takeda funded the first $20.0 million of U.S. commercial expenses. Amounts received under the launch allowance are non-refundable. As part of the launch allowance, under the Amendment, Takeda is entitled to deduct up to 8% from any payments made to us under the royalty and milestone provision until they have recouped an amount equal to $11.0 million (see Note 3 of Notes to Condensed Financial Statements). To date, Takeda deducted a total of $2.8 million against the profit equalization. Future royalties, if any, may be offset against the launch allowance which is classified as Advance from Takeda in the condensed balance sheet.

API Payments. Under the terms of the API Supply Agreement, we are responsible for the manufacture and supply of all quantities of API to be used in the development and commercialization of OMONTYS worldwide. Takeda reimburses us for our cost of API plus 20%. As of December 31, 2012 we had a remaining balance of $19.8 million recorded as an Advance from Takeda which is related to deferred revenue on API shipped to Takeda. As a result of the recall and the impairment charges recorded on the OMONTYS inventory during 2012, the remaining balance of deferred revenue has been reversed as of March 31, 2013.

Milestone Payments. As a result of the Amendment, Takeda assumed full responsibility for OMONTYS, including the ongoing recall and investigation of OMONTYS as well as any subsequent decisions as to whether the product may be subject to reintroduction if Takeda is able to complete the investigation and address the safety concerns to the satisfaction of the FDA. If Takeda decides to reintroduce OMONTYS, all of which is highly uncertain, we are eligible to receive royalties and (i) potential commercial milestone payments totaling up to $180.0 million consisting of the following: (a) $10.0 million is payable upon the first commercial sale after reintroduction of OMONTYS in the U.S.; (b) $10.0 million and another $10.0 million relates to U.S. sales-based milestones, and (c) $150.0 million relates to sales-based milestones outside of the U.S. as disclosed below but now including Japan as a result of the Amendment

and (ii) a potential development milestone payment of $5 million payable either upon regulatory approval in the E.U. or Japan. The royalties are tiered in the range of 13% to 17% with respect to net sales in the U.S. and in the range of 13% to 24% depending on the level of net sales by Takeda worldwide outside of the U.S. Although we are eligible to receive future milestones from Takeda, timing and amounts of future milestone payments, if any, are highly uncertain due to the recall.

Expense Reimbursement Payments. Through March 31, 2013, we were eligible to receive reimbursement from Takeda for 70% of all third-party expenses related to U.S. development in the U.S. (See Note 3 of Notes to Condensed Financial Statements). As part of the Amendment between us and Takeda, both Parties agreed that they will no longer share expenses related to third-party development (70/30 split) and commercialization (50/50 split) as of April 1, 2013. Any expenses incurred

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by either us or Takeda after April 1, 2013 shall be the responsibility of the respective party and neither us or Takeda has the obligation to share expenses with each other.

Settlement and License Agreement

In November 2011, we entered into the Settlement and License Agreement with Janssen, which required 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 U.S. 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. As a result of the product recall and related restructuring activities that occurred in March 2013, we incurred impairment charges of $1.9 million related to our license with Janssen during the first quarter of 2013.

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 agreed to pay up to $6.5 million in additional milestones to us in consideration of the upfront and milestone payments that we are required to make to Janssen under the Settlement and License Agreement (see Note 4 of Notes to Condensed Financial Statements). These milestones were substantive and at risk at the time that we entered into the amendment with Takeda. $5.25 million of these milestones were earned based on regulatory and commercial events in the U.S. and the remaining $1.25 million tied to regulatory events in the E.U., which was eliminated as part of the Amendment. During the first quarter of 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 was 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 and if it is approved in those regions.

Cash Flows During the Three Months Ended March 31, 2013 and 2012

In summary, our cash flows for the periods presented are as follows (in thousands):

	Three Months Ended March 31,	
	2013	2012
Net cash used in operating activities	$(24,620)	$(16,999)
Net cash provided by investing activities	3,600	11,127
Net cash provided by (used in) financing activities	(630)	11,310

Net cash used in operating activities for the three months ended March 31, 2013 and 2012 was $24.6 million and $17.0 million, respectively. Net cash used in operations for the three months ended March 31, 2013 reflects our net loss, noncash credit related to collaboration cost reimbursement and changes in accrued liabilities associated with compensation related accruals partially offset by the benefit of payments received from Takeda related to profit equalization revenue, and reimbursement for development and commercial expense and purchases of API by Takeda. Net cash used in operating activities for the three months ended March 31, 2012 was primarily due to changes in our receivable to Takeda as a result of the achievement of milestones related to FDA approval of OMONTYS which had

not yet been received and changes in other assets related to OMONTYS intellectual property rights and warrant costs associated with our notes payable. These were offset by our net income for the quarter, noncash expenses associated with depreciation and stock compensation expense and an increase in Advance from Takeda.

Net cash provided by investing activities for the three months ended March 31, 2013 of $3.6 million was due to proceeds from maturities of investments. Net cash provided by investing activities for the three months ended March 31, 2012 of $11.1 million was primarily due to proceeds from maturities of investments partially offset by purchases of property and equipment.

Net cash used in financing activities for the three months ended March 31, 2013 was primarily attributable to repayment of our note payable of $0.9 million partially offset by proceeds of $0.3 million received from the issuance of common stock upon

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exercise of stock options. Net cash provided by financing activities for the three months ended March 31, 2012 was primarily attributable to proceeds of $10.0 million received from the issuance of a notes payable and $1.3 million received from the issuance of common stock upon exercise of stock options.

In early 2013 and in consultation with the FDA, we and Takeda, voluntarily recalled OMONTYS nationwide from the market as a result of post-marketing reports regarding safety concerns, including anaphylaxis, which can be life-threatening or fatal. In connection with the recall, we and Takeda suspended all promotional and marketing activities for OMONTYS. If Takeda is unable to identify and rectify the causes of the safety concerns to the satisfaction of the FDA, OMONTYS may be withdrawn from the market and we may be unable to continue our operations as a going concern.

Contractual Obligations and Significant Commitments

Our future contractual obligations, including financing costs, at March 31, 2013, are as follows (in thousands):

	Payments Due by Period				
Contractual Obligations	Total	2013	2014 - 2015	2016 -2017	Thereafter
Operating lease obligations (1)	$6,444	$3,178	$3,266	$—	$—
Notes payable (2)	9,099	2,829	6,270	—	—
Interest payments on notes payable, fixed rate (2)	1,498	537	961	—	—
Manufacturing obligations (3)	32,944	32,349	595		
Total fixed contractual obligations (4)	$49,985	$38,893	$11,092	$—	$—

(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 which includes interest due on the loan and $0.5 million related to the final payment. On April 3, 2013, we entered into a Letter Agreement relating to the Loan Agreement with the Lenders. Pursuant to the terms of the Letter Agreement we paid all amounts due and owing so as to discharge our obligations thereunder which totaled $9.8 million including principal, interest, final payment and prepayment fees.

(3) Relates to significant non-cancelable orders and minimum commitments under our agreements with CMOs relating to the manufacturing of OMONTYS API.

(4) These fixed contractual obligations do not include the Advance from Takeda that may have to be refunded to Takeda.

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

Going Concern

Our financial statements have been presented on the basis that we continue as a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The lack of financial resources due to the recall of OMONTYS raises substantial doubt about our ability to continue as a going concern. The condensed financial statements do not include any adjustments that might be necessary if we are unable to continue as a going concern.

Off-Balance Sheet Arrangements

At March 31, 2013, we did not have any off-balance sheet arrangements, as defined in Item 303(a)(4)(ii) of Regulation S-K promulgated by the Securities and Exchange Commission, or SEC, that have or are reasonably likely to have a current or future effect on our financial condition, changes in our financial condition, revenues, or expenses, results of operations, liquidity, capital expenditures, or capital resources that is material to investors.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our condensed financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles, or GAAP. The preparation of these condensed financial statements requires us to make estimates, assumptions and judgments that affect

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the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the condensed 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 impairment of long-lived assets, restructuring charges, 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. We believe the following policies to be the most critical to an understanding of our financial condition and results of operations because they require us to make estimates, assumptions and judgments about matters that are inherently uncertain.

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, 2012 except as noted below:

Valuation of Long-Lived Assets

We assess the impairment of long-lived assets when events or changes in circumstances indicate that the carrying value of the assets or the asset grouping may not be recoverable. Factors that we consider in deciding when to perform an impairment review include significant negative industry or economic trends, and significant changes or planned changes in our use of the assets. We measure the recoverability of assets that will continue to be used in our operations by comparing the carrying value of the asset grouping to our estimate of the related total future undiscounted net cash flows. If an asset grouping's carrying value is not recoverable through the related undiscounted cash flows, the asset grouping is considered to be impaired. The impairment is measured by comparing the difference between the asset grouping's carrying value and its fair value. Fair value is the price that would be received from selling an asset in an orderly transaction between market participants at the measurement date. Long-lived assets such as intangible assets and property, plant and equipment are considered non-financial assets, and are recorded at fair value only when an impairment charge is recognized. We recorded impairment charges for the quarter ended March 31, 2013 of $5.1 million. These charges are reflected in the statement of comprehensive income (loss) in the Impairment of Prepaid Expenses, Fixed Assets and Intangible Assets line. In conjunction with the product recall and related restructuring activities, we have evaluated our property and equipment. Equipment and leasehold improvements categorized as held for use on the balance sheet at March 31, 2013 totaled $0.6 million. The fair value of the equipment and leasehold improvements was determined using Level 3 valuation inputs including broker estimates for similar assets plus estimated normal use charge based on depreciation for the remaining period of use. We are planning to sell substantially all of our remaining fixed assets in the near term and any sale proceeds received may differ substantially from the estimated realizable value. Actual amounts received may differ from estimated fair value which could result in incremental charges or benefit.

Restructuring Charges

As defined in ASC 420, Exit or Disposal Cost Obligations, we record costs and liabilities associated with exit and disposal activities at fair value in the period the liability is incurred. Restructuring charges consist of charges related to employee severance and benefits, contract termination fees and other restructuring related charges. Charges related to employee severance and benefits are determined based on the estimated severance and fringe benefit charge for identified employees.

2013 Restructuring

On February 23, 2013, we and Takeda announced a nationwide voluntary recall of OMONTYS as a result of postmarketing reports regarding safety concerns, including anaphylaxis, which can be life-threatening or fatal. As a result of the voluntary recall of OMONTYS, all marketing activities were suspended and we have also suspended or terminated manufacturing activities.

In March 2013, we commenced a re-organization plan to reduce operating costs and focus on the OMONTYS safety and other related FDA issues associated with the recall of the product. The reorganization plan included an initial

reduction in force of approximately 230 employees (75% of our workforce) which included our commercial and medical affairs field organizations as well as other officers and employees. We incurred $8.2 million in restructuring charges, all of which are related to expenditures for one-time employee termination benefits. We incurred all of these charges during the first quarter of 2013.

In April 2013, as part of our ongoing efforts to restructure our operations in order to further reduce costs, we commenced a process to notify substantially all of the remaining 25% of our workforce of estimated dates of separation and we engaged an experienced restructuring firm. With the engagement of the restructuring firm, we plan to terminate the employment of our remaining executive officers, including our Chief Executive Officer and Chief Financial Officer, by June 15, 2013.

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Recent Accounting Pronouncements
There were no recent accounting pronouncements which were applicable to us.

Item 3. Quantitative and Qualitative Disclosure About Market Risk

There were no significant changes to our exposure to market risks as compared to the disclosure in Item 7A in our Annual Report on Form 10-K for the year ended December 31, 2012.

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 March 31, 2013. 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 March 31, 2013, 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. There were no changes in our internal control over financial reporting during our quarter ended March 31, 2013 that have materially affected, or are reasonably likely to materially affect our internal control over financial reporting.

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PART II.

Item 1. Legal Proceedings

On February 27, 2013, a securities class action complaint was filed in the United States District Court for the Northern District of California, naming as defendants the Company, certain of its officers, Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals U.S.A., Inc. and Takeda Global Research & Development Center, Inc. A second complaint naming the same defendants was filed on March 6, 2013. The complaints, filed on behalf of purported stockholders of the Company, allege violations of Section 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder, in connection with allegedly false and misleading statements made by the defendants regarding the Company's business practices, financial projections and other disclosures between December 8, 2011 and February 22, 2013, or the Class Period. The plaintiff seeks to represent a class comprised of purchasers of the Company's common stock during the Class Period and seeks damages, costs and expenses and such other relief as determined by the Court.

On March 19, 2013 and March 29, 2013, respectively, two derivative lawsuits were filed purportedly on behalf of the Company in California Superior Court for the County of Santa Clara naming certain of our officers and directors as defendants. The lawsuits allege that certain of the Company's officers and directors breached their fiduciary duties related to the clinical trials for OMONTYS and for representations regarding the Company's business health, which was tied to the success of OMONTYS. The lawsuits also assert claims for unjust enrichment and corporate waste.

Additional complaints may be filed against us and our directors and officers related to our recall of OMONTYS.

Our management believes that we have meritorious defenses and intends to defend these lawsuits vigorously. However, these lawsuits are subject to inherent uncertainties, the actual cost may be significant, and we may not prevail. We believe we are entitled to coverage under our relevant insurance policies, subject to a retention, but coverage could be denied or prove to be insufficient.

Item 1A. Risk Factors

Our business faces significant risks, some of which are set forth below to enable readers to assess, and be appropriately apprised of, many of the risks and uncertainties applicable to the forward-looking statements made in this Quarterly Report on Form 10-Q. You should carefully consider these risk factors as each of these risks could adversely affect our business, operating results and financial condition. If any of the events or circumstances described in the following risks actually occurs, our business may suffer, the trading price of our common stock could decline and our financial condition or results of operations could be harmed. Given these risks and uncertainties, you are cautioned not to place undue reliance on forward-looking statements. 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 we face. Additional risks and uncertainties not presently known to us, or that we currently believe to be immaterial, may also adversely affect our business.

Risks Related to Our Business

In February 2013, we recalled OMONTYS nationwide due to safety concerns and OMONTYS may not be reintroduced to the market unless Takeda is able to rapidly identify and successfully address the causes of the safety concerns with the FDA. OMONTYS was our only product and the recall has severely harmed our business. We face significant challenges to our business and we may not be able to continue our business and operations as a result of the recall.

In February 2013, we announced the voluntary nationwide recall of OMONTYS from the market resulting from serious allergic reactions reported in patients receiving the product, including anaphylaxis related to deaths occurring after first administration of OMONTYS. While Takeda continues to investigate these cases and the nature and causes of the safety concerns, if Takeda is unable to rapidly identify and rectify the causes, the product could be permanently

withdrawn from the market. The recall has severely harmed our business and financial condition and prospects as a going concern and we may not be able to continue our business and operations.

In order to address the safety concerns resulting in the recall of OMONTYS, Takeda would have to complete its ongoing thorough investigation, identify the causes of the serious allergic reactions and provide a suitable plan to the FDA for approval. We are unable to predict when or if this process may be completed or the associated costs, but we expect that the investigation

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may be lengthy. Further, in an effort to continue our operations in the near term with our limited resources, we have continued to substantially reduce our operating costs, including further reductions in force of critical personnel and functions.

There can be no assurance that our business can continue or OMONTYS can be shown to be sufficiently safe to meet the requirements of the FDA for reintroduction by Takeda. Moreover, even if OMONTYS could be reintroduced, the commercial prospects for the product may be permanently diminished, coverage and reimbursement may not be available, and the product may no longer be commercially viable.

We have incurred significant operating losses since inception and anticipate that we will incur continued losses for the foreseeable future without revenues from OMONTYS, which was our only product. We have undertaken a restructuring and if we are unable to substantially further reduce our expenses, we may need to cease operations.

We have experienced significant operating losses since our inception in 2001. At March 31, 2013, we had an accumulated deficit of $570.4 million. Due to the recall of OMONTYS, the subsequent restructuring and the uncertainty of when or if we may receive any potential royalties or milestones based on any revenues from the product under our amended collaboration with Takeda, we anticipate that we will incur substantial losses in future periods. In particular, we expect to continue to spend substantial amounts in order to:

- support our ongoing obligations as well as to support our existing and potential future litigation; and
- maintain, manage or satisfy our ongoing contractual commitments to third parties including to OMONTYS contract manufacturing organizations, or CMOs, to reduce our obligations in view of the transfer of manufacturing responsibilities to Takeda.

As a result of the recall and the subsequent restructuring, there is significant uncertainty as to whether we will have sufficient cash, cash equivalents, and investments to fund our operations for at least the next 12 months. Even with our restructuring efforts, including the termination of substantially our entire workforce, there is no assurance that we will be able to reduce our operating expenses enough to meet our existing obligations and conduct ongoing operations. If Takeda is not able to reintroduce OMONTYS or we are not able obtain additional funding in the near future, our cash resources will rapidly be depleted and we will be required to significantly reduce or suspend operations, which would likely have a material adverse effect on our business, stock price and our relationships with third parties with whom we have business relationships.

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. Further challenges or delays related to Takeda's potential reintroduction of OMONTYS or our restructuring efforts could require us to raise additional funds to continue our operations. 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.

If Takeda is unable to identify quickly the causes of the OMONTYS safety concerns and commercialize OMONTYS successfully, or we are unable to negotiate and satisfy our obligations, or raise additional funds when required or on acceptable terms, we may have to:

- discontinue operations;
- abandon or relinquish some or all of our existing rights to OMONTYS milestones, royalties or other existing rights; or

- pursue alternatives such as a sale of the Company or its assets, a corporate merger, winddown of operations or even bankruptcy proceedings.

Our ability to obtain potential royalties or milestones from Takeda under our amended collaboration and our ability to continue as a going concern depend directly on Takeda's ability to successfully reintroduce and commercialize OMONTYS, which is highly uncertain and challenging. OMONTYS will require significant marketing efforts and substantial investment before it can provide any meaningful revenue, if ever. Even if the underlying causes of the safety concerns can be identified, which is uncertain, the timelines associated with the investigation and the feasibility and costs associated with implementing solutions to address the safety concerns to the satisfaction of the FDA are highly uncertain.

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We may be unable to continue our operations or meet our ongoing obligations as a result of the loss of services of substantially all of our personnel as part of our restructuring.

In March 2013, we announced an initial reduction in force of approximately 75% of our workforce. In April 2013, as part of our ongoing efforts to restructure our operations in order to further reduce costs, we commenced a process to notify substantially all of the remaining 25% of our workforce of estimated dates of separation and we engaged an experienced restructuring firm. With our engagement of the restructuring firm, we announced plans to terminate the employment of our remaining executive officers, including our Chief Executive Officer and Chief Financial Officer, by June 15, 2013. As a result of the loss of services of substantially all of our personnel, including all of our executive officers, we may be unable to continue our operations and meet our ongoing obligations even with our engagement of the restructuring firm.

Our independent registered public accounting firm has indicated that our financial condition raises substantial doubt as to our ability to continue as a going concern.
Our independent registered public accounting firm has included in their audit opinion on our financial statements for the year ended December 31, 2012, a statement with respect to substantial doubt as to our ability to continue as a going concern. Our financial statements have been prepared assuming we will continue to operate as a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. If we became unable to continue as a going concern, we may have to liquidate our assets and the values we receive for our assets in liquidation or dissolution could be significantly lower than the values reflected in our financial statements. The reaction of investors to the inclusion of a going concern statement in the report of our independent registered public accounting firm, our lack of cash resources, and our potential inability to continue as a going concern may materially adversely affect our share price and our ability to raise new capital or continue our operations.

If we fail to maintain our collaboration with Takeda as recently amended, such termination would have a further material adverse effect on our business and operations and substantially reduce the potential to reintroduce OMONTYS. Our business has already been severely harmed by the recall of OMONTYS, and any termination of the license agreement would substantially reduce our uncertain ability to meet our obligations, and may increase the likelihood of having to cease our operations, even with the ongoing restructuring efforts.

The maintenance and successful performance of our exclusive license to Takeda for OMONTYS is an essential part of our business as we continue to restructure our operations company-wide. Completion of the OMONTYS recall, investigation and reintroduction, for which Takeda assumes full responsibility, is critical to our ability to achieve any further cash flows through potential royalties or milestones. Takeda has full decision-making authority as to whether the product may be reintroduced if Takeda is able and willing to complete the investigation and address the safety concerns to the satisfaction of the FDA.

Moreover, Takeda has the ability to terminate our collaboration upon an uncured material breach by us or even in the absence of a material breach with three months notice prior to reintroduction of OMONTYS, which termination would have a further material adverse effect on OMONTYS and our business and operations, as we would be highly unlikely to be able to maintain the NDA to license to a third party. In the past, 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 increase the possibility that Takeda may elect to terminate the collaboration or limit the resources Takeda is willing to commit to OMONTYS. The safety concerns with OMONTYS combined with the recent U.S. recall may negatively impact the EMA decision and Takeda's view of the collaboration and its overall commitment to OMONTYS, including in the U.S., our major market opportunity.

We are currently subject to securities class action litigation and derivative litigation and may be subject to similar or other litigation such as products liability litigation in the future.

We and certain of our officers as well as Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals U.S.A., Inc. and Takeda Global Research & Development Center, Inc. have been named defendants in two lawsuits filed in February 2013 in the United States District Court for the Northern District of California, brought on behalf of stockholders of the Company that alleges violations of the Securities Exchange Act of 1934 in connection with allegedly false and misleading statements made by the defendants regarding our business practices, financial projections and other disclosures between December 8, 2011 and February 22, 2013, or the Class Period. The plaintiffs seek to represent a class comprised of purchasers of our common stock during the Class Period and seek damages, costs and expenses and such other relief as determined by the Court.

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In addition, in March 2013, two derivative lawsuits were filed purportedly on behalf of the Company in California Superior Court for the County of Santa Clara naming certain of our officers and directors as defendants. The lawsuits allege that certain of our officers and directors breached their fiduciary duties related to the clinical trials for OMONTYS and for representations regarding our business health, which was tied to the success of OMONTYS. The lawsuits also assert claims for unjust enrichment and corporate waste.

While we believe we have meritorious defenses and intend to defend these lawsuits vigorously, we cannot predict the outcome of these lawsuits. We believe that there may be additional suits or proceedings brought in the future. Monitoring and defending against legal actions, whether or not meritorious, is time-consuming for our management and detracts from our ability to fully focus our internal resources on our business activities and we cannot predict how long it may take to resolve these matters. In addition, legal fees and costs incurred in connection with such activities may be significant and we could, in the future, be subject to judgments or enter into settlements of claims for significant monetary damages. A decision adverse to our interests on these actions or resulting from these matters could result in the payment of substantial damages and could have a material adverse effect on our cash flow, results of operations and financial position.

Likewise, if product liability lawsuits are brought against us for injuries or deaths due to patients' adverse reactions to OMONTYS, we may be subject to additional liability. In any event, a potential product liability lawsuit would require significant financial and management resources. Regardless of the outcome, product liability claims may result in injury to our reputation, withdrawal of clinical trial participants, significant costs, diversion of management's attention and resources, substantial monetary awards, loss of revenue, and additional distractions from our efforts to address safety concerns that may allow us to reintroduce 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 reintroduction of OMONTYS.

With respect to any litigation, our insurance may not reimburse us or may not be sufficient to reimburse us for the expenses or losses we may suffer in contesting and concluding such lawsuits. Substantial litigation costs or an adverse result in any litigation may adversely impact our business, operating results or financial condition.

Our ability to obtain potential royalties and further milestone payments from Takeda depends solely on Takeda's efforts to complete the investigation and, if feasible, to reintroduce OMONTYS.

Our ability to obtain potential royalties and milestones from OMONTYS depends on Takeda's efforts to complete the investigation and, if feasible, to reintroduce the product and effectively and profitably commercialize it when and if it is reintroduced. There is no assurance that Takeda can identify and address the underlying cause of the serious hypersensitivity reactions. If Takeda fails to demonstrate the safety of OMONTYS, Takeda will not be able to reintroduce the product and we will not be able to obtain any potential royalties or milestones from the product. When and if Takeda reintroduces OMONTYS, our success will depend on Takeda's ability to:

- create market demand for OMONTYS through education, marketing and sales activities, including the ability to establish or demonstrate the safety of the product;
- build 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

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

When and if Takeda reintroduces OMONTYS, which is highly uncertain, it will be even more challenging for Takeda to accomplish these activities in view of the recall and related safety concerns particularly due to the long-term experience with currently marketed products and negative perceptions of OMONTYS' safety. If Takeda is unable to successfully reintroduce and commercialize OMONTYS, then we will not obtain any potential royalties or milestones from the product, which will have a material adverse impact on our business and our prospects.

Even if Takeda is able to reintroduce OMONTYS, Takeda may not be able to commercialize the product successfully.

If Takeda is able to reintroduce OMONTYS, Takeda must have, or build, internal sales, marketing, medical affairs, contracting, reimbursement and distribution capabilities with the training and experience necessary to commercialize the product successfully. If Takeda is unable to address these capabilities internally, then Takeda 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 customers of OMONTYS. In addition, to the extent that Takeda enters into co-promotion or other arrangements with respect to OMONTYS, any revenues Takeda receives from the product will depend upon the efforts of both parties, which may not be successful and will be only partially in Takeda's control. These factors may hinder Takeda's ability to commercialize OMONTYS successfully when and if it is reintroduced, which would adversely affect our ability to obtain potential royalties or milestones from the product.

Even if Takeda is able to reintroduce OMONTYS, Takeda would need to attain significant market acceptance for the product among physicians, patients, health care payors, and the major operators of dialysis clinics, and Takeda would need to reach 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 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 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, should it be reintroduced, 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 Takeda's 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 Takeda's efforts to attain significant market acceptance of OMONTYS should it be reintroduced, which would pose a risk to our ability to obtain potential royalties or milestones from the product.

Even if Takeda is able to reintroduce and achieve market acceptance of OMONTYS, if Takeda is unable to reach a long-term supply agreement with either or both of the largest operators of dialysis clinics in the U.S, Fresenius Medical Care North America and DaVita, Inc., or Fresenius and DaVita, respectively, on favorable terms or on a timely basis, then the revenue opportunity for OMONTYS could be significantly reduced. Takeda may not be able to reach a long-term supply agreement with either Fresenius or DaVita because both entered into a long-term supply agreement with Amgen that began in January 2012. In particular, Fresenius entered into a “multi-year” agreement with Amgen whereby Amgen would supply EPOGEN on a “non-exclusive” basis to Fresenius, and 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. The specific terms of the Amgen-Fresenius

agreement and the Amgen-DaVita agreement have not been publicly disclosed, and we cannot predict how these agreements may impact the commercial opportunity for OMONTYS should it be reintroduced. But these agreements may limit the market opportunity for the product and adversely impact our ability to obtain potential royalties or milestones from the product.

The opportunity to reintroduce OMONTYS is highly uncertain and challenging as a result of the negative perception of the safety of the product and ESAs as a class.

The safety concerns resulting in the OMONTYS recall and the safety concerns for ESAs as a class may make it challenging for Takeda to reintroduce OMONTYS and may significantly reduce the potential market for the product. For example:

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- In 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.

- In February 2013, in connection with the recall, the FDA announced that due to the severity of the public health risk, the FDA wanted to be certain that health care providers stop using OMONTYS and that it would investigate products and facilities associated with the recall and would provide updates.

The controversy surrounding ESAs and FDA safety concerns has, and may, further negatively affect OMONTYS when and if it is reintroduced. In addition, recent and future FDA actions represent additional challenges to the market for ESAs as a class and may affect the timing or costs associated with implementing a solution to address the safety concerns resulting in the OMONTYS recall to the satisfaction of the FDA. 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. Any of these factors could significantly delay or negatively impact the commercialization of OMONTYS when and if it is

reintroduced by Takeda, which would significantly affect our ability to obtain potential royalties and milestones from the product

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 the product when and if it is reintroduced by Takeda. 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

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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. Since OMONTYS was launched, over 25,000 patients have been treated with the product. Serious hypersensitivity reactions, including anaphylaxis, which can be life-threatening or fatal, have been reported. As a result, on February 23, 2013, we and Takeda announced a nationwide voluntary recall of OMONTYS and suspended the promotional activities and marketing of the product. This has severely harmed our business and future financial results. Any negative perception of OMONTYS' safety relative to other ESAs could further significantly limit any potential opportunity for Takeda to reintroduce and successfully commercialize the product, which would significantly limit any potential opportunity for us to obtain potential royalties and milestones from 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 would significantly negatively impact the commercial potential as well as any possible reintroduction of OMONTYS.

Takeda has continuing obligations with respect to OMONTYS and FDA approval remains subject to certain post-marketing requirements that could significantly increase costs or delay or limit Takeda's ability to successfully commercialize the product when and if it is reintroduced. If results, data or information with respect to Takeda's continuing obligations are negative or Takeda is unable to fulfill its continuing obligations to regulatory authorities or its post-marketing requirements, there may be changes to the product label or Takeda may be required to withdraw the product from the market.

The FDA approved OMONTYS subject to certain post-marketing requirements. An observational study and a randomized controlled trial must be conducted 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. Pediatric studies must be conducted with target dates for completion between 2016 and 2027. A REMS must be implemented, 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.

Even if Takeda is able to address the safety concerns resulting in the recall of OMONTYS to the satisfaction of the FDA, maintaining regulatory approval for the product will be increasingly difficult. If Takeda is unable to fulfill the requirements of regulatory authorities or the post-marketing requirements or to the extent there are other unfavorable results, data or other information arising therefrom, then there may be limitations imposed on the product label or Takeda may be required to permanently withdraw the product from the market.

Competition in the pharmaceutical industry is intense. The OMONTYS recall means that the product will have to overcome significant competitive issues relative to other approved ESAs on the market.

When and if OMONTYS is reintroduced, Takeda will face competition from established pharmaceutical and biotechnology companies, in particular companies that have an approved ESA on the market. The commercial opportunity for OMONTYS will be reduced or eliminated if competitors develop and commercialize products that are more effective, have fewer side effects or are less expensive than OMONTYS. The OMONTYS recall and the uncertainty of whether the product will be available on the market at all may mean that the product will be at a significant disadvantage upon the entry of competing products.

When and if OMONTYS is reintroduced, we anticipate that it 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 it will be in direct competition with OMONTYS, if Takeda is able to reintroduce the product, because of Mircera's ability to be long-acting; therefore, it could potentially limit the market for OMONTYS.

The introduction of biosimilars into the ESA market could also prove to be a significant threat when and if Takeda reintroduces OMONTYS as biosimilars could not only limit the market for the product, but could also drive down the price of ESAs.

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Takeda may also face competition from potential new anemia therapies when and if OMONTYS is reintroduced. There are several product candidates in various stages of active development for anemia indications by potential competitors that may promote the production of naturally-occurring EPO in patients, and some of these product candidates may enter the market as early as 2015. If these product candidates enter the market they may be in direct competition with OMONTYS when and if it is reintroduced. In addition, certain companies are developing potential new therapies for renal-related diseases that could reduce ESA utilization and thus limit the market for OMONTYS when and if it is reintroduced.

When and if Takeda reintroduces OMONTYS, the U.S. market opportunity for the product 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 accepted 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. Several biosimilar versions of rEPO are available for sale in the E.U. and biosimilar versions of rEPO are currently being studied in clinical trials in the U.S. For example, in January 2012, Hospira, Inc. announced the beginning of its Phase 3 clinical program for its biosimilar with results anticipated in 2013, and in October 2012, Sandoz announced the beginning of its Phase 3 clinical program for its biosimilar with results anticipated in 2014.

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 should it be reintroduced, and are expected to drive down its price and sales volume, which would adversely affect the commercial success of the product and our ability to obtain potential royalties or milestones from it.

With the amendment of our collaboration, the reintroduction and commercial success of OMONTYS in the U.S. depends entirely on the efforts of Takeda. Similarly, outside of the U.S., we are solely dependent on the efforts and commitments of Takeda, either directly or through third parties, to reintroduce or further commercialize OMONTYS. If our collaboration with Takeda does not continue, our ability to receive future royalties would be significantly reduced.

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

As a result of the recent amendment to the collaboration with Takeda, Takeda holds an exclusive license to develop and commercialize OMONTYS worldwide. We have no control or influence over Takeda's decision-making as to OMONTYS. If Takeda is unwilling to continue to make further investments of time, resources and fund in OMONTYS, including the completion of the ongoing investigation, which may not be feasible or successful, we may have no recourse and the product may never be reintroduced in the U.S. or approved in any other territories, including in Europe and Japan. As a consequence, any progress and commercial success in any territory is dependent solely on Takeda's efforts and commitment to the program, which may be substantially reduced as a result of the recall. Takeda's decision in December 2011 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 when and if Takeda reintroduces OMONTYS. In addition, Takeda may delay, reduce or terminate investigation and reintroduction efforts in the U.S. and 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.

Takeda's obligations to exercise diligence under the collaboration, as amended, are suspended until after approval by the FDA for reintroduction of OMONTYS without additional investigative, non-clinical or clinical activities. In the event that Takeda fails to diligently pursue the investigation or reintroduce OMONTYS, our collaboration agreement provides us the right to allege breach only after FDA approval for reintroduction and in limited circumstances which may be difficult to prove. Even if we were to successfully assert breach, termination of Takeda's rights in certain instances may not provide us with ability to

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realize any economic value from OMONTYS in view of our ongoing restructuring. Further, 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 unlikely to be feasible with the recent reductions in substantially all of our workforce. 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, including the reintroduction of OMONTYS when and if it occurs.

With the recent amendment of the collaboration, Takeda has assumed full responsibility for manufacturing of OMONTYS, including for API as well as finished product and as a consequence, we have limited ability to control risks associated with future manufacturing. Manufacturing difficulties, disruptions or delays could delay reintroduction of OMONTYS and have a further material adverse effect on our business.

Since the recall and as we have transferred manufacturing responsibility to Takeda for OMONTYS, we plan to suspend or terminate manufacturing activities to the extent practicable in order to decrease our ongoing manufacturing costs and commitments, including but not limited to, termination of orders and agreements. These actions may negatively impact the ability to reintroduce OMONTYS as Takeda will need to separately establish manufacturing contracts or capabilities which may require significant effort and cause delay.

Even if Takeda is able to reintroduce OMONTYS, the OMONTYS manufacturing process is complicated and time consuming. Manufacture of OMONTYS API involves long lead times. Manufacturing difficulties, disruptions or delays could limit reintroduction and supply of the product.

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 Takeda from successfully reintroducing and commercializing OMONTYS, including the following:

- product quality issues;
- cost overruns, process scale-up, process reproducibility;
- changes in demand forecasts that result in inventory write-offs;
- 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.

As we have transferred responsibility for the manufacture of OMONTYS to Takeda, and we therefore have limited control and ability to address risks associated with the manufacturing process, including single-sourced arrangements, leaving OMONTYS at greater risk of supply interruptions, potential delays and failure to be successfully reintroduced or commercialized.

Takeda and our third-party manufacturers are required to comply with applicable FDA manufacturing practice and other applicable regulations. If there is any failure to maintain compliance with these regulations, the production of OMONTYS could be interrupted, resulting in delays and additional costs should reintroduction of OMONTYS be feasible. Further, Takeda's lack of experience providing reliable supply of product, particularly as to the manufacturing of API, may cause delays in reintroduction of OMONTYS, and deter health care providers and dialysis centers from selecting, or switching to, OMONTYS from our competitors' products or from continuing to use OMONTYS should it be reintroduced.

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Our receipt of potential royalties and milestone payments associated with OMONTYS is based on the strength of the exclusive license to Takeda under our proprietary rights. We are dependent to a large extent on Takeda to protect our proprietary rights as we have given Takeda control in the first instance over such rights, and we may not be able to ensure their protection.

Our ability to receive potential royalties and milestones in connection with the reintroduction of OMONTYS will depend in part on obtaining and maintaining patent protection and trade secret protection of OMONTYS. Under the recent amendment to the collaboration, we have granted Takeda the first right, but not the obligation, to pursue prosecution and maintenance of these proprietary rights as well as successfully defending these patents against third-party challenges. The 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 and the extent to which Takeda pursues enforcement.

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, and any such control has generally been conferred to Takeda in connection with the amendment of our collaboration. 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 applications 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;
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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

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trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the U.S. are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

Our R&D 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.

Substantial costs may arise 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.

The ability to reintroduce and commercialize OMONTYS will depend, in part, on the 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 Takeda may file additional U.S. and foreign patent applications related thereto. There can be no assurance that any issued patents we or Takeda 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 reintroducing and 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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Risks Related to Our Industry

Even though OMONTYS approval by the FDA has not been permanently withdrawn, the OMONTYS approval is subject to continued FDA inspection of the safety concerns leading to the recall. Ongoing FDA review may result in significant additional expense and limit Takeda's ability to reintroduce and successfully commercialize OMONTYS.

Although the FDA approval of OMONTYS has not been withdrawn, the FDA may choose to do so as the investigation continues or to subject Takeda to various post-marketing requirements, including additional clinical trials, 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 recent cases of reported patients' serious hypersensitivity reactions to OMONTYS and any other subsequent discovery of previously unknown problems with the product, including adverse events of unanticipated severity or frequency, may result in withdrawal or restrictions on the marketing of the product, and could include regulatory actions from the FDA. The actions the FDA may take include, permanent withdrawal, additional studies or label restrictions, the use of informed consents, the addition of more restrictive REMs, further lowering of target hemoglobin levels, or even the removal of indications from the label altogether. In addition, the FDA's policies may change and additional government regulations may be enacted that could prevent or delay successful reintroduction and 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 Takeda is not able to maintain regulatory compliance or the FDA imposes additional requirements, then Takeda may not be able to reintroduce and successfully commercialize OMONTYS, which would prevent us from obtaining potential royalties or milestones from the product.

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;

- 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;

- the Federal Food, Drug and Cosmetic Act, which prohibits, among other things, individuals or entities from introducing into interstate commerce any food, drug, device or cosmetic that has been adulterated or misbranded; and

- state law equivalents of certain 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

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federal and state healthcare programs, including Medicare and Medicaid, and the curtailment or restructuring of operations. The recall has severely harmed our business and financial condition and prospects as a going concern and we may not be able to continue the business and operations of the Company. Accordingly, we may face challenges to maintain operations and a compliance program that are in material compliance with these laws. Because of the far-reaching nature of these laws and the significant disruption to our operations resulting from the recall, 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 Takeda from marketing OMONTYS abroad, which will prevent us from obtaining potential royalties and milestones through our amended collaboration with Takeda .

We and Takeda co-marketed OMONTYS in the U.S. before the product recall, and through our amended collaboration with Takeda we are entitled to potential royalties and milestones related to marketing the product in foreign jurisdictions. When and if Takeda reintroduces OMONTYS, in order to market the product in the E.U. and other foreign jurisdictions, Takeda or a sublicensee must obtain separate regulatory approvals. The regulatory 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 Takeda is not able to obtain regulatory approval in any foreign market, then Takeda 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 the future profitability of OMONTYS.

When and if Takeda reintroduces OMONTYS in the U.S., Takeda intends to seek approval to market the product in foreign jurisdictions. If Takeda obtains approval in one or more foreign jurisdictions, Takeda will be subject to rules and regulations in those jurisdictions relating to OMONTYS. In some foreign countries, particularly in the E.U., prescription drug pricing is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a drug candidate. To obtain reimbursement or pricing approval in some countries, Takeda may be required to conduct a clinical trial that compares the cost-effectiveness of OMONTYS 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, Takeda may be unable to achieve or sustain profitability of the product, which would adversely affect our ability to obtain potential royalties or milestones for the product.

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 have used 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.

Risks Related to the Ownership of Our Common Stock

We have been named as a defendant in securities class action lawsuits and related derivative lawsuits. These lawsuits could result in substantial damages and may divert management's time and attention from our business and operations.

On February 27, 2013, a securities class action complaint was filed in the United States District Court for the Northern District of California, naming as defendants us, certain of our officers, Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals U.S.A., Inc. and Takeda Global Research & Development Center, Inc. A second complaint naming the same defendants was filed on March 6, 2013. The complaints, filed on behalf of purported stockholders of the Company, allege violations of Section 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder, in connection with allegedly false and misleading statements made by the defendants regarding our business practices, financial

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projections and other disclosures between December 8, 2011 and February 22, 2013, or the Class Period. The plaintiff seeks to represent a class comprised of purchasers of our common stock during the Class Period and seeks damages, costs and expenses and such other relief as determined by the Court.

On March 19, 2013 and March 29, 2013, respectively, two derivative lawsuits were filed purportedly on behalf of the Company in California Superior Court for the County of Santa Clara naming certain of our officers and directors as defendants. The lawsuits allege that certain of our officers and directors breached their fiduciary duties related to the clinical trials for OMONTYS and for representations regarding our business health, which was tied to the success of OMONTYS. The lawsuits also assert claims for unjust enrichment and corporate waste.

Our management believes that we have meritorious defenses and intends to defend these lawsuits vigorously. However, these lawsuits are subject to inherent uncertainties, and the actual cost will depend upon many unknown factors. The outcome of litigation is necessarily uncertain, we could be forced to expend significant resources in the defense of these lawsuits and we may not prevail. Monitoring and defending against legal actions is time consuming for our management and detracts from our ability to fully focus our internal resources on our business activities. In addition, we may incur substantial legal fees and costs in connection with litigation and, although we believe we are entitled to coverage under the relevant insurance policies, subject to a retention, coverage could be denied or prove to be insufficient. We are not currently able to estimate the possible cost to us from these lawsuits, as they are currently at an early stage and we cannot be certain how long it may take to resolve these matters or the possible amount of any damages that we may be required to pay. We have not established any reserves for any potential liability relating to these lawsuits. It is possible that we could, in the future, incur judgments or enter into settlements of claims for monetary damages. A decision adverse to our interests on these actions could result in the payment of substantial damages, or possibly fines, and could have a material adverse effect on our cash flow, results of operations and financial position. In addition, the uncertainty of the currently pending lawsuits could lead to more volatility in our stock price.

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 March 31, 2013, the closing price of our common stock ranged between a high of $27.46 per share and a low of $1.05 per share. The closing price for our common stock as reported by The NASDAQ Stock Market on April 30, 2013 was $0.90 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:

- Takeda's ability to rapidly identify and address the cause of the safety concerns related to OMONTYS;
- Takeda's ability to demonstrate safety of OMONTYS to the satisfaction of the FDA and reintroduce the product;
- our ability to fund our operations and continue as a going concern;
- litigation, including the securities class action lawsuits and derivative lawsuits pending against us and certain of our officers;
- changes in the market valuations of similar companies;
- actual or anticipated results from, and any delays in, commercialization of OMONTYS should Takeda reintroduce the product;
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actual or anticipated contractual arrangements for OMONTYS should Takeda reintroduce 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 the FDA and CMS with respect to ESAs generally or OMONTYS specifically;

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- new products or services introduced or announced by Takeda 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 for OMONTYS;
- changes in laws or regulations applicable to OMONTYS;
- developments concerning our amended collaboration arrangement with Takeda;
- actual or anticipated variations in our quarterly operating results due to our restructuring efforts;
- 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;
- sales of common stock or other securities by us or our stockholders in the future;
- the loss of services of substantially all of our personnel, including all of our executive officers;
- 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.

We may be delisted from The NASDAQ Stock Market if our share price or market value of publicly held shares does not meet certain thresholds. We are also subject to additional expenses and administrative burden as a public company.

The risk of delisting and the potential for additional securities litigation may be particularly relevant for us because we have experienced greater than average stock price volatility, as have other biotechnology companies in recent years. We are currently subject to securities class action and other litigation and we may be subject to additional lawsuits or proceedings in the future. The securities class action litigation could result in substantial costs and divert management's attention and resources, which could harm our business, operating results and financial condition. Our current stock price may result in our delisting from The NASDAQ Stock Market if we are unable to meet the applicable listing requirements.

In addition, as a public company, we incur significant legal, accounting and other expenses and our administrative staff is required to perform additional tasks, such as adopting additional internal controls, disclosure controls and procedures, retaining a transfer agent and bearing all of the internal and external costs of preparing and distributing periodic public reports in compliance with our obligations under the securities laws.

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

The Sarbanes-Oxley Act of 2002 requires, among other things, that we maintain effective internal control over financial reporting and disclosure controls and procedures. We have not identified any material weaknesses in our internal controls during the years ended December 31, 2012, 2011 or 2010. We did identify a material weakness in the operation of our internal control over financial reporting that occurred during the second quarter of 2008 which has been fully remediated. We cannot assure you that material weaknesses in our internal controls will not be identified in future periods. There can be no assurance

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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 internal controls 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. The recall of OMONTYS and our workforce reductions have severely harmed our business and financial condition so we may have challenges in maintaining 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 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”. Prior to 2012, we experienced ownership changes as defined by Sections 382 and 383 of the Internal Revenue Code. Due to our announcement of our voluntary recall of OMONTYS in February 2013, there has been an extremely high volume of trading of our stock, which has caused a significant drop in the value of our stock. As a result of the high trading volume, there may be a shift of ownership amongst our 5% stockholders that could result in an ownership change, under Section 382 of the Internal Revenue Code of 1986, as amended. 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.

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:

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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

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- 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 equity securities by us during the quarter ended March 31, 2013.

Issuer Purchases of Equity Securities

We did not repurchase any of our equity securities during the quarter ended March 31, 2013.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

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

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Exhibit number		Description
3.3		Amended and Restated Certificate of Incorporation(1)
3.5		Amended and Restated Bylaws(2)
4.1		Reference is made to exhibits 3.3 and 3.5
4.2		Specimen Common Stock Certificate(1)
4.4		Amended and Restated Investor Rights Agreement, dated September 7, 2006, by and between the Registrant and certain of its stockholders(3)
4.5		Form of Warrant to Oxford Finance Corporation to Purchase shares of Common Stock(4)
4.6		Form of Warrant to Silicon Valley Bank to Purchase shares of Common Stock(4)
4.7		Form of Warrant to Purchase shares of Common Stock(5)
10.29		Executive Employment Agreement, as amended January 31, 2013, by and between the Registrant and Anne-Marie Duliege(6)
10.30		Executive Employment Agreement, as amended January 31, 2013, by and between the Registrant and Robert Venteicher(6)
10.48		Executive Employment Agreement, dated January 31, 2013, by and between the Registrant and Jeffrey H. Knapp(6)
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

(1) Incorporated by reference to the indicated exhibit in our registration statement on Form S-1/A, registration no. 333-136125, filed with the Securities and Exchange Commission on November 30, 2006.

(2) Incorporated by reference to the indicated exhibit in our Form 8-K as filed with the Securities and Exchange Commission on September 10, 2007.

(3) Incorporated by reference to the indicated exhibit in our registration statement on Form S-1/A, registration no. 333-136125, filed with the Securities and Exchange Commission on October 2, 2006.

(4) Incorporated by reference to the indicated exhibit in our Form 10-Q as filed with the Securities and Exchange Commission on May 9, 2012.

(5) Incorporated by reference to Exhibit 4.5 in our Form 8-K as filed with the Securities and Exchange Commission on February 19, 2009.

(6) Incorporated by reference to the indicated exhibit in our Form 10-K as filed with the Securities and Exchange Commission on April 2, 2013

†The certification attached as Exhibit 32.1 accompany this Annual Report on Form 10-K, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Affymax, Inc., under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Annual Report on Form 10-K, irrespective of any general incorporation language contained in such filing.

#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: May 9, 2013	By:	/s/ JOHN A.ORWIN John A. Orwin Chief Executive Officer and Member of the Board of Directors
Dated: May 9, 2013	By:	/s/ HERB CROSS Herb Cross Chief Financial Officer (Principal Financial Officer)

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