AFFYMAX INC
Form 10-Q
May 06, 2014
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

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FORM 10-Q

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

For the fiscal quarter ended March 31, 2014

or

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

or Commission File Number 001-33213

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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)

19200 Stevens Creek Blvd. Suite 240 Cupertino, CA 95014
(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	Over The Counter (OTC)

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 o

Non-accelerated filer x
(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, 2014, 37,490,095 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 and per share data)

	March 31, 2014 (unaudited)	December 31, 2013
Assets		
Current assets		
Cash	$4,856	$5,597
Prepaid expenses	600	725
Total current assets	5,456	6,322
Other assets	1,007	1,121
Total assets	$6,463	$7,443
Liabilities and Stockholders' Deficit		
Current liabilities		
Accounts payable	$236	$101
Accrued restructuring	179	315
Other accrued liabilities	195	266
Advance from Takeda	8,189	8,189
Total current liabilities	8,799	8,871
Total liabilities	8,799	8,871
Stockholders' deficit		
Common stock: $0.001 par value, 100,000,000 shares authorized, 37,490,095 shares issued and outstanding	37	37
Additional paid-in capital	557,156	556,672
Accumulated deficit	(559,529)	(558,137)
Total stockholders' deficit	(2,336)	(1,428)
Total liabilities and stockholders' deficit	$6,463	$7,443

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

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

	Three Months Ended March 31,	
	2014	2013
Revenue:		
Collaboration revenue	$—	$839
License and royalty revenue	—	5
Total revenue	—	844
Operating expenses:		
Research and development	—	9,789
Selling, general and administrative	1,493	24,644
Collaboration cost reimbursement	—	(20,378)
Impairment of prepaid expenses, fixed assets and intangible assets	—	5,140
2013 Restructuring charge	(101)	8,216
Total operating expenses	1,392	27,411
Loss from operations	(1,392)	(26,567)
Interest income	—	15
Interest expense	—	(492)
Loss before provision for income taxes	(1,392)	(27,044)
Provision for income taxes	—	1
Net loss	$(1,392)	$(27,045)
Net loss per share:		
Basic and diluted net loss per share	$(0.04)	$(0.72)
Weighted-average shares used in computing basic and diluted net loss per share		
Basic and diluted	37,490	37,469
Total comprehensive loss	$(1,392)	$(27,045)

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,	
	2014	2013
Cash flows from operating activities		
Net loss	$(1,392)	$(27,045)
Adjustments to reconcile net loss 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
Amortization of premium on investments	—	6
Stock-based compensation expense	484	3,717
Noncash interest expense	—	271
Changes in operating assets and liabilities:		
Receivable from Takeda	—	17,485
Prepaid expenses	125	(228)
Other current assets	114	2,968
Other assets	—	220
Accounts payable	135	2,715
Accrued liabilities	(207)	(9,337)
Accrued clinical trial expenses	—	(610)
Deposit from Takeda	—	(559)
Other long-term liabilities	—	(256)
Net cash used in operating activities	(741)	(24,620)
Cash flows from investing activities		
Proceeds from maturities of investments	—	3,600
Net cash provided by investing activities	—	3,600
Cash flows from financing activities		
Proceeds from issuance of common stock upon exercise of stock options	—	271
Repayment of note payable	—	(901)
Net cash used in financing activities	—	(630)
Net decrease in cash and cash equivalents	(741)	(21,650)
Cash and cash equivalents at beginning of the period	5,597	68,265
Cash and cash equivalents at end of the period	$4,856	$46,615

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. In March 2012, the U.S. Food and Drug Administration, or FDA, approved our 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, access to funds and prospects as a going concern.We may be unable to continue our operations or to succeed in existing and potential future litigation, in view of our limited resources and funds. As of March 31, 2014, we had an accumulated deficit of $559.5 million.

Product Recall

On February 23, 2013, we and Takeda announced a nationwide voluntary recall of OMONTYS as a result of post marketing 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 a reduction in force of approximately 305 employees. As of March 31, 2014 there are three employees remaining. We incurred approximately $16.1 million in restructuring charges for the year ended December 31, 2013, all of which are related to expenditures for one-time employee termination benefits (see Note 6 of the Notes to Condensed Financial Statements). 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).

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.

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. 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

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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. 2014, we have retained a liability for an advance from Takeda on our condensed balance sheet of approximately $8.2 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).

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 $559.5 million as of March 31, 2014. 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 to fund our operations for the next 12 months. Given our limited resources, there is no assurance that we will be able to reduce our operating expenses enough to meet our existing and future 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 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, 2013, 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.

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.

Cash and Cash Equivalents

Cash and cash equivalents are stated at cost, which approximates market value. As of December 31, 2013 and March 31, 2014, the Company did not hold any investments in marketable debt or equity securities, including any cash equivalents.

Revenue Recognition

Collaboration Revenue

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We account for our Arrangement with Takeda under ASC 605-25, Multiple Element Arrangements 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 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.

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. Except for certain transition services that we performed in April 2013 for full reimbursement of $0.5 million, any expenses incurred by either us or Takeda after April 1, 2013 shall be the responsibility of the respective party and neither we nor Takeda have an 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 allocated 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 was 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 was 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 was 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 was 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.

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Below is a summary of the components of our collaboration revenue for the three months ended March 31, 2014, and 2013 (in thousands):

	Three months ended March 31,	
	2014	2013
Net expense reimbursement after CAPM	—	839
Total collaboration revenue	$—	$839

Net Loss Per Common Share

Basic and diluted net loss per share is computed by dividing net loss by the weighted-average number of shares of common stock outstanding during the period. Stock options were not included in the diluted net loss per common share calculation for the periods presented because the inclusion of such shares would have had an antidilutive effect.

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

	Three months ended March 31,	
	2014	2013
Options to purchase common stock	1,598	4,803
Common stock issuable pursuant to the 2006 Employee Stock Purchase Plan	—	125
Restricted stock units	—	437
Warrant to purchase common stock	—	424

3. Advance from Takeda

Under our agreement with Takeda, 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. 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). As of March 31, 2014, our liability balance under the launch allowance is $8.2 million.

Due to voluntary recall of OMONTYS in February 2013, all marketing activities have been suspended and there is no certainty as to when those activities will restart. The launch allowance will remain as a liability until we can determine, if at all, the timing of when that liability will be extinguished or if the collaboration is terminated. If our collaboration with Takeda is terminated prior to Takeda's recoupment of the balance, there is no obligation that we repay these amounts.

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4. Commitments and Contingencies

Legal Proceedings

Shareholder 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 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. On May 2, 2013, the securities class action complaint that was filed on February 27, 2013 was voluntarily dismissed by the plaintiff. On May 21, 2013, the Court appointed a lead plaintiff in the remaining securities class action complaint that had been filed on March 6, 2013. On July 22, 2013, a consolidated amended class action complaint was filed on behalf of purported stockholders of the Company, naming as defendants the Company and certain of its former officers. The consolidated amended complaint alleges 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 OMONTYS, the Company's business practices, financial projections and other disclosures between August 8, 2012 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 September 20, 2013, the Company and the individual defendants (collectively, "Defendants") filed a motion to dismiss the consolidated amended complaint. On November 19, 2013, the plaintiff filed her opposition to the motion to dismiss and on December 19, 2013, Defendants filed their reply in support of their motion to dismiss. The hearing on the motion to dismiss occurred on January 15, 2014. On January 21, 2014, the Court issued its order granting the motion to dismiss regarding violations of Section 20(a) against all Defendants and it granted the motion to dismiss in part, denying the motion to dismiss in part, and providing plaintiffs with an opportunity to amend the complaint. On February 18, 2014, the Court, pursuant to a stipulation by the parties, stayed the litigation for ninety days to allow the parties to conduct settlement discussions.

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 current and former officers and directors as defendants (the "State Court Derivative Action"). 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. On May 31, 2013, the Court consolidated the two actions and appointed lead plaintiff. On June 11, 2013, lead plaintiff designated the complaint filed on March 29, 2013 as the operative complaint. On August 6, 2013, the Court stayed the State Court Derivative Action pending the outcome of the motion to dismiss in the securities class action. Subsequent to the order regarding the motion to dismiss in the securities class action, on January 31, 2014, the Court ordered that the State Court Derivative Action be stayed in its entirety until resolution of the securities class action.

On August 19, 2013, another derivative lawsuit was filed purportedly on behalf of the Company in the United States District Court for the Northern District of California naming certain of our current and former officers and directors as defendants (the "Federal Derivative Action"). The lawsuit's allegations are substantially similar to the allegations in the State Court Derivative Action. On October 21, 2013, the Court ordered a stay in the Federal Derivative Action pending the outcome of the motion to dismiss in the securities class action. Subsequent to the order regarding the motion to dismiss in the securities class action, on January 31, 2014, the Court ordered that the Federal Derivative Action be stayed until resolution of the securities class action. On April 30, 2014, plaintiff in the Federal Derivative Action filed a notice of voluntary dismissal without prejudice.

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

Product Liability Litigation

On or about February 13, 2014, a complaint was filed by an individual plaintiff in the Fourth Judicial District Court (Ouachita Parish) of the State of Louisiana, naming as defendants the Company, Takeda Pharmaceuticals America, Inc., Takeda Pharmaceuticals U.S.A., Inc., Takeda Development Center Americas, Inc., Takeda Pharmaceuticals International, Inc., Takeda

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Pharmaceutical Company Limited, Fresenius Medical Care Monroe, LLC, and Fresenius Medical Care Holdings, Inc., and indicating an intention to add two physicians as defendants. The plaintiff seeks to hold the defendants liable in connection with the death of her husband on February 15, 2013. The complaint alleges that the Company and certain other defendants are liable under the Louisiana Products Liability Act, La.R.S. 9:2800.51, et seq., other Louisiana statutes, and otherwise in connection with their alleged acts and omissions with respect to OMONTYS. The plaintiff seeks various categories or types of damages, including, without limitation, damages for her and her late husband's alleged losses and injuries, punitive or exemplary damages, the price of OMONTYS and reasonable expenses occasioned by the sale of that drug, and other relief as set forth in the complaint. On April 11, 2014, we filed our initial response to the claim, denying that the Company is liable for the plaintiff's damages as set forth in the complaint. Although this is the only lawsuit that the Company is aware of at this time, there can be no assurances that additional product liability complaints will not be brought.

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.

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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5. Stock-Based Compensation

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

	Three Months Ended March 31,	
	2014	2013
Research and development	$—	$1,244
Selling, general and administrative	484	2,473
Total	$484	$3,717

Stock Option Activity

The following tables summarize information about stock option activity for the three months ended March 31, 2014:

	Number of Shares	Weighted-Average Exercise Price (Per Share)	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Stock Options:				
Balances at December 31, 2013	1,839,857	$16.24		
Granted	—	—		
Exercised	—	—		
Forfeited	(5,236)	15.65		
Cancelled	(236,773)	21.18		
Balances at March 31, 2014	1,597,848	15.50	3.76	$—
Options exercisable at March 31, 2014	1,370,003	16.16	3.09	$—

6. Restructuring Charge

2013 Restructuring

In March 2013, we implemented 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. As of March 31, 2013, we completed a reduction in force of almost all our personnel, including all of our commercial and medical affairs field forces as well as other employees throughout the organization. We incurred $8.2 million in restructuring charges, all of which were related to the workforce reduction during the first quarter of 2013.

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

	Total
Balance at December 31, 2013	$315
Cash payments	(35)
Adjustment	$(101)
Balance at March 31, 2014	$179

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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, 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

We are a biopharmaceutical company 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 agreement 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 implemented 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. As of December 31, 2013, we completed a reduction in force of almost all our personnel, including all of our commercial and medical affairs field forces as well as other employees throughout the organization. We have recorded $16.1 million in restructuring charges related to the workforce reduction during the year ended December 31, 2013. As a result of this restructuring and the recall, we also recorded impairment charges of $4.4 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 year ended December 31, 2013.

In April 2013, as part of our efforts to restructure our operations in order to reduce costs, in addition to our reduction in force, we engaged an experienced restructuring firm, The Brenner Group, Inc. With the engagement of the restructuring firm, we terminated the employment of our former executive officers, including our Chief Executive Officer and Chief Financial Officer.

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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. 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.

We have experienced significant operating losses since inception. We have funded our operations primarily through the sale of equity securities, reimbursement for development expenses and 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, 2014, we had an accumulated deficit of $559.6 million.

Litigation

Shareholder 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 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. On May 2, 2013, the securities class action complaint that was filed on February 27, 2013 was voluntarily dismissed by the plaintiff. On May 21, 2013, the Court appointed a lead plaintiff in the remaining securities class action complaint that had been filed on March 6, 2013. On July 22, 2013, a consolidated amended class action complaint was filed on behalf of purported stockholders of the Company, naming as defendants the Company and certain of its former officers. The consolidated amended complaint alleges 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 OMONTYS, the Company's business practices, financial projections and other disclosures between August 8, 2012 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 September 20, 2013, the Company and the individual defendants (collectively, "Defendants") filed a motion to dismiss the consolidated amended complaint. On November 19, 2013, the plaintiff filed her opposition to the motion to dismiss and on December 19, 2013, Defendants filed their reply in support of their motion to dismiss. The hearing on the motion to dismiss occurred on January 15, 2014. On January 21, 2014, the Court issued its order granting the motion to dismiss regarding violations of Section 20(a) against all Defendants and it granted the motion to dismiss in part, denying the motion to dismiss in part, and providing plaintiffs with an opportunity to amend the complaint. On February 18, 2014, the

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Court, pursuant to a stipulation by the parties, stayed the litigation for ninety days to allow the parties to conduct settlement discussions.

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 current and former officers and directors as defendants (the "State Court Derivative Action"). 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. On May 31, 2013, the Court consolidated the two actions and appointed lead plaintiff. On June 11, 2013, lead plaintiff designated the complaint filed on March 29, 2013 as the operative complaint. On August 6, 2013, the Court stayed the State Court Derivative Action pending the outcome of the motion to dismiss in the securities class action. Subsequent to the order regarding the motion to dismiss in the securities class action, on January 31, 2014, the Court ordered that the State Court Derivative Action be stayed in its entirety until resolution of the securities class action.

On August 19, 2013, another derivative lawsuit was filed purportedly on behalf of the Company in the United States District Court for the Northern District of California naming certain of our current and former officers and directors as defendants (the "Federal Derivative Action"). The lawsuit's allegations are substantially similar to the allegations in the State Court Derivative Action. On October 21, 2013, the Court ordered a stay in the Federal Derivative Action pending the outcome of the motion to dismiss in the securities class action. Subsequent to the order regarding the motion to dismiss in the securities class action, on January 31, 2014, the Court ordered that the Federal Derivative Action be stayed until resolution of the securities class action. On April 30, 2014, plaintiff in the Federal Derivative Action filed a notice of voluntary dismissal without prejudice.

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

Product Liability Litigation

On or about February 13, 2014, a complaint was filed by an individual plaintiff in the Fourth Judicial District Court (Ouachita Parish) of the State of Louisiana, naming as defendants the Company, Takeda Pharmaceuticals America, Inc., Takeda Pharmaceuticals U.S.A., Inc., Takeda Development Center Americas, Inc., Takeda Pharmaceuticals International, Inc., Takeda Pharmaceutical Company Limited, Fresenius Medical Care Monroe, LLC, and Fresenius Medical Care Holdings, Inc., and indicating an intention to add two physicians as defendants. The plaintiff seeks to hold the defendants liable in connection with the death of her husband on February 15, 2013. The complaint alleges that the Company and certain other defendants are liable under the Louisiana Products Liability Act, La.R.S. 9:2800.51, et seq., other Louisiana statutes, and otherwise in connection with their alleged acts and omissions with respect to OMONTYS. The plaintiff seeks various categories or types of damages, including, without limitation, damages for her and her late husband's alleged losses and injuries, punitive or exemplary damages, the price of OMONTYS and reasonable expenses occasioned by the sale of that drug, and other relief as set forth in the complaint. On April 11, 2014, we filed our initial response to the claim, denying that the Company is liable for the plaintiff's damages as set forth in the complaint. Although this is the only lawsuit that the Company is aware of at this time, there can be no assurances that additional product liability complaints will not be brought.

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 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, 2014, we had an accumulated deficit of $559.5 million.

We believe we have sufficient cash to fund our operations through the third quarter of 2014. However, there is significant uncertainty as to whether we will have sufficient existing cash to fund our operations beyond the third quarter of 2014. Given our limited resources, there is no assurance that we will be able to reduce our operating expenses enough to meet our existing

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and future 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 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 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.

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

Results of Operations

Revenue

During the commercialization period, which commenced in June 2011 and continued through April 30, 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 was calculated on a quarterly basis as the amount required so that the profit or loss realized by both Affymax and Takeda on OMONTYS equated to 50% of the total product profit or loss. Total product profit or loss on OMONTYS was 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.

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

	Three Months Ended March 31,		Percent Change
	2014	2013	
Collaboration revenue	$—	$839	(100)%
License and royalty revenue	—	5	(100)%

Total revenue	$—	$844	(100)%

Revenue decreased $0.8 million from $0.8 million to $0.0 million for the three months ended March 31, 2014. The decrease in collaboration revenue for the three months ended March 31, 2014 compared to the three months ended March 31, 2013 was primarily due to suspension of all marketing and research activities, as a result of the product recall of OMONTYS. During the three months ended March 31, 2013, we recognized $0.8 million in collaboration revenue for the last profit equalization payment from Takeda which includes all commercial and US developement expenses that the parties agreed to share equally.

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

	Three Months Ended March 31,	
	2014	2013
Milestone payments	$—	$0
Net expense reimbursement after CAPM	—	839
Total collaboration revenue	$—	$839

Takeda Amendment

On February 23, 2013, we and Takeda announced a nationwide voluntary recall of OMONTYS as a result of post marketing 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 sales were ceased.

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. 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.

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):

	Three Months Ended March 31,		Percent Change
	2014	2013	
Research and development expenses	$—	$9,789	(100)%

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R&D expenses declined $9.8 million from 2013 to 2014. The decrease in R&D expenses in 2014 compared to 2013 was due to the recall of OMONTYS in February 2013. After the recall, we undertook a restructuring of the Company which involved the cessation of all R&D activity and a significant reduction in workforce including all R&D personnel.

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 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 expect research and development expenses to be immaterial in future quarters as we are no longer undertaking any research and development activities.

Selling, General and Administrative Expenses

SG&A expenses consist principally of salaries, employee benefits, consulting, professional fees for legal, auditing and tax services SG&A expenses as compared to the prior year are as follows (in thousands):

	Three Months Ended March 31,		Percent Change
	2014	2013	
Selling, general and administrative expenses	$1,493	$24,644	(94)%

SG&A expenses decreased $23.2 million from 2013 to 2014. The decrease in SG&A expenses in 2014 compared to 2013 was due to the recall of OMONTYS in February 2013. After the recall, we undertook a restructuring of the Company which involved a significant reduction in workforce.

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. We expect selling, general and administrative expenses for the foreseeable future to include a minimum level of salaries, benefits, and professional fees to maintain the corporate administrative responsibilities.

Collaboration Cost Reimbursement

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

	Three Months Ended March,		Percent Change
	2014	2013	
Collaboration cost reimbursement	—	(20,378)	NM

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 write-down 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 in the quarter ended March 31, 2013, primarily related to the Takeda Q1 profit equalization payment.

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.

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Impairment (Gain on Disposal) 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
	2014	2013	
Impairment (gain on disposal) of prepaid expenses, fixed assets and intangible assets	$—	$5,140	NM

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
	2014	2013	
Restructuring charges	$(101)	$8,216	NM

Beginning 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. By June 30, 2013, in addition to transitioning most activities to our collaborator, Takeda, we completed a reduction in force of most of our remaining employees, including all of our commercial and medical affairs field forces as well as other employees throughout the organization and incurred $8.2 million in restructuring charges. The benefit recorded in the first quarter of 2014 was due to an adjustment in the estimate of remaining benefits due to employees.

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
	2014	2013	
Interest income	$—	$15	(100)%
Interest expense	—	(492)	(100)%
Interest income (expense), net	$—	$(477)	(100)%

The decrease in interest income (expense), net during the quarter ended March 31, 2014 compared to the same period in 2013 was due primarily to final payment of interest and prepayment fees associated with the discharge of obligations under our loan agreement with Lenders, our launch allowance with Takeda, lower interest rates and lower average cash balance.

Provision for Income Taxes

We are subject to federal and state income taxes. We anticipate being in a net operating loss position for 2014 and therefore have not recorded any federal or state taxes, other than the minimum statutory California tax, related to the current period for the three months ended March 31, 2014..

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Liquidity and Capital Resources

Our cash, at March 31, 2014 and December 31, 2013 was as follows (in thousands):

	March 31, 2014	December 31 2013
Cash	$4,856	$5,597

Working Capital (Deficit)

Our working capital (deficit) was $(3.3) million at March 31, 2014, an increase in the deficit of $0.8 million from the working capital deficit as of December 31, 2013.

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 to fund our operations for the next 12 months. We believe we have sufficient cash to fund our operations through the third quarter of 2014. However, there is significant uncertainty as to whether we will have sufficient existing cash to fund our operations beyond the third quarter of 2014. Our liabilities exceed our assets. Given our limited resources, there is no assurance that we will be able to reduce our operating expenses enough to meet our existing and future obligations. If Takeda is not able to reintroduce the product or we are not able to obtain additional funding in the 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 and it is likely that investors will lose some or all of their investment in us. Any failure to dispel any continuing doubts about our ability to continue as a going concern could 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, we undertook a reduction in force of almost all of our employees, including our commercial and medical affairs field forces as well as other employees throughout the organization.

Beginning in April 2013, in an effort to restructure our operations and reduce costs, we commenced a process to notify substantially all of our workforce of estimated dates of separation and we engaged an experienced restructuring firm, The Brenner Group, Inc.. With the engagement of the restructuring firm, we terminated the employment of our former executive officers, including our Chief Executive Officer and Chief Financial Officer.

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. 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

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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.

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

Takeda 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 of $8.2 million which is classified as Advance from Takeda in the condensed balance sheet.

Cash Flows During the Three Months Ended March 31, 2014 and 2013

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

	Three Months Ended March 31,	
	2014	2013
Net cash provided by (used in) operating activities	$(741)	$(24,620)
Net cash provided by investing activities	—	3,600
Net cash provided by (used in) financing activities	—	(630)

Net cash used in operating activities for the three months ended March 31, 2014 and 2013 was $0.7 million and $24.6 million, respectively. Net cash used in operations for the three months ended March 31, 2014 reflects our net loss, adjusted for non-cash stock based compensation charges, and changes in accrued liabilities associated with compensation related accruals partially offset by increases in accounts payable and decreases in prepaid expenses and other assets. Net cash used in operations for the three months ended March 31, 2013 reflects our net loss, non-cash 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 the profit equalization revenue, and reimbursement for development and commercial expense and purchases of API by Takeda.

Net cash provided by investing activities for the three months ended March 31, 2014 was $0.0 million. Net cash provided by investing activities for the three months ended March 31, 2013 of $3.6 million was primarily due to

proceeds from maturities of investments.

Net cash used in financing activities for the three months ended March 31, 2014 was $0.0 million. 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 exercise of stock options.

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Contractual Obligations and Significant Commitments

There were no significant changes in our commercial commitments and capital obligations from the amounts disclosed in our Annual Report on Form 10-K for the year ended December 31, 2013.

Off-Balance Sheet Arrangements

At March 31, 2014, 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

There are no significant changes in our critical accounting policies from the disclosure provided in our Annual Report on Form 10-K for the year ended December 31, 2013.

Item 3. Quantitative and Qualitative Disclosure About Market Risk

There are no significant changes in our market risks from the disclosure provided in our Annual Report on Form 10-K for the year ended December 31, 2013.

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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. 2014. 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, 2014, our disclosure controls and procedures were effective at the reasonable assurance level.

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

Changes in Internal Control over Financial Reporting. Our management, has evaluated any changes in our internal control over financial reporting that occurred during the quarter ended March 31, 2014, and has concluded that there were no changes during such quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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PART II.

Item 1. Legal Proceedings

Shareholder 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 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. On May 2, 2013, the securities class action complaint that was filed on February 27, 2013 was voluntarily dismissed by the plaintiff. On May 21, 2013, the Court appointed a lead plaintiff in the remaining securities class action complaint that had been filed on March 6, 2013. On July 22, 2013, a consolidated amended class action complaint was filed on behalf of purported stockholders of the Company, naming as defendants the Company and certain of its former officers. The consolidated amended complaint alleges 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 OMONTYS, the Company's business practices, financial projections and other disclosures between August 8, 2012 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 September 20, 2013, the Company and the individual defendants (collectively, "Defendants") filed a motion to dismiss the consolidated amended complaint. On November 19, 2013, the plaintiff filed her opposition to the motion to dismiss and on December 19, 2013, Defendants filed their reply in support of their motion to dismiss. The hearing on the motion to dismiss occurred on January 15, 2014. On January 21, 2014, the Court issued its order granting the motion to dismiss regarding violations of Section 20(a) against all Defendants and it granted the motion to dismiss in part, denying the motion to dismiss in part, and providing plaintiffs with an opportunity to amend the complaint. On February 18, 2014, the Court, pursuant to a stipulation by the parties, stayed the litigation for ninety days to allow the parties to conduct settlement discussions.

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 current and former officers and directors as defendants (the "State Court Derivative Action"). 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. On May 31, 2013, the Court consolidated the two actions and appointed lead plaintiff. On June 11, 2013, lead plaintiff designated the complaint filed on March 29, 2013 as the operative complaint. On August 6, 2013, the Court stayed the State Court Derivative Action pending the outcome of the motion to dismiss in the securities class action. Subsequent to the order regarding the motion to dismiss in the securities class action, on January 31, 2014, the Court ordered that the State Court Derivative Action be stayed in its entirety until resolution of the securities class action.

On August 19, 2013, another derivative lawsuit was filed purportedly on behalf of the Company in the United States District Court for the Northern District of California naming certain of our current and former officers and directors as defendants (the "Federal Derivative Action"). The lawsuit's allegations are substantially similar to the allegations in the State Court Derivative Action. On October 21, 2013, the Court ordered a stay in the Federal Derivative Action pending the outcome of the motion to dismiss in the securities class action. Subsequent to the order regarding the motion to dismiss in the securities class action, on January 31, 2014, the Court ordered that the Federal Derivative Action be stayed until resolution of the securities class action. On April 30, 2014, plaintiff in the Federal Derivative Action filed a notice of voluntary dismissal without prejudice.

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

Product Liability Litigation

On or about February 13, 2014, a complaint was filed by an individual plaintiff in the Fourth Judicial District Court (Ouachita Parish) of the State of Louisiana, naming as defendants the Company, Takeda Pharmaceuticals America, Inc., Takeda Pharmaceuticals U.S.A., Inc., Takeda Development Center Americas, Inc., Takeda Pharmaceuticals International, Inc., Takeda Pharmaceutical Company Limited, Fresenius Medical Care Monroe, LLC, and Fresenius Medical Care Holdings, Inc., and indicating an intention to add two physicians as defendants. The plaintiff seeks to hold the defendants liable in connection with the death of her husband on February 15, 2013. The complaint alleges that the Company and certain other defendants are liable under the Louisiana Products Liability Act, La.R.S. 9:2800.51, et seq., other Louisiana statutes, and otherwise in connection

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with their alleged acts and omissions with respect to OMONTYS. The plaintiff seeks various categories or types of damages, including, without limitation, damages for her and her late husband's alleged losses and injuries, punitive or exemplary damages, the price of OMONTYS and reasonable expenses occasioned by the sale of that drug, and other relief as set forth in the complaint. On April 11, 2014, we filed our initial response to the claim, denying that the Company is liable for the plaintiff's damages as set forth in the complaint. Although this is the only lawsuit that the Company is aware of at this time, there can be no assurances that additional product liability complaints will not be brought.

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 Annual Report on Form 10-K. 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 Annual Report on Form 10-K, 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 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 have ceased most company operations and may not be able to continue our business 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 have ceased most company operations and may not be able to continue our business.

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. To date, no causes have been identified and we are unable to predict when, or if, this process may be completed or the associated costs. Further, in an effort to continue our operations in the near term with our limited resources, we have substantially reduced our operating costs, including a reduction in force of nearly all of our

employees and cessation of most operating functions. The Brenner Group, Inc., a restructuring firm, has been retained to oversee and implement the ongoing operations.

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.

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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 have limited resources with which to continue basic company operations until the future of OMONTYS (if any) is determined. If the Takeda led investigation takes an extended period, or results in OMONTYS not being reintroduced commercially to the market, we may need to cease operations.

We have experienced significant operating losses since our inception in 2001. At March 31, 2014, we had an accumulated deficit of $559.6 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 have limited resources with which to continue our operations and we have substantial ongoing obligations. In particular, we expect to continue to spend significant amounts in defense of our existing and potential future litigation.

As a result of the recall and the subsequent restructuring, we believe that we have enough cash to fund our resources through the third quarter of 2014. Even with our restructuring efforts, including the termination of substantially our entire workforce, there is no assurance that our reduced resources will be sufficient to meet our existing obligations and conduct ongoing operations. If Takeda is not able to reintroduce OMONTYS or we are not able to obtain additional funding, our cash resources will rapidly be depleted and we may need to cease operations.

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 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, wind-down 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.

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.

As of June 30, 2013 we dramatically reduced our workforce and engaged an experienced restructuring firm, The Brenner Group, Inc. With our engagement of The Brenner Group, Inc., we terminated the employment of our former executive officers, including our Chief Executive Officer and Chief Financial Officer. 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, 2013, a statement with respect to substantial doubt as to our ability to continue as a going concern.

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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. Our business has already been severely harmed by the recall of OMONTYS, and any termination of the collaboration agreement would substantially reduce our ability to meet our obligations, and may increase the likelihood of having to cease our operations, even with the ongoing restructuring efforts.

The maintenance of our collaboration with Takeda for OMONTYS is an essential part of our business. 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 OMONTYS may be reintroduced if Takeda completes the investigation and addresses the safety concerns to the satisfaction of the FDA.

Moreover, Takeda has the right 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 assume the regulatory responsibilities required to maintain the NDA. 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 if the MAA is resubmitted 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 as well as product liability litigation and we may be subject to similar or other litigation in the future.

We and certain of our former officers are defendants in a lawsuit filed 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 OMONTYS and our business practices, financial projections and other disclosures between August 8, 2012 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.

In addition, in March 2013 and August 2013, a total of three 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 current and former 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. 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. In addition, it is possible total liability could exceed our insurance limits.

On or about February 13, 2014, a complaint was filed by an individual plaintiff in the Fourth Judicial District Court (Ouachita Parish) of the State of Louisiana, naming as defendants the Company, Takeda Pharmaceuticals America, Inc., Takeda Pharmaceuticals U.S.A., Inc., Takeda Development Center Americas, Inc., Takeda Pharmaceuticals International, Inc., Takeda Pharmaceutical Company Limited, Fresenius Medical Care Monroe, LLC, and Fresenius Medical Care Holdings, Inc., and indicating an intention to add two physicians as defendants. The plaintiff seeks to hold the defendants liable in connection with the death of her husband on February 15, 2013. The complaint alleges that the Company and certain other defendants are liable under the Louisiana Products Liability Act, La.R.S. 9:2800.51, et seq., other Louisiana statutes, and otherwise in connection with their alleged acts and omissions with respect to OMONTYS. The plaintiff seeks various categories or types of damages, including, without limitation, damages for her and her late husband's alleged losses and injuries, punitive or exemplary damages, the price of OMONTYS and reasonable expenses occasioned by the sale of that drug, and other relief as set forth in the complaint. On April 11, 2014, we filed our initial response to the claim, denying that the Company is liable for the

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plaintiff's damages as set forth in the complaint. Although this is the only lawsuit that the Company is aware of at this time, there can be no assurances that additional product liability complaints will not be brought.

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 additional 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. Regardless of the outcome, product liability claims may result in injury to our reputation, significant costs, diversion of management's attention and resources, substantial monetary awards and loss of revenue. 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

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

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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 erythropoiesis-stimulating agents, or 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:

- 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.

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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 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

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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 regulatory 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.

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

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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, Hospira, Inc. has received approval from the EMA for its biosimilar in the EU as it continues development efforts in the U.S. to obtain approval.

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 funding 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 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

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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 have terminated all of our manufacturing activities. 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 limited 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 limited resources to pursue any enforcement ourselves that Takeda chooses not to pursue.

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;

- 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

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willfully disclose our information to competitors. Enforcing a claim that a third party illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the U.S. are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

Our 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. We have limited financial resources with which to maintain and enforce patent protection should Takeda choose not to take protective action.

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 agreement 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 or royalties 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 as well as product liability lawsuits. These lawsuits could result in substantial damages.

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. On May 2, 2013, the securities class action complaint that was filed on February

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27, 2013 was voluntarily dismissed by the plaintiff. On May 21, 2013, the Court appointed a lead plaintiff in the remaining securities class action complaint that had been filed on March 6, 2013. On July 22, 2013, a consolidated amended class action complaint was filed on behalf of purported stockholders of the Company, naming as defendants the Company and certain of its former officers. The consolidated amended complaint alleges 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 OMONTYS, the Company's business practices, financial projections and other disclosures between August 8, 2012 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 September 20, 2013, the Company and the individual defendants (collectively, “Defendants”) filed a motion to dismiss the consolidated amended complaint. On November 19, 2013, the plaintiff filed her opposition to the motion to dismiss and on December 19, 2013, Defendants filed their reply in support of their motion to dismiss. The hearing on the motion to dismiss occurred on January 15, 2014. On January 21, 2014, the Court issued its order granting the motion to dismiss regarding violations of Section 20(a) against all Defendants and it granted the motion to dismiss in part, denying the motion to dismiss in part, and providing plaintiffs with an opportunity to amend the complaint. On February 18, 2014, the Court, pursuant to a stipulation by the parties, stayed the litigation for ninety days to allow the parties to conduct settlement discussions.

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 current and former officers and directors as defendants (the “State Court Derivative Action”). 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. On May 31, 2013, the Court consolidated the two actions and appointed lead plaintiff. On June 11, 2013, lead plaintiff designated the complaint filed on March 29, 2013 as the operative complaint. On August 6, 2013, the Court stayed the State Court Derivative Action pending the outcome of the motion to dismiss in the securities class action. Subsequent to the order regarding the motion to dismiss in the securities class action, on January 31, 2014, the Court ordered that the State Court Derivative Action be stayed in its entirety until resolution of the securities class action.

On August 19, 2013, another derivative lawsuit was filed purportedly on behalf of the Company in the United States District Court for the Northern District of California naming certain of our current and former officers and directors as defendants (the “Federal Derivative Action”). The lawsuit’s allegations are substantially similar to the allegations in the State Court Derivative Action. On October 21, 2013, the Court ordered a stay in the Federal Derivative Action pending the outcome of the motion to dismiss in the securities class action. Subsequent to the order regarding the motion to dismiss in the securities class action, on January 31, 2014, the Court ordered that the Federal Derivative Action be stayed until resolution of the securities class action. On April 30, 2014, plaintiff in the Federal Derivative Action filed a notice of voluntary dismissal without prejudice.

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

On or about February 13, 2014, a complaint was filed by an individual plaintiff in the Fourth Judicial District Court (Ouachita Parish) of the State of Louisiana, naming as defendants the Company, Takeda Pharmaceuticals America, Inc., Takeda Pharmaceuticals U.S.A., Inc., Takeda Development Center Americas, Inc., Takeda Pharmaceuticals International, Inc., Takeda Pharmaceutical Company Limited, Fresenius Medical Care Monroe, LLC, and Fresenius Medical Care Holdings, Inc., and indicating an intention to add two physicians as defendants. The plaintiff seeks to hold the defendants liable in connection with the death of her husband on February 15, 2013. The complaint alleges that the Company and certain other defendants are liable under the Louisiana Products Liability Act, La.R.S. 9:2800.51, et seq., other Louisiana statutes, and otherwise in connection with their alleged acts and omissions with respect to OMONTYS. The plaintiff seeks various categories or types of damages, including, without limitation, damages for her and her late husband’s alleged losses and injuries, punitive or exemplary damages, the price of OMONTYS and reasonable expenses occasioned by the sale of that drug, and other relief as set forth in the

complaint. On April 11, 2014, we filed our initial response to the claim, denying that the Company is liable for the plaintiff's damages as set forth in the complaint. Although this is the only lawsuit that the Company is aware of at this time, there can be no assurances that additional product liability complaints will not be brought.

Our management believes that we have meritorious defenses and intends to defend these lawsuits vigorously. 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. In addition, it is possible total liability could exceed our insurance limits.

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We have been delisted from The NASDAQ Stock Market and our shares currently trade Over The Counter. We remain subject to additional expenses and administrative burden as a public company.

On May 28, 2013, we received a determination letter from the Nasdaq Stock Market indicating that Nasdaq believes that our stock should be delisted pursuant to Rule 5101 of the Nasdaq Listing Rules. Specifically, Nasdaq notified us that in their opinion we are operating as a "public shell" and has determined that, following the Company's announcement regarding the voluntary recall of OMONTYS, we no longer have an operating business.

Nasdaq has determined that public shells could be detrimental to the interests of the investing public. Nasdaq Listing Rule 5100 provides Nasdaq with discretionary authority to apply more stringent criteria for continued listing and the ability to terminate the inclusion of particular securities based on any event, condition or circumstance that exists or occurs that in the opinion of Nasdaq makes inclusion of the securities on Nasdaq inadvisable or unwarranted.

We did not appeal this determination and as a result, on the opening of business June 6, 2013, we were suspended from the Nasdaq Stock Market and began trading on the Over The Counter electronic market (OTCQB). On July 19, we received notice from the Nasdaq Stock Market that Nasdaq filed a Form 25 with the Securities and Exchange Commission to complete delisting.

The risk resulting from Nasdaq 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. OTC markets are generally considered less liquid which may lead to greater stock price volatility. 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.

In addition, as a public company, we continue to 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.

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, 2014, the closing price of our common stock ranged between a high of $2.08 per share and a low of $0.76 per share. The closing price for our common stock as reported by The OTCMKTS Stock Market on April 30, 2014 was $0.54 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;
- actual or anticipated contractual arrangements for OMONTYS should Takeda reintroduce OMONTYS or competing products;

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- 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;
- 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.

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, 2013, 2012 or 2011. Because we are not an accelerated filer, as defined by rule 12b-2 of the exchange act, Ernst and Young LLP was not required to issue an opinion on our internal

control over financial reporting pursuant to Section 404 of the Sarbanes Oxley Act of 2002. We cannot assure you that material weaknesses in our internal controls will not be identified in future periods. We may have particular difficulty maintaining segregation of responsibilities with only four employees plus the services of the The Brenner Group, Inc. There can be no assurance that we will successfully and timely report on the effectiveness of our internal control over financial reporting in future periods. If we do experience a material weakness in 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

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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 2013, 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:

- authorizing the issuance of “blank check” preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval;
- limiting the removal of directors by the stockholders;
- prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders;

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

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

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

In addition, we are subject to Section 203 of the Delaware General Corporation Law, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with an interested stockholder for a

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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, 2014.
Issuer Purchases of Equity Securities
We did not repurchase any of our equity securities during the quarter ended March 31, 2014.
Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

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Item 6. Exhibits

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

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)
10.49		Consulting Engagement Agreement, date April 19, 2013 between Registrant and The Brenner Group
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 6, 2014

By: /s/ RICHARD M. BRENNER
Richard M. Brenner
Chief Executive Officer and
Member of the Board of Directors

Dated: May 6, 2014

By: /s/ MARK G. THOMPSON
Mark G. Thompson
Chief Financial Officer