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 lice