ARRAY BIOPHARMA INC
Form 10-Q
May 09, 2014

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended March 31, 2014

or

[ ] TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from to

Commission File Number: 001-16633

Array BioPharma Inc.
(Exact Name of Registrant as Specified in Its Charter)

Delaware	84-1460811
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
3200 Walnut Street, Boulder, CO	80301
(Address of Principal Executive Offices)	(Zip Code)

(303) 381-6600
(Registrant's Telephone Number, Including Area Code)

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 ¨

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 ¨

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

Large Accelerated Filer ¨	Accelerated Filer x

Non-Accelerated Filer ¨ Smaller Reporting Company ¨
(do not check if smaller reporting company)

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

As of April 30, 2014, the registrant had 125,984,565 shares of common stock outstanding.

ARRAY BIOPHARMA INC.
QUARTERLY REPORT ON FORM 10-Q
FOR THE QUARTERLY PERIOD ENDED MARCH 31, 2014
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PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

ARRAY BIOPHARMA INC.
Balance Sheets
(In thousands, except share and per share data)
(Unaudited)

	March 31, 2014	June 30, 2013
Assets		
Current assets		
Cash and cash equivalents	$52,178	$60,736
Marketable securities	57,714	47,505
Accounts receivable	4,433	9,595
Prepaid expenses and other current assets	3,743	3,473
Total current assets	118,068	121,309
Long-term assets		
Marketable securities	593	465
Property and equipment, net	7,838	10,049
Other long-term assets	8,656	4,165
Total long-term assets	17,087	14,679
Total assets	$135,155	$135,988
Liabilities and Stockholders' Deficit		
Current liabilities		
Accounts payable	$7,020	$5,396
Accrued outsourcing costs	8,036	5,576
Accrued compensation and benefits	7,221	9,481
Other accrued expenses	2,170	1,135
Co-development liability	11,967	10,990
Deferred rent	3,717	3,646
Deferred revenue	5,733	14,353
Total current liabilities	45,864	50,577
Long-term liabilities		
Deferred rent	5,032	7,834
Deferred revenue	4,329	—
Long-term debt, net	102,675	99,021
Other long-term liabilities	593	465
Total long-term liabilities	112,629	107,320
Total liabilities	158,493	157,897
Commitments and contingencies		
Stockholders' deficit		
Preferred stock, $0.001 par value; 10,000,000 shares authorized, no shares issued and outstanding	—	—

Common stock, $0.001 par value; 220,000,000 shares authorized; 125,969,565 and 116,878,021 shares issued and outstanding as of March 31, 2014 and June 30, 2013, respectively	126	117
Additional paid-in capital	626,843	571,270
Warrants	39,385	39,385
Accumulated other comprehensive income (loss)	7	(2)
Accumulated deficit	(689,699)	(632,679)
Total stockholders' deficit	(23,338)	(21,909)
Total liabilities and stockholders' deficit	$135,155	$135,988

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

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ARRAY BIOPHARMA INC.
Statements of Operations and Comprehensive Loss
(In thousands, except per share data)
(Unaudited)

	Three Months Ended March 31,		Nine Months Ended March 31,	
	2014	2013	2014	2013
Revenue				
License and milestone revenue	$4,287	$6,848	$23,639	$33,340
Collaboration revenue	3,486	3,107	12,428	10,825
Total revenue	7,773	9,955	36,067	44,165
Operating expenses				
Cost of partnered programs	10,756	8,624	34,524	23,072
Research and development for proprietary programs	14,131	15,105	35,322	42,580
General and administrative	5,405	5,001	16,056	14,390
Total operating expenses	30,292	28,730	85,902	80,042
Loss from operations	(22,519)	(18,775)	(49,835)	(35,877)
Other income (expense)				
Interest income	22	18	61	42
Interest expense	(2,435)	(2,837)	(7,246)	(8,456)
Total other expense, net	(2,413)	(2,819)	(7,185)	(8,414)
Net loss	$(24,932)	$(21,594)	$(57,020)	$(44,291)
Change in unrealized gains and losses on marketable securities	7	—	9	3
Comprehensive loss	$(24,925)	$(21,594)	$(57,011)	$(44,288)
Weighted average shares outstanding – basic and diluted	125,471	116,665	122,277	104,806
Net loss per share – basic and diluted	$(0.20)	$(0.19)	$(0.47)	$(0.42)

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

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ARRAY BIOPHARMA INC.
Statement of Stockholders' Deficit
(In thousands)
(Unaudited)

	Common Stock		Additional Paid-in Capital	Warrants	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total
	Shares	Amounts					
Balance as of July 1, 2013	116,878	$ 117	$571,270	$39,385	$ (2)	$ (632,679)	$(21,909)
Issuance of common stock under stock option and employee stock purchase plans	1,045	1	3,416	—	—	—	3,417
Share-based compensation expense	—	—	3,080	—	—	—	3,080
Issuance of common stock, net of offering costs	8,047	8	49,107	—	—	—	49,115
Offering costs for convertible senior notes, equity portion	—	—	(30)	—	—	—	(30)
Change in unrealized loss on marketable securities	—	—	—	—	9	—	9
Net loss	—	—	—	—	—	(57,020)	(57,020)
Balance as of March 31, 2014	125,970	$ 126	$626,843	$39,385	$ 7	$ (689,699)	$(23,338)

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

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ARRAY BIOPHARMA INC.
Statements of Cash Flows
(In thousands)
(Unaudited)

	Nine Months Ended March 31,	
	2014	2013
Cash flows from operating activities		
Net loss	$(57,020)	$(44,291)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	3,576	3,350
Non-cash interest expense	3,899	3,266
Share-based compensation expense	3,080	2,385
Payment of employee bonus with stock	—	2,857
Non-cash license revenue	(4,500)	—
Changes in operating assets and liabilities:		
Accounts receivable	5,162	(2,489)
Prepaid expenses and other assets	(449)	(1,069)
Accounts payable and other accrued expenses	2,659	1,085
Accrued outsourcing costs	2,460	(334)
Accrued compensation and benefits	(2,260)	143
Co-development liability	977	(2,184)
Deferred rent	(2,731)	(2,616)
Deferred revenue	(4,291)	(32,977)
Other liabilities	(6)	(110)
Net cash used in operating activities	(49,444)	(72,984)
Cash flows from investing activities		
Purchases of property and equipment	(1,365)	(2,011)
Purchases of marketable securities	(80,457)	(73,447)
Proceeds from sales and maturities of marketable securities	70,262	64,354
Net cash used in investing activities	(11,560)	(11,104)
Cash flows from financing activities		
Payments of long-term debt principal	—	(150)
Proceeds from the issuance of common stock	50,155	75,555
Proceeds from employee stock purchases and options exercised	3,417	1,539
Payment of debt issuance costs	(86)	—
Payment of stock offering costs	(1,040)	(4,657)
Net cash provided by financing activities	52,446	72,287
Net decrease in cash and cash equivalents	(8,558)	(11,801)
Cash and cash equivalents at beginning of period	60,736	55,799
Cash and cash equivalents at end of period	$52,178	$43,998
Supplemental disclosure of cash flow information		
Cash paid for interest	$2,246	$5,189

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

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ARRAY BIOPHARMA INC.
Notes to the Unaudited Financial Statements

NOTE 1 – OVERVIEW AND BASIS OF PRESENTATION

Organization

Array BioPharma Inc. (also referred to as "Array," "we," "us," or "our"), incorporated in Delaware on February 6, 1998, is a biopharmaceutical company focused on the discovery, development and commercialization of targeted small molecule drugs to treat patients afflicted with cancer.

Basis of Presentation

The accompanying unaudited financial statements have been prepared pursuant to the rules and regulations of the Securities and Exchange Commission ("SEC") for interim reporting and, as permitted under those rules, do not include all of the disclosures required by U.S. generally accepted accounting principles ("U.S. GAAP") for complete financial statements. The unaudited financial statements reflect all normal and recurring adjustments that, in the opinion of management, are necessary to present fairly our financial position, results of operations and cash flows for the interim periods presented. Operating results for an interim period are not necessarily indicative of the results that may be expected for a full year.

These unaudited financial statements should be read in conjunction with our audited financial statements and the notes thereto for the fiscal year ended June 30, 2013, included in our Annual Report on Form 10-K filed with the SEC, from which we derived our balance sheet data as of June 30, 2013.

Use of Estimates

The preparation of these financial statements in conformity with U.S. GAAP requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue and expenses, and related disclosure of contingent assets and liabilities. We base our estimates on historical experience and on various other assumptions that we believe are reasonable under the circumstances. These estimates are the basis for our judgments about the carrying values of assets and liabilities, which in turn may impact our reported revenue and expenses. Our actual results could differ significantly from these estimates under different assumptions or conditions.

We believe our financial statements are most significantly impacted by the following accounting estimates and judgments: (i) the identification of deliverables under partnerships and collaborations involving multiple elements and determining whether such deliverables are separable from other aspects of the contractual relationship; (ii) estimating the selling price of deliverables for the purpose of allocating arrangement consideration for revenue recognition; (iii) estimating the periods over which the allocated consideration for deliverables is recognized; (iv) estimating accrued outsourcing costs for clinical trials and preclinical testing; (v) determining the fair value of the debt component for our convertible senior notes exclusive of the conversion feature; and (vi) estimating the fair value of non-marketable equity received from licensing transactions.

Liquidity

We have incurred operating losses and an accumulated deficit as a result of ongoing research and development spending since inception. As of March 31, 2014, we had an accumulated deficit of $689.7 million. We had net losses of $24.9 million and $57.0 million for the three and nine months ended March 31, 2014, respectively, and net losses of

$61.9 million, $23.6 million and $56.3 million for the fiscal years ended June 30, 2013, 2012 and 2011, respectively.

We have historically funded our operations from up-front fees and license and milestone payments received under our drug partnerships, the sale of equity securities, and debt provided by convertible debt and other credit facilities. Management believes that our cash, cash equivalents and marketable securities as of March 31, 2014 will enable us to continue to fund operations in the normal course of business for at least the next 12 months. Until we can generate sufficient levels of cash from current operations, which we do not expect to achieve in the

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foreseeable future, and because sufficient funds may not be available to us when needed from existing partnerships, we expect that we will be required to continue to fund our operations in part through the sale of debt or equity securities and through licensing select programs that include up-front and/or milestone payments.

Our ability to successfully raise sufficient funds through the sale of debt or equity securities or from debt financing from lenders when needed is subject to many risks and uncertainties and, even if we are successful, future equity issuances would result in dilution to our existing stockholders. We also may not successfully consummate new partnerships that provide for up-front fees or milestone payments, or we may not earn milestone payments under such partnerships when anticipated, or at all. Our ability to realize milestone or royalty payments under existing partnership agreements and to enter into new partnering arrangements that generate additional revenue through up-front fees and milestone or royalty payments is subject to a number of risks, many of which are beyond our control. For example, although following the recently announced transaction by Novartis to exchange certain assets with GlaxoSmithKline, Novartis has indicated that it will continue to honor its obligations under its License Agreement with Array for the development of binimetinib, including the three Phase 3 trials currently underway, there can be no assurance that development efforts, and any potential future milestone or royalty revenue, will not be affected by this transaction.

In addition, our assessment of our future need for funding and our ability to continue to fund our operations is a forward-looking statement that is based on assumptions that may prove to be wrong and that involve substantial risks and uncertainties.

If we are unable to generate enough revenue from our existing or new partnerships when needed or secure additional sources of funding, it may be necessary to significantly reduce the current rate of spending through further reductions in staff and delaying, scaling back, or stopping certain research and development programs, including more costly Phase 2 and Phase 3 clinical trials on our wholly-owned or co-development programs as these programs progress into later stage development. Insufficient liquidity may also require us to relinquish greater rights to product candidates at an earlier stage of development or on less favorable terms to us and our stockholders than we would otherwise choose in order to obtain up-front license fees needed to fund operations. These events could prevent us from successfully executing our operating plan and, in the future, could raise substantial doubt about our ability to continue as a going concern. Further, as discussed in Note 4 – Long-term Debt, if at any time our balance of total cash, cash equivalents and marketable securities at Comerica Bank and approved outside accounts falls below $22 million, we must maintain a balance of cash, cash equivalents and marketable securities at Comerica at least equivalent to the entire outstanding debt balance with Comerica, which is currently $14.6 million. We must also maintain a monthly liquidity ratio if we draw down on the revolving line of credit.

Equity Investment

From time to time, we may enter into collaboration and license agreements under which we receive an equity interest as consideration for all or a portion of up-front, license or other fees under the terms of the agreement. We report equity securities received from non-publicly traded companies in which we do not exercise a significant or controlling interest at cost in other long-term assets in the accompanying balance sheets. We monitor our investments for impairment at least annually, and consider events or changes in circumstances we know of that may have a significant adverse effect on the fair value. We make appropriate reductions in the carrying value if it is determined that an impairment has occurred, based primarily on the financial condition and near and long-term prospects of the issuer. We do not report the fair value of our equity investments because it is not practical to do so.

In July 2013, Array entered into a collaboration agreement with Loxo Oncology, Inc. under which we received shares of non-voting preferred stock as consideration for licensing rights granted to Loxo. We estimated the fair value of these shares to be $4.5 million based on a valuation analysis prepared with the assistance of a third-party valuation firm. The full estimated value of $4.5 million is reflected as a long-term asset in our balance sheet as of March 31,

2014, and was recorded as license revenue in our statement of operations and comprehensive loss during the first quarter of fiscal 2014. Further discussion regarding assumptions and estimates related to the determination of the fair value of the shares and related revenue recognition can be found in Note 3 - Collaboration and License Agreements – Loxo Oncology, Inc.

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In addition, as of both March 31, 2014 and June 30, 2013, we held shares of preferred stock of VentiRx Pharmaceuticals, Inc. valued at $1.5 million that we received under a February 2007 collaboration and licensing agreement with VentiRx.

Accrued Outsourcing Costs

Substantial portions of our preclinical studies and clinical trials are performed by third-party laboratories, medical centers, contract research organizations and other vendors (collectively "CROs"). These CROs generally bill monthly or quarterly for services performed, or bill based upon milestone achievement. For preclinical studies, we accrue expenses based upon estimated percentage of work completed and the contract milestones remaining. For clinical studies, expenses are accrued based upon the number of patients enrolled and the duration of the study. We monitor patient enrollment, the progress of clinical studies and related activities to the extent possible through internal reviews of data reported to us by the CROs, correspondence with the CROs and clinical site visits. Our estimates depend on the timeliness and accuracy of the data provided by the CROs regarding the status of each program and total program spending. We periodically evaluate the estimates to determine if adjustments are necessary or appropriate based on information we receive.

Convertible Senior Notes

Our 3.00% convertible senior notes due 2020 are accounted for in accordance with Financial Accounting Standards Board ("FASB") Accounting Standards Codification (“ASC”) 470, Accounting for Convertible Debt Instruments That May be Settled in Cash upon Conversion (Including Partial Cash Settlement). ASC 470-20 requires the issuer of convertible debt that may be settled in shares or cash upon conversion at the issuer's option, such as our notes, to account for the liability (debt) and equity (conversion option) components separately. The value assigned to the debt component is the estimated fair value, as of the issuance date, of a similar debt instrument without the conversion option. The amount of the equity component (and resulting debt discount) is calculated by deducting the fair value of the liability component from the principal amount of the convertible debt instrument. The resulting debt discount is amortized as additional non-cash interest expense over the expected life of the notes utilizing the effective interest method. Although ASC 470 has no impact on our actual past or future cash flows, it requires us to record non-cash interest expense as the debt discount is amortized. For additional information, see Note 4 – Long-term Debt.

Revenue Recognition

We recognize revenue for the performance of services or the shipment of products when each of the following four criteria is met: (i) persuasive evidence of an arrangement exists; (ii) products are delivered or as services are rendered; (iii) the sales price is fixed or determinable; and (iv) collectability is reasonably assured.

We follow ASC 605-25, Revenue Recognition – Multiple-Element Arrangements and ASC 808, Collaborative Arrangements, if applicable, to determine the recognition of revenue under our collaborative research, development and commercialization agreements. The terms of these agreements generally contain multiple elements, or deliverables, which may include (i) grants of licenses, or options to obtain licenses, to our intellectual property, (ii) research and development services, (iii) drug product manufacturing, and/or (iv) participation on joint research and/or joint development committees. The payments we may receive under these arrangements typically include one or more of the following: non-refundable, up-front license fees; option exercise fees; funding of research and/or development efforts; amounts due upon the achievement of specified objectives; and/or royalties on future product sales.

ASC 605-25 provides guidance relating to the separability of deliverables included in an arrangement into different units of accounting and the allocation of arrangement consideration to the units of accounting. The evaluation of multiple-element arrangements requires management to make judgments about (i) the identification of deliverables,

(ii) whether such deliverables are separable from the other aspects of the contractual relationship, (iii) the estimated selling price of each deliverable, and (iv) the expected period of performance for each deliverable.

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To determine the units of accounting under a multiple-element arrangement, management evaluates certain separation criteria, including whether the deliverables have stand-alone value, based on the relevant facts and circumstances for each arrangement. Management then estimates the selling price for each unit of accounting and allocates the arrangement consideration to each unit utilizing the relative selling price method. The allocated consideration for each unit of accounting is recognized over the related obligation period in accordance with the applicable revenue recognition criteria.

If there are deliverables in an arrangement that are not separable from other aspects of the contractual relationship, they are treated as a combined unit of accounting, with the allocated revenue for the combined unit recognized in a manner consistent with the revenue recognition applicable to the final deliverable in the combined unit. Payments received prior to satisfying the relevant revenue recognition criteria are recorded as deferred revenue in the accompanying balance sheets and recognized as revenue when the related revenue recognition criteria are met.

We typically receive non-refundable, up-front payments when licensing our intellectual property, which often occurs in conjunction with a research and development agreement. When management believes that the license to our intellectual property has stand-alone value, we generally recognize revenue attributed to the license upon delivery provided that there are no future performance requirements for use of the license. When management believes that the license to our intellectual property does not have stand-alone value, we typically recognize revenue attributed to the license on a straight-line basis over the contractual or estimated performance period. When the performance period is not specifically identifiable from the agreement, we estimate the performance period based upon provisions contained within the agreement, such as the duration of the research or development term.

Most of our agreements provide for non-refundable milestone payments. We recognize revenue that is contingent upon the achievement of a substantive milestone in its entirety in the period in which the milestone is achieved. A milestone is considered substantive when the consideration payable to us for such milestone (i) is consistent with our performance necessary to achieve the milestone or the increase in value to the partnership or collaboration resulting from our performance, (ii) relates solely to our past performance and (iii) is reasonable relative to all of the other deliverables and payments within the arrangement. In making this assessment, we consider all facts and circumstances relevant to the arrangement, including factors such as the scientific, regulatory, commercial and other risks that must be overcome to achieve the milestone, the level of effort and investment required to achieve the milestone and whether any portion of the milestone consideration is related to future performance or deliverables.

For payments payable on achievement of milestones that do not meet all of the conditions to be considered substantive, we recognize a portion of the payment as revenue when the specific milestone is achieved, and the contingency is removed, based on the applicable percentage earned of the estimated research or development effort, or other performance obligations that have elapsed, to the total estimated research and/or development effort attributable to the milestone. In other cases, when a non-substantive milestone payment is attributed to our future research or development obligations, we recognize the revenue on a straight-line basis, or other appropriate method, over the estimated remaining research or development effort. Other contingent event-based payments for which payment is either contingent solely upon the passage of time or the result of our partner's or collaborator's performance are recognized when earned.

We periodically review the expected performance periods under each of our agreements that provide for non-refundable up-front payments, license fees or milestone payments. We adjust the amortization periods when appropriate to reflect changes in assumptions relating to the duration of expected performance periods. We could accelerate revenue recognition for non-refundable up-front payments, license fees and milestone payments in the event of early termination of programs or if our expectations change. Alternatively, we could decelerate such revenue recognition if programs are extended or delayed. While changes to such estimates have no impact on our reported cash flows, our reported revenue may be significantly influenced by our estimates of the period over which our obligations

are expected to be performed and, therefore, over which revenue is recognized.

See Note 3 – Collaboration and License Agreements for further information about our partnerships and collaborations.

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Segments

We operate in one reportable segment and, accordingly, no segment disclosures have been presented herein. All of our equipment, leasehold improvements and other fixed assets are physically located within the U.S., and all agreements with our partners are denominated in U.S. dollars.

Concentration of Business Risks

Significant Partnerships

The following significant partnerships contributed greater than 10% of our total revenue during at least one of the periods set forth below. The revenue from these partners as a percentage of total revenue was as follows:

	Three Months Ended March 31,		Nine Months Ended March 31,	
	2014	2013	2014	2013
AstraZeneca AB	0.2 %	0.2 %	14.1 %	0.4 %
Celgene	12.6	32.3	7.7	21.5
Genentech, Inc.	6.9	13.7	7.7	13.3
Loxo Oncology, Inc.	16.4	—	22.2	—
Novartis International Pharmaceutical Ltd.	48.2	34.5	31.2	23.5
Oncothyreon Inc.	10.8	—	7.4	—
Amgen Inc.	—	—	—	25.2
	95.1 %	80.7 %	90.3 %	83.9 %

The loss of one or more of our significant partners could have a material adverse effect on our business, operating results or financial condition. We do not require collateral from our partners, though most pay in advance. Although we are impacted by economic conditions in the biotechnology and pharmaceutical sectors, management does not believe significant credit risk exists as of March 31, 2014.

Geographic Information

The following table details revenue from partnerships by geographic area based on the country in which our partners are located (in thousands):

	Three Months Ended March 31,		Nine Months Ended March 31,	
	2014	2013	2014	2013
North America	$4,007	$6,495	$19,713	$33,623
Europe	3,765	3,460	16,318	10,539
Asia Pacific	1	—	36	3
Total revenue	$7,773	$9,955	$36,067	$44,165

Accounts Receivable

Novartis and Oncothyreon accounted for 78% and 19%, respectively, of our total accounts receivable balances as of March 31, 2014, compared with 91% of our total accounts receivable balances attributable to Novartis as of June 30, 2013.

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NOTE 2 – MARKETABLE SECURITIES

Marketable securities consisted of the following as of March 31, 2014 (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Short-term available-for-sale securities:				
U.S. treasury securities	$57,388	$7	$—	$57,395
Mutual fund securities	319	—	—	319
	57,707	7	—	57,714
Long-term available-for-sale securities:				
Mutual fund securities	593	—	—	593
	593	—	—	593
Total	$58,300	$7	$—	$58,307

Marketable securities consisted of the following as of June 30, 2013 (in thousands):

		Gross	Gross