ARRAY BIOPHARMA INC Form 10-O

October 30, 2018

**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 September 30, 2018

or

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

For the transition period from to

\_\_\_\_\_

Commission File Number: 001-16633

\_\_\_\_\_

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 every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes x No "

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

Large Accelerated Filer x

Accelerated Filer "

Non-Accelerated Filer "

Smaller Reporting Company "

Emerging Growth Company "

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. "

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

As of October 26, 2018, the registrant had 213,072,082 shares of common stock outstanding.

ARRAY BIOPHARMA INC. QUARTERLY REPORT ON FORM 10-Q FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2018 TABLE OF CONTENTS

		Page No.
PART I	FINANCIAL INFORMATION	
<u>Item 1.</u>	Condensed Consolidated Financial Statements	
	Condensed Consolidated <u>Balance Sheets as of</u> September 30, 2018 and June 30, 2018 (unaudited)	<u>3</u>
	Condensed Consolidated Statements of Operations and Comprehensive Loss for the three months ended September 30, 2018 and 2017 (unaudited)	<u>4</u>
	Condensed Consolidated Statement of Stockholders' Equity for the three months ended September 30, 2018 (unaudited)	<u>5</u>
	Condensed Consolidated <u>Statements of Cash Flows for the</u> three months ended September 30, 2018 and 2017 (unaudited)	<u>6</u>
	Notes to the Unaudited Condensed Consolidated Financial Statements	7
	Management's Discussion and Analysis of Financial Condition and Results of	
Item 2.	<u>Operations</u>	<u>24</u>
	Quantitative and Qualitative Disclosures About Market Risk	<u>36</u>
<u>Item 4.</u>	Controls and Procedures	<u>36</u>
PART I	IOTHER INFORMATION	
	<u>Legal Proceedings</u>	<u>38</u>
<u>Item</u> <u>1A.</u>	Risk Factors	<u>38</u>
Item 5.	Other Information	<u>38</u>
Item 6.	<u>Exhibits</u>	<u>38</u>
<u>SIGNA</u>	<u>TURES</u>	<u>40</u>
<u>EXHIB</u>	<u>IT INDEX</u>	

## Table of Contents

## PART I. FINANCIAL INFORMATION

## ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Condensed Consolidated Balance Sheets (In thousands, except share and per share data) (Unaudited)

(Chaudited)	September 30, 2018	June 30, 2018
Assets		
Current assets		
Cash and cash equivalents	\$130,507	\$114,748
Marketable securities	283,886	297,739
Accounts receivable	44,378	32,084
Prepaid expenses and other current assets	17,439	6,972
Total current assets	476,210	451,543
Non-current assets		
Marketable securities	998	919
Property and equipment, net	6,860	7,128
Other non-current assets	151	774
Total non-current assets	8,009	8,821
Total assets	\$484,219	\$460,364
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	\$14,609	\$14,059
Accrued outsourcing costs	34,264	31,853
Accrued compensation and benefits	17,194	16,695
Other accrued expenses	6,550	1,868
Deferred rent	724	707
Notes payable at fair value		15,899
Deferred revenue	11,425	12,350
Current portion of long-term debt		2,500
Total current liabilities	84,766	95,931
Non-current liabilities		
Deferred rent	5,414	5,598
Deferred revenue	42,635	44,470
Long-term debt, net	131,093	93,376
Other non-current liabilities	1,243	1,246
Total non-current liabilities	180,385	144,690
Total liabilities	265,151	240,621

Commitments and contingencies

Stockholders' equity

Preferred stock, \$0.001 par value; 10,000,000 shares authorized, no shares issued and outstanding Common stock, \$0.001 par value; 280,000,000 shares authorized as of September 30, 2018 and June 30, 2018, 213,026,650 and 211,289,922 shares issued and outstanding as of September 30,213 211 2018 and June 30, 2018, respectively Additional paid-in capital 1,309,985 1,286,000 Accumulated other comprehensive loss (312)) (461 Accumulated deficit (1,090,818) (1,066,007) Total stockholders' equity 219,068 219,743 Total liabilities and stockholders' equity \$484,219 \$460,364 The accompanying notes are an integral part of these unaudited condensed consolidated financial statements. 3

## Table of Contents

## ARRAY BIOPHARMA INC.

Condensed Consolidated Statements of Operations and Comprehensive Loss (In thousands, except per share data) (Unaudited)

	Three Mor September 2018	nths Ended r 30, 2017
Revenue		
Product sales, net	\$13,993	<b>\$</b> —
Collaboration and license revenue	31,028	11,554
Reimbursement revenue	11,889	18,192
Total revenue	56,910	29,746
Operating expenses		
Cost of goods sold	195	_
Research and development	55,550	53,204
Selling, general and administrative	24,890	12,048
Total operating expenses	80,635	65,252
Loss from operations	(23,725)	(35,506)
Other income (expense)		
Realized gain on investments	35	
Change in fair value of notes payable	(65)	200
Interest income	1,524	525
Interest expense	(2,580)	(3,213)
Total other income (expense), net		(2,488 )
Net loss	\$(24,811)	\$(37,994)
Change in unrealized gain on marketable securities	149	34
Comprehensive loss	\$(24,662)	\$(37,960)
Weighted average shares outstanding – basic	212,193	174,772
Weighted average shares outstanding – diluted	212,193	174,772
Net loss per share – basic	\$(0.12)	
Net loss per share – diluted	\$(0.12)	\$(0.22)

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

# **Table of Contents**

## ARRAY BIOPHARMA INC.

Condensed Consolidated Statement of Stockholders' Equity (In thousands) (Unaudited)

	Common	n Stock Amounts	Additional Paid-in Capital	Accumulated Other Comprehensiv	Accumulated ve Deficit	Total
Balance as of June 30, 2018	211,290	\$ 211	\$1,286,000	Loss \$ (461 )	\$(1,066,007)	\$219,743
Shares issued for cash under employee share plans	503	1	2,255	_	_	2,256
Share-based compensation expense			4,812	_	_	4,812
Issuance of common stock, net of offering costs / At-the-market offering	1,234	1	16,918	_	_	16,919
Change in unrealized loss on marketable securities	_	_		149	_	149
Net loss		—		_	, ,	(24,811 )
Balance as of September 30, 2018	213,027	\$ 213	\$1,309,985	\$ (312)	\$(1,090,818)	\$219,068

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

# Table of Contents

## ARRAY BIOPHARMA INC.

Condensed Consolidated Statements of Cash Flows (In thousands)

(Unaudited)

(Unaudited)		
	Three Mor	nths Ended
	September	30,
	2018	2017
Cash flows from operating activities		
Net loss	\$(24,811)	\$(37,994)
Adjustments to reconcile net loss to net cash used in operating activities:	,	
Depreciation and amortization expense	533	577
Non-cash interest expense		1,961
Share-based compensation expense	4,812	5,583
Realized gain from investments, net	•	
Change in fair value of notes payable	65	(200
* * *	03	(200)
Changes in operating assets and liabilities:	(12.204	4.670
Accounts receivable	(12,294)	
Prepaid expenses and other assets		886
Accounts payable and other accrued expenses	4,268	1,287
Accrued outsourcing costs		6,145
Accrued compensation and benefits	1,632	2,013
Deferred rent		(88)
Deferred revenue	(2,760)	(2,926)
Other long-term liabilities	(51)	34
Net cash used in operating activities	(34,800)	(18,044)
Cash flows from investing activities		
Purchases of property and equipment	(265)	(24)
Proceeds from investment	35	
Purchases of marketable securities	(87,308)	(104,468)
Proceeds from sales and maturities of marketable securities		44,746
Net cash provided by (used in) investing activities	13,741	(59,746)
	,	, , ,
Cash flows from financing activities		
Proceeds from issuance of common stock / Public offering		258,750
Offering costs for issuance of common stock / Public offering		(15,732)
Proceeds from issuance of common stock / At-the-market offering	17,288	2,917
Offering costs for the issuance of common stock / At-the-market offering		(87)
Net proceeds from employee stock purchases and options exercised	1,123	1,423
Payment of note payable	(15,000)	•
Proceeds from the modification of long-term debt, net	33,776	_
<del>-</del>		
Net cash provided by financing activities	36,818	247,271
Not be seen to seek and seek aming lands	15.750	1.60 401
Net increase in cash and cash equivalents	15,759	169,481
Cash and cash equivalents at beginning of period	114,748	125,933
Cash and cash equivalents at end of period	\$130,507	\$295,414
Supplemental disclosure of cash flow information	<b>4.1.7.</b>	Φ.0.0
Cash paid for interest	\$1,151	\$89

Change in unrealized loss on marketable securities

\$149 \$34

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

#### **Table of Contents**

#### ARRAY BIOPHARMA INC.

Notes to the Unaudited Condensed Consolidated Financial Statements

# NOTE 1 – OVERVIEW, BASIS OF PRESENTATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

#### Organization

Array BioPharma Inc. ("Array,","we", "us", "our" or "the Company") is a fully-integrated, biopharmaceutical company focused on the discovery, development and commercialization of transformative and well-tolerated targeted small molecule drugs to treat patients afflicted with cancer and other high-burden diseases. We were incorporated in the State of Delaware in 1998. Since our founding, we have progressed two drugs through clinical development and received regulatory approval. BRAFTOVI and MEKTOVI were approved by the Food and Drug Administration ("FDA") for commercial sales in the United States ("U.S.") in June 2018 and by the European Commission for commercial sales in the European Union through our partner, Pierre Fabre, in September 2018.

#### **Basis of Presentation**

The accompanying unaudited condensed consolidated 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 condensed consolidated 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. Our management performed an evaluation of our activities through the date of filing of this Quarterly Report on Form 10-Q.

These unaudited condensed consolidated financial statements should be read in conjunction with our audited financial statements and the notes thereto for the fiscal year ended June 30, 2018, included in our Annual Report on Form 10-K filed with the SEC on August 14, 2018, from which we derived our balance sheet data as of June 30, 2018.

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 the vast majority of our agreements with partners are denominated in U.S. dollars.

#### Use of Estimates

The preparation of condensed consolidated financial statements in conformity with U.S. GAAP requires our management 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 our historical experience and on various other assumptions that we believe are reasonable under the circumstances. Our actual results could differ significantly from these estimates under different assumptions or conditions.

On an ongoing basis, we evaluate our estimates, including our most significant estimates related to revenue recognition, gross-to-net product sales adjustments, and estimating accrued outsourcing costs for clinical trials and preclinical testing.

## Liquidity

As of September 30, 2018 and June 30, 2018, we held cash, cash equivalents and marketable securities totaling \$415.4 million and \$413.4 million, respectively. With the exception of fiscal year 2015, we have incurred operating losses and an accumulated deficit as a result of ongoing research and development spending since inception. As of September 30, 2018, we had an accumulated deficit of \$1.1 billion. Our results of operations were net losses of \$24.8 million for the three months ended September 30, 2018 and \$147.3 million, \$116.8 million and \$92.8 million for the fiscal years ended June 30, 2018, 2017 and 2016, respectively.

#### **Table of Contents**

We have historically funded our operations from upfront fees, proceeds from research and development reimbursement arrangements, license and milestone payments received under our drug collaborations and license agreements, and proceeds from the sale of equity securities and debt provided by convertible debt and other credit facilities. We believe that our cash, cash equivalents and marketable securities as of September 30, 2018 will enable us to continue to fund operations in the normal course of business for more than a twelve-month period from the date of filing this Quarterly Report on Form 10-Q. Until we can generate sufficient levels of cash from operations, which we do not expect to achieve in at least the next two years, and because sufficient funds may not be available to us when needed from existing collaborations, we expect that we will be required to continue to fund our operations in part through the sale of debt or equity securities, or through licensing select programs or partial economic rights that include upfront, royalty and/or milestone payments.

Our assessment of our future need for funding and our ability to continue to fund our operations are forward-looking statements that are based on assumptions that may prove to be wrong and that involve substantial risks and uncertainties. Our actual future capital requirements could vary as a result of a number of factors.

#### Concentration of Business Risks

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

Three Months
Ended
September 30,
2018 2017
Novartis Pharmaceutical 20.9% 61.2%

Pierre Fabre 38.2% 13.8% Loxo Oncology 11.3% 11.3% Total 70.4% 86.3%

The loss of one or more of our significant partners or collaborators could have a material adverse effect on our business, operating results or financial condition. Although we are impacted by economic conditions in the biotechnology and pharmaceutical sectors, management does not believe significant credit risk exists as of September 30, 2018.

## Geographic Information

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

Three Months

Ended

September 30,

2018 2017

Europe \$33,688 \$22,296 North America 22,280 5,501 Asia Pacific 942 1,949 Total \$56,910 \$29,746

#### Accounts Receivable

Novartis Pharmaceutical Ltd. and Novartis Pharma AG (collectively, "Novartis") accounted for 25% and 52% of our total accounts receivable balance as of September 30, 2018 and June 30, 2018, respectively Loxo Oncology ("Loxo") accounted for 0% and 14% of our total accounts receivable balance as of September 30, 2018 and June 30, 2018, respectively. Pierre Fabre Medicament SAS ("Pierre Fabre") accounted for 43% and 13% of our total accounts receivable balance as of September 30, 2018 and June 30, 2018, respectively.

## Summary of Significant Accounting Policies

Our significant accounting policies are described in Note 1 to our audited financial statements for the fiscal year ended June 30, 2018, included in our Annual Report on Form 10-K. Our significant accounting policies for the three

#### **Table of Contents**

months ended September 30, 2018 also included the policies discussed below related to revenue and cost of goods sold for commercial product sales. With the exception of those noted below, there have been no other material changes in our significant accounting policies as previously disclosed in our Annual Report on Form 10-K for the fiscal year ended June 30, 2018.

#### Product Sales, Net

We received approval from the FDA on June 27, 2018 to market BRAFTOVI + MEKTOVI in the U.S. for the treatment of patients with unresectable or metastatic melanoma with a BRAFV<sup>600E</sup> or BRAF<sup>V600K</sup> mutation. We began selling BRAFTOVI + MEKTOVI in the U.S. in July 2018. We distribute our products principally through a limited number of specialty distributor and specialty pharmacy providers, collectively, our Customers. Our Customers subsequently sell our products to patients and health care providers. Separately, we enter into arrangements with third parties that provide for government-mandated and privately-negotiated rebates, chargebacks and discounts. Revenue is recognized when the Customer obtains control of our product, typically upon delivery to the Customer.

Revenue from product sales are recognized when our performance obligations are satisfied, which is when customers obtain control of our product and occurs at a point in time, typically upon delivery.

#### Reserves for Variable Consideration

Revenues from product sales are recorded at the net sales price (transaction price), which includes estimates of variable consideration, including rebates, chargebacks, discounts, patient assistance programs, estimated product returns and other allowances that are offered within contracts between us and our Customers. These estimates are based on the amounts earned or to be claimed for related sales and are classified as reductions of accounts receivable if the amount is payable to our customers or a current liability if the amount is payable to a party other than a customer. Where appropriate, these estimates take into consideration a range of possible outcomes which are probability-weighted for relevant factors such as industry data and forecasted customer buying and payment patterns, our historical experience, current contractual and statutory requirements, specific known market events and trends. Overall, these reductions to gross sales reflect our best estimates of the amount of consideration to which we are entitled based on the terms of the contract. Variable consideration is included in the transaction price only to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. Actual amounts of consideration ultimately received may differ from our estimates. If actual results in the future vary from our estimates, we adjust these estimates, which would affect product revenue and earnings in the period such variances become known.

Rebates: Rebates include mandated discounts under the Medicaid Drug Rebate Program and the Medicare coverage gap program. Rebates are amounts owed after the final dispensing of products to a benefit plan participant and are based upon contractual agreements or legal requirements with the public-sector benefit providers. These estimates for rebates are recorded in the same period the related gross revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability which is included in accrued expenses on the consolidated balance sheet. We estimate our Medicaid and Medicare rebates based upon a range of possible outcomes that are probability-weighted for the estimated payor mix. The accrual for rebates is based on statutory discount rates and known sales to specialty pharmacy patients or expected utilization for specialty distributor sales to healthcare providers. As we gain more historical experience, estimates will be based on the expected utilization from historical data we have accumulated since the BRAFTOVI + MEKTOVI product launch. Rebates are generally invoiced and paid quarterly in arrears.

Chargebacks: Chargebacks are discounts that occur when contracted purchasers purchase directly from our specialty distributors at a discounted price. The specialty distributor, in turn, charges back the difference between the price initially paid to us by the specialty distributor and the discounted price paid to the specialty distributor by the contracted purchaser. Amounts for estimated chargebacks are established in the same period that the related gross revenue is recognized, resulting in a reduction of product revenue and accounts receivable. The accrual for specialty distributor chargebacks is estimated based on known chargeback rates, known sales to specialty distributors, and estimated utilization by types of contracted purchasers.

Discounts and Fees: Our payment terms are generally 45 days. Specialty distributors and specialty pharmacies are offered various forms of consideration, including service fees and prompt pay discounts for payment within a specified

#### **Table of Contents**

period. We expect these customers will earn prompt pay discounts and therefore, we deduct the full amount of these discounts and service fees from product sales when revenue is recognized.

Other Reserves: Patients who have commercial insurance and meet certain eligibility requirements may receive co-pay assistance. We estimate the amount of co-pay assistance provided to eligible patients based on the terms of the program when product is dispensed by specialty pharmacies to patients. These estimates are based on redemption information provided by third-party claims processing organizations and are recorded in accounts payable, accrued expenses and other liabilities on the unaudited condensed consolidated balance sheet.

We are offering a quick start program in the form of vouchers to certain eligible patients. We record amounts for estimated voucher redemptions in the same period that the related gross revenue is recognized, resulting in a reduction of product revenue and these amounts are recorded in accounts payable, accrued expenses and other liabilities on the unaudited condensed consolidated balance sheet. Our accrual for voucher redemptions is estimated based on observed voucher redemption rates.

#### Cost of goods sold

We capitalize inventory costs associated with the production of our products after regulatory approval or when, based on management's judgment, future commercialization is considered probable and the future economic benefit is expected to be realized. Otherwise, such costs are expensed as research and development. Certain of the costs of BRAFTOVI + MEKTOVI units recognized as revenue during the three months ended September 30, 2018 were expensed prior to FDA approval on June 27, 2018, and a minimal amount is included in cost of goods sold during the current period. We expect our cost of goods sold to remain negligible until the inventory with previously expensed material and production cost is sold. We believe our cost of goods sold for the three months ended September 30, 2018 would have been \$0.3 million higher if we had not previously expensed certain material and production costs for with the units sold. As of September 30, 2018, we had approximately \$16.2 million of inventory on hand that was previously expensed as research and development expense and will not be reported as cost of goods sold in future periods when sales of BRAFTOVI + MEKTOVI are recognized as revenue.

## Recently Adopted Accounting Standards

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2014-09, "Revenue from Contracts with Customers (Topic 606)" ("ASU 2014-09") and has subsequently issued a number of amendments to ASU 2014-09 (collectively, "ASC 606"). The new standard, as amended, requires entities to recognize revenue from the transfer of promised goods or services to customers based on the amount of the consideration to which the entity expects to be entitled to receive in exchange for those goods or services.

Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. ASC 606 also impacts certain other areas, such as the accounting for costs to obtain or fulfill a contract. The standard also requires disclosure of the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers.

The new standard was effective for us on July 1, 2018, prior to our first commercial product sale, and we elected to adopt it using a modified retrospective transition method applied only to contracts that were not completed as of July

1, 2018. Our adoption of ASU 2014-09 did not require any cumulative effect adjustment to opening retained earnings as of July 1, 2018 and did not have a material impact on our unaudited condensed consolidated financial statements.

We have examined our revenue recognition policies and contracts related to our collaboration, co-development and product revenue streams to determine the impact of the new standard using the five-step process prescribed by ASC 606 and recognize revenue for our categories of revenue as follows:

Product sales: Revenue from product sales is recognized when our performance obligations are satisfied, which is when customers obtain control of our product and occurs at a point in time, typically upon delivery.

#### **Table of Contents**

Licenses of intellectual property: If the license granted to our intellectual property is determined to be a discrete performance obligation from the other performance obligations identified in the arrangement, we recognize revenue from non-refundable, upfront fees allocated to the license when the license is transferred to the licensee and the recipient of the license is able to use and benefit from the license. For licenses that are determined to not be distinct from other performance obligations, such as development activities, we recognize revenue over time, using an input method as the related performance obligations are satisfied. Upfront payments are recorded as deferred revenue upon receipt and are recognized as revenue during subsequent periods as our performance obligations are met.

Milestone payments: Developmental, regulatory and commercial milestone payments generally relate to performance obligations that have been completed in the past and are recognized as revenue in the period in which the milestone is achieved. We are eligible to receive certain time-based commercial milestones, following regulatory approval, which we expect to recognize as revenue over time once material risk of reversal of revenue has passed. Adoption of ASC 606 will have the effect of accelerating recognition of revenue for certain commercial milestone payments as compared to the legacy accounting guidance.

Product royalty revenues: We have entered into arrangements that include sales-based royalties for which the license is deemed to be the predominant item to which the royalties relate. We will recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty was allocated has been satisfied (or partially satisfied). Although we had no product royalty revenue during the three months ended September 30, 2018, two products for which we have previously granted licenses in exchange for the right to receive sales-based royalties have been granted regulatory approval as of September 30, 2018.

In August 2016, the FASB issued ASU No. 2016-15, "Statement of Cash Flows (Topic 230)" ("ASU 2016-15"). This amendment provides guidance on the presentation and classification of specific cash flow items to improve consistency within the statement of cash flows. ASU 2016-15 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2017, with early adoption permitted. We adopted the new standard on July 1, 2018 and did not have a material impact on our consolidated financial statements.

#### Recently Issued Accounting Standards

In February 2016, the FASB issued ASU No. 2016-02, "Leases (Topic 842)" ("ASU 2016-02") which supersedes FASB ASC Topic 840, Leases (Topic 840) and provides principles for the recognition, measurement, presentation and disclosure of leases for both lessees and lessors. In July 2018, the FASB issued ASU 2018-11, "Leases (Topic 842): Targeted Improvements" and ASU 2018-10, "Codification Improvements to Topic 842, Leases." ASU 2016-02 and the subsequent modifications are identified as "ASC 842." The new standard requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method or on a straight-line basis over the term of the lease, respectively. A lessee is also required to record a right-of-use asset and a lease liability for all leases with a term of greater than twelve months regardless of classification. Leases with a term of twelve months or less will be accounted for similar to existing guidance for operating leases. The standard is effective for annual and interim periods beginning after December 15, 2018, with early adoption permitted upon issuance. We are currently evaluating the impact that ASU 2016-02 will have on our unaudited condensed consolidated financial statements and related disclosures and plan to adopt the new standard on July 1, 2019.

In May 2017, the FASB issued ASU 2017-09, "Compensation - Stock Compensation (Topic 718): Scope of Modification Accounting ("ASU 2017-09"), which clarifies when to account for a change to the terms or conditions of a share-based payment award as a modification. Under the new guidance, modification accounting is required only if the fair value, the vesting conditions, or the classification of the award (as equity or liability) changes as a result of the

change in terms or conditions. It is effective prospectively for the annual period ending June 30, 2019 and interim periods within that annual period. Early adoption is permitted. We do not expect ASU 2017-09 to have a material impact on our unaudited condensed consolidated financial statements upon adoption.

In August 2018, the SEC adopted the final rule under SEC Release No. 33-10532, Disclosure Update and Simplification, amending certain disclosure requirements that were redundant, duplicative, overlapping, outdated or superseded. In addition, the amendments expanded the disclosure requirements on the analysis of stockholders' equity for interim financial statements. Under the amendments, an analysis of changes in each caption of stockholders'

#### **Table of Contents**

equity presented in the balance sheet must be provided in a note or separate statement. The analysis should present a reconciliation of the beginning balance to the ending balance of each period for which a statement of comprehensive income is required to be filed. This final rule is effective on November 5, 2018. We are evaluating the impact of this guidance on our unaudited condensed consolidated financial statements.

#### NOTE 2 - MARKETABLE SECURITIES

Marketable securities consisted of the following as of September 30, 2018 and June 30, 2018 (in thousands):

	Septembe	r 30, 2018		
		Gross	Gross	
	Amortize	dUnrealized	Unrealized	Fair
	Cost	Gains	Losses	Value
Short-term available-for-sale securities:				
U.S. treasury securities	\$283,952	\$ -	-\$ (312 )	\$283,640
Mutual fund securities	246		_	246
	284,198		(312)	283,886
Long-term available-for-sale securities:				
Mutual fund securities	998		_	998
	998		_	998
Total	\$285,196	\$ -	-\$ (312 )	\$284,884
	June 30, 2	2018		
	June 30, 2	2018 Gross	Gross	
				Fair
		Gross		Fair Value
Short-term available-for-sale securities:	Amortize Cost	Gross dUnrealized	Unrealized	
Short-term available-for-sale securities: U.S. treasury securities	Amortize Cost	Gross dUnrealized Gains	Unrealized	Value
	Amortized Cost	Gross dUnrealized Gains	Unrealized Losses	Value
U.S. treasury securities	Amortized Cost \$297,965	Gross dUnrealized Gains	Unrealized Losses	Value \$297,504
U.S. treasury securities	Amortized Cost \$297,965 235 298,200	Gross dUnrealized Gains	Unrealized Losses -\$ (461 )	Value \$297,504 235
U.S. treasury securities Mutual fund securities	Amortized Cost \$297,965 235 298,200	Gross dUnrealized Gains	Unrealized Losses -\$ (461 )	Value \$297,504 235
U.S. treasury securities Mutual fund securities Long-term available-for-sale securities:	Amortized Cost \$297,965 235 298,200	Gross dUnrealized Gains	Unrealized Losses -\$ (461 )	Value \$297,504 235 297,739

The mutual fund securities shown in the above tables are securities held under the Array BioPharma Inc. Deferred Compensation Plan.

The fair value of marketable securities is determined using quoted market prices from daily exchange-traded markets based on the closing price as of the balance sheet date and are classified as Level 1, as described in Note 6 - Fair Value Measurements to our financial statements included elsewhere in this Quarterly Report on Form 10-Q.

As of September 30, 2018, the amortized cost and estimated fair value of available-for-sale debt securities by contractual maturity were as follows (in thousands):

Amortized Fair
Cost Value
Due in one year or less \$283,952 \$283,640

NOTE 3 – PRODUCT REVENUE

Our commercial stage products include BRAFTOVI + MEKTOVI, which received FDA approval on June 27, 2018 for the treatment of patients with unresectable or metastatic melanoma with BRAF $^{V600E}$  or BRAF $^{V600K}$  mutation, as detected by an FDA-approved test.

We record gross-to-net sales accruals for rebates, chargebacks, discounts, estimated product returns and other allowances that are offered within contracts between us and our Customers and other indirect customers relating to the sales of our products.

#### **Table of Contents**

Our provisions for discounts, early payments, rebates, sales returns, distributor service fees and chargebacks, and other incentives are under terms that are customary in the industry and are provided for in the same period in which the related sales are recorded.

Net product revenues by product for the three months ended September 30, 2018 was as follows:

BRAFTOVI \$7,015 MEKTOVI 6,978 Total Net Product Sales \$13,993

Gross-to-net sales accruals and the balance in the related accounts receivable allowance accounts for the three months ended September 30, 2018 were as follows:

1	Returr	ns Other	Total	
Balance as of June 30, 2018	\$ —	\$(78	)\$(78	)
Allowances for sales during prior periods			_	
Allowances for sales during the current period	50	3,410	3,460	
Credits/deductions issued for prior year sales				
Credits/deductions issued for sales during the current period	(11	) (798	)(809	)
Balance as of September 30, 2018	\$ 39	\$2,534	\$2,573	3

The balance as of June 30, 2018 included prepayments for incentives. There were no product sales or gross-to-net accruals during the three months ended September 30, 2017.

## NOTE 4 – COLLABORATION AND OTHER AGREEMENTS

The following table summarizes total revenue recognized for the periods indicated (in thousands):

-	Three Months		
	Ended		
	Septemb	er 30,	
	2018	2017	
Collaboration and other revenue			
Pierre Fabre	\$6,029	\$3,349	
Loxo	2,403	2,258	
Mirati	994	1,389	
Other partners	684	1,012	
Total collaboration and other revenue	10,110	8,008	
License and milestone revenue			
Pierre Fabre	15,750	750	
Loxo	4,000	1,107	
Ono	918	918	
Other partners	250	771	
Total license and milestone revenue	20,918	3,546	
Total collaboration and license revenue	\$31,028	\$11,554	
Reimbursement revenue			
Novartis	\$11,889	\$18,192	

#### **Table of Contents**

#### Collaboration and License Revenue

The terms of our collaboration and license agreements include substantial ongoing collaboration and cost-sharing activities between the companies and may require us to perform future development and commercialization activities. In accordance with the revenue recognition criteria under ASC 606, Revenue from Contracts with Customers, we identified the following performance obligations in each of the following collaboration agreements, excluding Loxo: (1) the license rights and (2) clinical development and other services. For each agreement, we determined that the license rights are not distinct from the clinical development and other activities, and as such, are combined with other activities to form one performance obligation. Accordingly, any non-refundable upfront payments received under the agreements have been recorded as deferred revenue and are being recognized over the period during which management expects that substantial development activities will be performed.

#### Pierre Fabre

On November 10, 2015, we entered into an agreement with Pierre Fabre (the "PF Agreement") pursuant to which we granted Pierre Fabre rights to commercialize encorafenib and binimetinib in all countries except for the U.S., Canada, Japan, Korea and Israel, where we retain our ownership rights (subject to rights granted to Ono under the agreement with Ono).

The PF Agreement closed in December 2015 (the "Effective Date"). All clinical trials involving encorafenib and binimetinib that were ongoing or planned at the Effective Date, including the NEMO and COLUMBUS trials and other then-ongoing Novartis sponsored and investigator sponsored clinical studies, continued to be conducted pursuant to the terms of the Novartis Agreements. Further worldwide development activities are governed by a Global Development Plan ("GDP") with Pierre Fabre. Pierre Fabre will jointly fund worldwide development costs under the GDP, with Array covering 60% and Pierre Fabre covering 40% of such costs.

In connection with the PF Agreement, we received a \$30.0 million upfront payment during the year ended June 30, 2016 which has been recorded as deferred revenue and is being recognized through 2025 which is the period through which management expects that substantial development activities will be performed. During the three months ended September 30, 2018, we earned a \$15.0 million milestone under the PF Agreement upon regulatory approval in the European Union which was fully recognized as collaboration and license revenue during the period. There were no development expenses reimbursed by us to Pierre Fabre during the comparable period of the prior fiscal year. The PF Agreement contains additional substantive potential milestone payments of up to \$390.0 million for achievement of seven commercialization milestones if certain net sales amounts are achieved for any licensed indications. We are further eligible for multiple tiered double-digit royalties on annual net sales of encorafenib and binimetinib in the PF territory, starting at 20% for annual net sales under €50.0 million and increasing to 35% for annual net sales in excess of €100.0 million subject to certain adjustments.

Ono Pharmaceutical Co., Ltd.

Effective May 31, 2017, we entered into a License, Development and Commercialization Agreement (the "Ono Agreement") with Ono, pursuant to which we granted Ono exclusive rights to commercialize encorafenib and binimetinib in Japan and the Republic of Korea (the "Ono Territory"), along with the right to develop these products in the Ono Territory. We retain all rights outside the Ono Territory, as well as the right to conduct development and manufacturing activities in the Ono Territory.

All ongoing clinical trials involving encorafenib and binimetinib, including the BEACON CRC and COLUMBUS trials, continued as planned as of the effective date of the Ono Agreement, and Ono is entitled to the data derived from such studies. As part of the Ono Agreement, Ono obtained the right to participate in any future global development of encorafenib and binimetinib by contributing 12% of those future costs. Ono is responsible for seeking, and for any development of encorafenib and binimetinib specifically necessary to obtain, regulatory and marketing approvals for products in the Ono Territory. We will furnish clinical supplies of drug substance to Ono for use in Ono's development efforts, and Ono may elect to have us provide commercial supplies of drug product to Ono pursuant to a commercial supply agreement to be entered into between Ono and us, in each case the costs of which will be borne by Ono. We have also agreed to discuss and agree on a strategy with Ono to ensure the supply to Ono of companion diagnostics for

use with encorafenib and binimetinib in certain indications in the Ono Territory.

Under the terms of the Ono Agreement, we received a non-refundable upfront cash payment of ¥3.5 billion, or \$31.2 million, and we retain all rights to conduct, either on our own or through third parties, all clinical studies and file related

#### **Table of Contents**

regulatory filings with respect to encorafenib and binimetinib and to develop, manufacture and commercialize encorafenib and binimetinib outside the Ono Territory (subject to rights we have granted to Pierre Fabre in certain countries). The upfront payment has been recorded as deferred revenue and is being recognized through 2025 which is the period through which management expects that substantial development activities will be performed. We are entitled to receive potential milestone payments of up to ¥900.0 million for the achievement of two remaining development milestones, ¥5.0 billion for the achievement of eight regulatory milestones relating to certain Marketing Authorization Application filings and approval in Japan for two specified indications, and ¥10.5 billion for the achievement of five commercialization milestones if certain annual net sales targets are achieved. A portion of these milestones is related to the advancement of the Phase 3 BEACON CRC trial in the Ono Territory. We are further eligible for tiered double-digit royalties on annual net sales of encorafenib and binimetinib in the Ono Territory, starting at 22% for annual net sales under ¥10.0 billion and increasing to 25% for annual net sales in excess of ¥10.0 billion subject to certain adjustments. As of September 30, 2018, ¥1.0 billion was the equivalent of approximately \$8.8 million.

#### Loxo

We are party to a Drug Discovery Collaboration Agreement, as amended, with Loxo (the "Loxo Agreement"). Under the terms of the Loxo Agreement, Loxo funded discovery and preclinical programs conducted by us, including LOXO-195, a next generation selective TRK inhibitor, LOXO-292, a RET inhibitor, and FGFR programs (the "Loxo Programs"). The research phase concluded in September 2018. Loxo is responsible for all additional preclinical and clinical development and commercialization.

In accordance with the revenue recognition criteria under ASC Topic 606, Revenue from Contracts with Customers, we identified the following performance obligations: (1) the conduct of the research activities under the discovery program, including related technology transfer (the "research services deliverable"), (2) an exclusive worldwide license granted to Loxo to certain of our technology and our interest in collaboration technology, as well as exclusive worldwide marketing rights (the "license deliverable") and (3) participation on the Joint Research Committee ("JRC"). The Loxo Agreement provides for no general right of return for any non-contingent performance obligation. All the identified non-contingent performance obligations were considered distinct; therefore they are treated as separate performance obligations. Delivery of the research services and JRC participation obligations were completed throughout the research discovery program term. The license deliverable was complete as of September 30, 2013. During the three months ended September 30, 2018, we earned a \$4.0 million milestone under the Loxo Agreement for the initiation of a registration enabling study for LOXO-292 which was fully recognized as collaboration and license revenue during the period.

The Drug Discovery Collaboration Agreement with Loxo contains substantive potential milestone payments of up to \$7.0 million for two remaining development milestones and up to \$635.0 million for the achievement of twenty-three commercialization milestones if certain net sales amounts are achieved for any licensed drug candidates in the U.S., the European Union and Japan plus royalties on sales of any resulting drugs.

#### Mirati

We are party to agreements with Mirati Therapeutics, Inc. (the "Mirati Agreements"). During April 2018, Mirati elected to exercise an option to take an exclusive, worldwide license to an active compound under the second agreement for which we received \$2.0 million and will receive additional fees as reimbursement for research and development services. The option exercise fee, received in the three months ended June 30, 2018, was recorded as deferred revenue and is being recognized as revenue over two years, the period during which we expect that substantial development activities will be performed.

The Mirati Agreements contain substantive potential milestone payments of up to \$18.3 million for seven remaining developmental milestones and up to \$674.0 million for the achievement of fourteen commercialization milestones if certain net sales amounts are achieved in the U.S., the European Union and Japan.

Dr. Charles Baum, a current member of our Board of Directors, is the President and Chief Executive Officer of Mirati.

#### **Table of Contents**

#### Other Collaboration Arrangements

In addition to the collaboration arrangements described above, we have entered into a number of additional collaborative arrangements that include the potential for us to receive future milestone payments of up to \$62.5 million for development milestones, up to \$73.0 million for regulatory milestones, up to \$299.5 million for sales milestones over a period of several years in addition to royalties on potential future product sales. Our ability to receive payments under these collaborations is contingent upon both our and our collaboration partners' continued involvement in the programs and the lack of any adverse events which could cause the discontinuance of the programs.

#### Deferred Revenue

Deferred revenue balances were as follows for the dates indicated (in thousands):

	September	June 30,
	30,	2010
	2018	2018
Ono	\$ 26,636	\$27,555
Pierre Fabre (1)	24,229	22,394
Mirati	1,695	2,468
Loxo		2,403
Other	1,500	2,000
Total deferred revenue	54,060	56,820
Less: Current portion	(11,425)	(12,350)
Deferred revenue, long-term portion	\$42,635	\$44,470

(1) Balance as of September 30, 2018 includes a \$2.6 million prepayment for commercial drug supply of BRAFTOVI and MEKTOVI

#### Reimbursement Revenue

On March 2, 2015 (the "Effective Date"), we regained development and commercialization rights to binimetinib under the Termination and Asset Transfer Agreement with Novartis and to encorafenib under the Asset Transfer Agreement with Novartis (which we collectively refer to as the "Novartis Agreements"). Along with global ownership of both assets, the Novartis Agreements transferred to us a 2% royalty obligation offset by certain expenses; which is payable based on net sales of encorafenib and is expensed as costs of goods sold as incurred.

Amounts provided by Novartis related to the development and commercialization of binimetinib and encorafenib are reported as Reimbursement Revenue on our unaudited condensed consolidated statements of operations. See Note 3 of Notes to Consolidated Financial Statements included in our Annual Report on Form 10-K for the fiscal year ended June 30, 2018 for additional details related to our agreements with Novartis related to encorafenib and binimetinib. NOTE 5 – DEBT

Outstanding debt consists of the following (in thousands):

	September 30,	June 30,	
	2018	2018	
Notes payable at fair value	\$—	\$15,899	
2024 convertible senior notes	\$126,060	\$126,060	
Silicon Valley Bank term loan (1)	53,500	16,200	
Long-term debt, gross	179,560	142,260	
Less: Unamortized debt discount and fees	(48,467)	(46,384	)
Long-term debt, net	131,093	95,876	
Less: Current portion	_	(2,500	)
Long-term debt, non-current portion	\$131,093	\$93,376	

(1) Outstanding debt owed to Silicon Valley Bank includes a final payment fee of \$3.5 million and \$1.2 million as of

#### **Table of Contents**

September 30, 2018 and June 30, 2018, respectively.

Redmile Notes Payable

On August 6, 2018, the Redmile Notes Payable matured and became payable pursuant to the Note Purchase Agreement dated September 2, 2016, as amended. On that date, we repaid \$16.0 million to the Note holders, which included the \$10.0 million principal, a \$5.0 million exit fee and approximately \$1.0 million accrued interest. Following the repayment of the Redmile Notes Payable, we had no notes payable recorded at fair value.

Silicon Valley Bank Term Loan

On August 10, 2018 (the "Amended Effective Date"), we entered into an Amended and Restated Loan and Security Agreement (the "Amended Loan Agreement") with Silicon Valley Bank ("SVB") providing for a term loan in the original principal amount of \$50.0 million and maintaining our existing letters of credit with SVB. The Amended Loan Agreement amends and restates our prior Loan and Security Agreement (the "Loan Agreement") with SVB. We utilized the proceeds from the term loan for repayment in full all outstanding obligations under our prior Loan Agreement with SVB, repayment in full of our obligations under the Redmile Notes Payable, and as working capital to fund general business requirements. The entire term loan amount was borrowed on the Amended Effective Date.

The outstanding principal amount under the term loan bears interest at a floating per annum rate equal to the Prime Rate minus 2.0% (but not less than 0.0%) and was 3.25% as of September 30, 2018. We must make monthly payments of interest under the term loan commencing with the first month after the Amended Effective Date until maturity and, commencing on September 1, 2020 and monthly thereafter, we must make payments of principal under the term loan based on a thirty-six-month amortization schedule. A final payment of principal, accrued interest on the term loan and on any outstanding advances, as well as the final payment fee associated with the Amended Loan Agreement of \$3.5 million are due on the maturity date of August 1, 2023. The resulting debt discount is being recognized using the effective interest method over the term of the loan. In accordance with ASC 470-50, we accounted for the exchange as a debt modification and the issuance costs associated with the Amended Loan Agreement were recorded as debt discount and were added to the remaining unamortized debt discount associated with prior Loan Agreement.

We granted SVB a first priority security interest in all of our assets other than our intellectual property, provided that accounts and proceeds of our intellectual property constitutes collateral and we have agreed not to encumber our intellectual property without SVB's consent. The Amended Loan Agreement contains customary covenants, including restrictions on changes in control of Array, the incurrence of additional indebtedness, future encumbrances on our assets, the payment of dividends or distributions on our common stock and the sale, lease, transfer or disposition of encorafenib and binimetinib outside of certain markets if our cash and cash equivalents maintained with SVB fall below certain levels. In addition, we must maintain a liquidity ratio, defined as (i) our unrestricted cash and cash equivalents divided by (ii) all of our outstanding obligations owed to SVB, of at least 2.00 to 1.00, measured monthly.

#### 2.625% Convertible Senior Notes Due 2024

On December 1, 2017, we issued and sold \$126.1 million aggregate principal amount of 2.625% convertible senior notes due 2024 (the "2024 Notes") in exchange for our now retired 2020 Notes. The 2024 Notes are our direct unsecured obligations and rank equal in right of payment with all of our other existing and future unsecured and unsubordinated indebtedness. The 2024 Notes are effectively subordinated to any of our existing and future secured indebtedness, including our indebtedness under the Amended Loan Agreement with SVB, to the extent of the value of our assets that secure such indebtedness.

The 2024 Notes will mature on December 1, 2024 and bear interest at a rate of 2.625%, payable semiannually in arrears on June 1 and December 1 of each year, beginning on June 1, 2018.

In accordance with ASC 470-20, we used an effective interest rate of 9.75% to determine the liability component of the 2024 Notes. This resulted in the recognition of \$80.4 million as the liability component of the 2024 Notes and the recognition of the residual \$45.7 million as the debt discount with a corresponding increase to additional paid-in capital for the equity component of the 2024 Notes. The underwriting discount and estimated offering expenses of \$4.3 million were allocated between the debt and equity issuance costs in proportion to the allocation of the liability and equity components of the 2024 Notes. Equity issuance costs of \$1.6 million were recorded as an offset to additional paid-in capital. Total debt issuance costs of \$2.7 million were recorded on the issuance date and are r

#### **Table of Contents**

eflected in our unaudited condensed consolidated balance sheets for all periods presented on a consistent basis with the debt discount, or as a direct deduction from the carrying value of the associated debt liability. The debt discount and debt issuance costs will be amortized as non-cash interest expense through December 1, 2024. The balance of unamortized debt issuance costs was \$2.5 million and \$2.6 million as of September 30, 2018 and June 30, 2018, respectively.

The fair value of the 2024 Notes was approximately \$158.4 million and \$169.0 million at September 30, 2018 and June 30, 2018, respectively, and was determined using Level 2 inputs based on their quoted market values.

#### Summary of Interest Expense

The following table shows the details of our interest expense for all of our debt arrangements outstanding during the periods presented, including contractual interest, and amortization of debt discount, debt issuance costs and loan transaction fees that were charged to interest expense (in thousands):

Three Months Ended

September 30, 2018 2017

Silicon Valley Bank Term Loan

Simple interest \$ 282