AMARIN CORP PLC\UK
Form 10-Q
August 02, 2017

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended June 30, 2017

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 No. 000-21392

Amarin Corporation plc

(Exact Name of Registrant as Specified in its Charter)

England and Wales	Not applicable
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)

2 Pembroke House, Upper Pembroke Street 28-32	Dublin 2, Ireland
(Address of Principal Executive Offices)	(Zip Code)

Registrant’s telephone number, including area code: +353 (0) 1 6699 020

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 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 (§229.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). YES 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		Accelerated filer
Non-accelerated filer	(Do not check if smaller reporting company)	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 Act). YES NO

270,792,058 common shares were outstanding as of July 31, 2017, including 270,341,777 shares held as American Depositary Shares (ADSs), each representing one Ordinary Share, 50 pence par value per share and 450,281 Ordinary Shares. In addition, 32,818,464 ordinary share equivalents were issuable in exchange for outstanding preferred shares as of July 31, 2017, for a total of 303,610,522 ordinary shares and ordinary share equivalents outstanding as of July 31, 2017.

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PART I

AMARIN CORPORATION PLC

CONDENSED CONSOLIDATED BALANCE SHEETS

(Unaudited, in thousands, except share amounts)

	June 30, 2017	December 31, 2016
ASSETS		
Current Assets:		
Cash and cash equivalents	$85,464	$98,251
Restricted cash	600	600
Accounts receivable, net	37,475	19,985
Inventory	24,814	20,507
Prepaid and other current assets	2,076	6,983
Total current assets	150,429	146,326
Property, plant and equipment, net	52	78
Deferred tax assets	11,082	11,082
Other long-term assets	173	741
Intangible asset, net	8,449	8,772
TOTAL ASSETS	$170,185	$166,999
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current Liabilities:		
Accounts payable	$16,455	$6,062
Accrued expenses and other current liabilities	49,102	37,720
Current portion of exchangeable senior notes, net of discount	455	15,351
Current portion of long-term debt from royalty-bearing instrument	18,833	15,944
Deferred revenue, current	1,447	1,172
Total current liabilities	86,292	76,249
Long-Term Liabilities:		
Exchangeable senior notes, net of discount	28,884	—
Long-term debt from royalty-bearing instrument	79,283	85,155
Deferred revenue, long-term	13,332	13,943
Other long-term liabilities	1,158	710
Total liabilities	208,949	176,057
Commitments and contingencies (Note 6)		
Stockholders' Deficit:		
Series A Convertible Preferred Stock, £0.05 par, unlimited authorized; 328,184,640 shares issued and outstanding as of June 30, 2017 and December 31, 2016 (equivalent to 32,818,464 ordinary shares upon future consolidation and redesignation at a 10:1 ratio)	24,364	24,364
Common stock, £0.50 par, unlimited authorized; 272,401,857 issued, 270,792,058 outstanding as of June 30, 2017; 270,183,201 issued, 269,363,696 outstanding	208,556	207,166

as of December 31, 2016		
Additional paid-in capital	970,797	964,914
Treasury stock; 1,609,799 shares as of June 30, 2017; 819,505 shares as of December 31, 2016	(3,902)	(1,498)
Accumulated deficit	(1,238,579)	(1,204,004)
Total stockholders' deficit	(38,764)	(9,058)
TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT	$170,185	$166,999

See notes to condensed consolidated financial statements.

AMARIN CORPORATION PLC

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited, in thousands, except per share amounts)

	Three months ended June 30,		Six months ended June 30,	
	2017	2016	2017	2016
Product revenue, net	$44,948	$32,815	$79,292	$58,122
Licensing revenue	293	296	586	532
Total revenue, net	45,241	33,111	79,878	58,654
Less: Cost of goods sold	11,401	8,861	19,599	15,757
Gross margin	33,840	24,250	60,279	42,897
Operating expenses:				
Selling, general and administrative	31,545	26,066	65,716	54,086
Research and development	13,694	12,578	24,517	26,308
Total operating expenses	45,239	38,644	90,233	80,394
Operating loss	(11,399)	(14,394)	(29,954)	(37,497)
Gain on change in fair value of derivative liabilities	—	5,810	—	4,560
Interest expense, net	(2,315)	(5,616)	(4,696)	(11,202)
Other income (expense), net	80	(182)	75	(303)
Loss from operations before taxes	(13,634)	(14,382)	(34,575)	(44,442)
Benefit from income taxes	—	1,028	—	1,317
Net loss	$(13,634)	$(13,354)	$(34,575)	$(43,125)
Loss per share:				
Basic	$(0.05)	$(0.07)	$(0.13)	$(0.23)
Diluted	$(0.05)	$(0.07)	$(0.13)	$(0.23)
Weighted average shares:				
Basic	270,725	184,471	270,445	184,262
Diluted	270,725	184,471	270,445	184,262

See notes to condensed consolidated financial statements.

AMARIN CORPORATION PLC

CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' DEFICIT

(Unaudited, in thousands, except share amounts)

	Preferred Shares	Common Shares	Treasury Shares	Preferred Stock	Common Stock	Additional Paid-in Capital	Treasury Stock	Accumulated Deficit	Total
December 31, 2016	328,184,640	270,183,201	(819,505)	$24,364	$207,166	$964,914	$(1,498)	$(1,204,004)	$(9,058)
Exercise of stock options	—	221,345	—	—	139	257	—	—	396
Vesting of restricted stock units	—	1,997,311	(790,294)	—	1,251	(1,284)	(2,404)	—	(2,437)
Stock-based compensation	—	—	—	—	—	6,910	—	—	6,910
Loss for the period	—	—	—	—	—	—	—	(34,575)	(34,575)
June 30, 2017	328,184,640	272,401,857	(1,609,799)	$24,364	$208,556	$970,797	$(3,902)	$(1,238,579)	$(38,764)

See notes to condensed consolidated financial statements.

AMARIN CORPORATION PLC

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited, in thousands)

	Six months ended June 30,	
	2017	2016
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$(34,575)	$(43,125)
Adjustments to reconcile loss to net cash used in operating activities:		
Depreciation and amortization	38	79
Loss on sale of fixed assets	—	48
Stock-based compensation	6,976	6,962
Amortization of debt discount and debt issuance costs	1,147	5,038
Amortization of intangible asset	323	322
Gain on change in fair value of derivative liabilities	—	(4,560)
Deferred income taxes	—	(1,846)
Changes in assets and liabilities:		
Accounts receivable, net	(17,490)	(3,813)
Inventory	(4,307)	(1,321)
Prepaid and other current assets	4,907	(2,324)
Other long-term assets	568	—
Accrued interest payable	(3,828)	(1,416)
Deferred revenue	(336)	1,470
Accounts payable and other current liabilities	21,709	10,773
Other long-term liabilities	448	(67)
Net cash used in operating activities	(24,420)	(33,780)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of equipment	(12)	(21)
Net cash used in investing activities	(12)	(21)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of exchangeable debt	30,000	—
Payment of debt issuance costs	(1,207)	—
Proceeds from exercise of stock options, net of transaction costs	396	124
Repurchase of exchangeable senior notes	(15,107)	—
Taxes paid related to stock-based awards	(2,437)	(793)
Net cash provided by (used in) financing activities	11,645	(669)
NET DECREASE IN CASH AND CASH EQUIVALENTS	(12,787)	(34,470)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	98,251	106,961
CASH AND CASH EQUIVALENTS, END OF PERIOD	$85,464	$72,491
Supplemental disclosure of cash flow information:		
Cash paid during the year for:		
Interest	$7,546	$7,668
Income taxes	$778	$767

See notes to condensed consolidated financial statements.

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AMARIN CORPORATION PLC

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

For purposes of this Quarterly Report on Form 10-Q, our ordinary shares may also be referred to as “common shares” or “common stock.”

(1) Nature of Business and Basis of Presentation

Nature of Business

Amarin Corporation plc (“Amarin” or the “Company”) is a biopharmaceutical company with expertise in lipid science focused on the commercialization and development of therapeutics to improve cardiovascular health.

The Company’s lead product, Vascepa® (icosapent ethyl) capsules, is approved by the U.S. Food and Drug Administration, or FDA, for use as an adjunct to diet to reduce triglyceride levels in adult patients with severe (TG >500 mg/dL) hypertriglyceridemia. Vascepa is available in the United States by prescription only. In January 2013, the Company began selling and marketing 1-gram size Vascepa capsules in the United States, and in October 2016, introduced a smaller 0.5-gram size capsule. In August 2015, in addition to marketing Vascepa for severe hypertriglyceridemia, the Company commenced marketing Vascepa for use in adult patients with mixed dyslipidemia, as an adjunct to diet and an add-on to statin therapy in patients who despite statin therapy have high triglycerides (TGs >200 mg/dL and <500 mg/dL), which the Company also refers to as persistently high triglycerides. This expanded promotion of Vascepa commenced pursuant to a federal court order and is continuing pursuant to an agreement among the Company, the FDA and the U.S. government. The Company sells Vascepa principally to a limited number of major wholesalers, as well as selected regional wholesalers and specialty pharmacy providers, or collectively, its Distributors or its customers, that in turn resell Vascepa to retail pharmacies for subsequent resale to patients and healthcare providers. The Company markets Vascepa through its direct sales force of approximately 150 sales professionals, including sales representatives and their managers. In May 2014, Kowa Pharmaceuticals America, Inc. commenced co-promotion of Vascepa in accordance with a co-promotion agreement with the Company. Kowa Pharmaceuticals America, Inc. co-promotes Vascepa in conjunction with its promotion of its primary product, a branded statin for patients with high cholesterol. The Company operates in one business segment.

The Company is also developing Vascepa for FDA approval of potential additional indications for use. In particular, the Company is conducting a cardiovascular outcomes study of Vascepa, titled REDUCE-IT (Reduction of Cardiovascular Events with EPA—Intervention Trial). The REDUCE-IT study, which commenced in 2011 and completed patient enrollment and randomization of 8,175 individual patients in 2016, is designed to evaluate the efficacy of Vascepa in reducing major cardiovascular events in a high-risk patient population on statin therapy.

Basis of Presentation

The condensed consolidated financial statements included herein have been prepared by the Company, without audit, in accordance with accounting principles generally accepted in the United States of America (the “U.S.” or the “United States”) and pursuant to the rules and regulations of the Securities and Exchange Commission, or the SEC. Certain information in the footnote disclosures of the financial statements has been condensed or omitted where it substantially duplicates information provided in the Company’s latest audited consolidated financial statements, in accordance with the rules and regulations of the SEC. These condensed consolidated financial statements should be read in conjunction with the Company’s audited consolidated financial statements and notes included in its Annual Report on Form 10-K for the fiscal year ended December 31, 2016, or the 2016 Form 10-K, filed with the SEC. The balance sheet amounts at December 31, 2016 in this report were derived from the Company’s audited 2016 consolidated financial statements included in the 2016 Form 10-K.

The condensed consolidated financial statements reflect all adjustments of a normal and recurring nature that, in the opinion of management, are necessary to present fairly the Company's financial position, results of operations and cash flows for the periods indicated. The preparation of the Company's condensed consolidated financial statements in conformity with U.S. Generally Accepted Accounting Principles ("GAAP") requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. The results of operations for the three and six months ended June 30, 2017 and 2016 are not necessarily indicative of the results for the entire fiscal year or any future period. Certain numbers presented throughout this document may not add precisely to the totals provided due to rounding. Absolute and percentage changes are calculated using the underlying amounts in thousands.

The accompanying condensed consolidated financial statements of the Company and subsidiaries have been prepared on a basis which assumes that the Company will continue as a going concern, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business.

As of June 30, 2017, the Company had cash and cash equivalents of $85.5 million. The Company's condensed consolidated balance sheets also include long-term debt from royalty-bearing instrument and exchangeable senior notes. In January 2017, the Company issued $30.0 million in aggregate principal amount of January 2017 3.5% exchangeable senior notes due 2047, or the 2017 Notes. The terms of the 2017 Notes are such that they may be redeemed by the Company for cash on or after January 19, 2021 and may be put back to the Company by the holders on January 19, 2022 for cash equal to 100% of the principal amount plus any accrued and unpaid interest. The 2017 Notes are exchangeable into ADSs at the option of holders at any time after issuance and prior to maturity and are exchangeable into ADSs at the option of the Company upon satisfaction of certain equity conditions. Accordingly, the exchangeable senior notes do not represent a short-term claim on the liquid assets of the Company as of June 30, 2017. The terms of the Company's January 2012 3.5% exchangeable senior notes due 2032, or the 2012 Notes, which were repaid in full during the first quarter of 2017, allowed for repurchase in cash by the Company at the option of the holders on January 19, 2017, as well as redemption by the Company for cash of all or part of the 2012 Notes on or after January 19, 2017, both at a price equal to 100% of the principal amount of the 2012 Notes to be repurchased or redeemed, plus accrued and unpaid interest to, but excluding, the repurchase or redemption date. Accordingly, $15.1 million in principal amount of 2012 Notes represented a short-term claim on the liquid assets of the Company as of December 31, 2016.

The Company believes its cash and cash equivalents will be sufficient to fund its projected operations through the results of the REDUCE-IT study, which we anticipate will be available in the second or third quarter of 2018. Depending on the level of cash generated from operations, additional capital may be required to sustain operations, fund debt obligations or expand promotion of Vascepa as contemplated following anticipated successful results of the REDUCE-IT study. The Company anticipates that quarterly net cash outflows in future periods will be variable.

(2) Significant Accounting Policies

Principles of Consolidation

The condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation.

Use of Estimates

Accounting estimates are based on historical experience and other factors that are considered reasonable under the circumstances. Estimates are used in determining such items as provisions for sales returns, rebates and incentives, chargebacks, and other sales allowances; depreciable/amortizable lives; asset impairments; valuation allowance on deferred taxes; probabilities of achievement of performance conditions for certain equity awards; amounts recorded for licensing revenue; contingencies and accruals; and valuations of derivative and long-term debt instruments. Because of the uncertainties inherent in such estimates, actual results may differ from these estimates. Management periodically evaluates estimates used in the preparation of the condensed consolidated financial statements for continued reasonableness.

Use of Forecasted Financial Information in Accounting Estimates

The use of forecasted financial information is inherent in many of the Company's accounting estimates including, but not limited to, determining the estimated fair values of derivatives, debt instruments and intangible assets, evaluating the need for valuation allowances for deferred tax assets, and assessing the Company's ability to continue as a going concern. Such forecasted financial information is comprised of numerous assumptions regarding the Company's future revenues, cash flows, and operational results. Management believes that its financial forecasts are reasonable and appropriate based upon current facts and circumstances. Because of the inherent nature of forecasts, however, actual results may differ from these forecasts. Management regularly reviews the information related to these forecasts and adjusts the carrying amounts of the applicable assets prospectively, if and when actual results differ from previous estimates.

Revenue Recognition

The Company sells Vascepa principally to a limited number of major wholesalers, as well as selected regional wholesalers and specialty pharmacy providers, or collectively, its Distributors or its customers, that in turn resell Vascepa to retail pharmacies for subsequent resale to patients and healthcare providers. Patients are required to have a prescription in order to purchase Vascepa. In accordance with GAAP, the Company's revenue recognition policy requires that: (i) there is persuasive evidence that an arrangement exists between the Company and the Distributor, (ii) delivery has occurred, (iii) collectability is reasonably assured and (iv) the price is fixed or determinable.

The Company has contracts with its primary Distributors and delivery generally occurs when a Distributor receives Vascepa. The Company evaluates the creditworthiness of each of its Distributors to determine whether revenues can be recognized upon delivery, subject to satisfaction of the other requirements, or whether recognition is required to be delayed until receipt of payment. In order to conclude that the price is fixed or determinable, the Company must be able to (i) calculate its gross product revenues from the sales to Distributors and (ii) reasonably estimate its net product revenues. The Company calculates gross product revenues generally based on the wholesale acquisition cost that the Company charges its Distributors for Vascepa. The Company estimates its net product revenues by deducting from its gross product revenues (a) trade allowances, such as invoice discounts for prompt payment and distributor fees, (b) estimated government and private payor rebates, chargebacks and discounts, such as Medicaid reimbursements, (c) reserves for expected product returns and (d) estimated costs of incentives offered to certain indirect customers, including patients.

Trade Allowances: The Company generally provides invoice discounts on Vascepa sales to its Distributors for prompt payment and pays fees for distribution services, such as fees for certain data that Distributors provide to the Company. The payment terms for sales to Distributors generally include a 2% discount for prompt payment while the fees for distribution services are based on contractual rates agreed with the respective Distributors. Based on judgment and experience, the Company expects its Distributors to earn these discounts and fees, and deducts the full amount of these discounts and fees from its gross product revenues and accounts receivable at the time such revenues are recognized.

Rebates, Chargebacks and Discounts: The Company contracts with Medicaid, other government agencies and various private organizations, or collectively, Third-party Payors, so that Vascepa will be eligible for purchase by, or partial or full reimbursement from, such Third-party Payors. The Company estimates the rebates, chargebacks and discounts it will provide to Third-party Payors and deducts these estimated amounts from its gross product revenues at the time the revenues are recognized. The Company estimates the rebates, chargebacks and discounts that it will provide to Third-party Payors based upon (i) the Company's contracts with these Third-party Payors, (ii) the government-mandated discounts applicable to government-funded programs, (iii) information obtained from the Company's Distributors and (iv) information obtained from other third parties regarding the payor mix for Vascepa.

Product Returns: The Company's Distributors have the right to return unopened unprescribed Vascepa during the 18-month period beginning six months prior to the labeled expiration date and ending twelve months after the labeled expiration date. The expiration date for Vascepa is three years after it has been converted into capsule form, which is the last step in the manufacturing process for Vascepa and generally occurs within a few months before Vascepa is delivered to Distributors. The Company estimates future product returns on sales of Vascepa based on: (i) data provided to the Company by its Distributors (including weekly reporting of Distributors' sales and inventory held by Distributors that provided the Company with visibility into the distribution channel in order to determine what quantities were sold to retail pharmacies and other providers), (ii) information provided to the Company from retail pharmacies, (iii) data provided to the Company by a third-party data provider which collects and publishes prescription data, and other third parties, (iv) historical industry information regarding return rates for similar pharmaceutical products, (v) the estimated remaining shelf life of Vascepa previously shipped and currently being shipped to Distributors and (vi) contractual agreements intended to limit the amount of inventory maintained by the Company's Distributors.

Other Incentives: Other incentives that the Company offers to indirect customers include co-pay mitigation rebates provided by the Company to commercially insured patients who have coverage for Vascepa and who reside in states that permit co-pay mitigation programs. The Company's co-pay mitigation program is intended to reduce each participating patient's portion of the financial responsibility for Vascepa's purchase price to a specified dollar amount. Based upon the terms of the program and information regarding programs provided for similar specialty pharmaceutical products, the Company estimates the average co-pay mitigation amounts and the percentage of patients that it expects to participate in the program in order to establish its accruals for co-pay mitigation rebates and deducts these estimated amounts from its gross product revenues at the time the revenues are recognized. The

Company adjusts its accruals for co-pay mitigation rebates based on actual redemption activity and estimates regarding the portion of issued co-pay mitigation rebates that it estimates will be redeemed.

The following tables summarize activity in each of the net product revenue allowance and reserve categories described above for the six months ended June 30, 2017 and 2016:

In thousands	Trade Allowances	Rebates, Chargebacks and Discounts	Product Returns	Other Incentives	Total
Balance as of December 31, 2016	$ 3,743	$ 20,915	$ 859	$ 1,681	$ 27,198
Provision related to current period sales	15,685	53,078	1,259	6,768	76,790
Provision related to prior period sales	(298)	(841)	—	(82)	(1,221)
Credits/payments made for current period sales	(5,496)	(34,771)	(21)	(4,922)	(45,210)
Credits/payments made for prior period sales	(3,107)	(16,722)	(24)	(1,770)	(21,623)
Balance as of June 30, 2017	$ 10,527	$ 21,659	$ 2,073	$ 1,675	$ 35,934

In thousands	Trade Allowances	Rebates, Chargebacks and Discounts	Product Returns	Other Incentives	Total
Balance as of December 31, 2015	$ 4,296	$ 9,881	$ 535	$ 1,084	$15,796
Provision related to current period sales	10,048	28,945	257	5,614	44,864
Provision related to prior period sales	(87)	(466)	—	—	(553)
Credits/payments made for current period sales	(6,415)	(10,750)	—	(2,910)	(20,075)
Credits/payments made for prior period sales	(4,180)	(8,497)	(226)	(1,284)	(14,187)
Balance as of June 30, 2016	$ 3,662	$ 19,113	$ 566	$ 2,504	$25,845

Such net product revenue allowances and reserves are included within accrued expenses and other current liabilities within the condensed consolidated balance sheets, with the exception of trade allowances and chargebacks, which are included within accounts receivable, net as discussed below.

Multiple-Element Arrangements and Licensing Revenue

When evaluating multiple-element arrangements, the Company identifies the deliverables included within the agreement and evaluates which deliverables represent separate units of accounting based on whether the delivered element has stand-alone value to the customer or if the arrangement includes a general right of return for delivered items.

The consideration received is allocated between each of the separable elements in the arrangement using the relative selling price method. The selling price used for each separable element will be based on vendor specific objective evidence (“VSOE”) if available, third-party evidence if VSOE is not available, or estimated selling price if neither VSOE nor third-party evidence is available. Revenue is then recognized as each of the separable elements to which the revenue has been allocated is delivered.

The Company may receive up-front, non-refundable payments when licensing its intellectual property in conjunction with research, development and commercialization agreements. In determining the units of accounting, management evaluates whether the license has stand-alone value from the undelivered elements to the collaborative partner based on the consideration of the relevant facts and circumstances for each arrangement. Factors considered in this determination include the stage of development of the license delivered, research and development capabilities of the partner and the ability of partners to develop and commercialize Vascepa independent of the Company.

When management believes the license to its intellectual property does not have stand-alone value from the other deliverables to be provided in the arrangement, the Company generally recognizes revenue attributable to the license over the Company’s contractual or estimated performance period. Any unrecognized portion of license revenue is classified within deferred revenue in the accompanying condensed consolidated balance sheets. When management believes the license to its intellectual property has stand-alone value, the Company recognizes revenue attributed to the license upon delivery. The periods over which revenue is recognized is subject to estimates by management and may change over the course of the agreement. Such a change could have a material impact on the amount of revenue the Company records in future periods.

Milestones

Contingent consideration from activities that is earned upon the achievement of a substantive milestone is recognized in its entirety in the period in which the milestone is achieved. At the inception of each arrangement that includes milestone payments, the Company evaluates whether each milestone is substantive. This evaluation includes an assessment of whether: (a) the consideration is commensurate with either (1) the entity's performance to achieve the milestone, or (2) the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from the entity's performance to achieve the milestone, (b) the consideration relates solely to past performance and (c) the consideration is reasonable relative to all of the deliverables and payment terms within the arrangement. The Company evaluates factors such as the scientific, clinical, regulatory, commercial and other risks that must be overcome to achieve the respective milestone, the level of effort and investment required and whether the milestone consideration is reasonable relative to all deliverables and payment terms in the arrangement in making this assessment.

See Note 9—Development, Commercialization and Supply Agreements for further information regarding licensing revenue and milestones primarily related to the Company's multiple-element arrangement with Eddingpharm (Asia) Macao Commercial Offshore Limited.

Distribution Costs

The Company records distribution costs related to shipping product to its customers, primarily through the use of common carriers or external distribution services, in cost of goods sold.

Cash and Cash Equivalents and Restricted Cash

Cash and cash equivalents consist of cash, deposits with banks and short-term highly liquid money market instruments with remaining maturities at the date of purchase of 90 days or less. Restricted cash represents cash and cash equivalents pledged to guarantee repayment of certain expenses which may be incurred for business travel under corporate credit cards held by employees.

Accounts Receivable, net

Accounts receivable, net, comprised of trade receivables, are generally due within 30 days and are stated at amounts due from customers. The Company recognizes an allowance for losses on accounts receivable in an amount equal to the estimated probable losses net of any recoveries. The allowance is based primarily on assessment of specific identifiable customer accounts considered at risk or uncollectible, as well as an analysis of current receivables aging and expected future write-offs. The expense associated with the allowance for doubtful accounts is recognized as selling, general, and administrative expense. The Company has not historically experienced any credit losses.

The following table summarizes the impact of accounts receivable reserves on the gross trade accounts receivable balances as of June 30, 2017 and December 31, 2016:

In thousands	June 30, 2017	December 31, 2016
Gross trade accounts receivable	$48,367	$ 24,127
Trade allowances	(10,527)	(3,743)
Chargebacks	(353)	(387)
Allowance for doubtful accounts	(12)	(12)
Accounts receivable, net	$37,475	$ 19,985

Inventory

The Company states inventories at the lower of cost or net realizable value. Cost is determined based on actual cost using the average cost method. Net realizable value is the estimated selling price in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. An allowance is established when management determines that certain inventories may not be saleable. If inventory cost exceeds expected net realizable value due to obsolescence, damage or quantities in excess of expected demand, changes in price levels or other causes, the Company will reduce the carrying value of such inventory to net realizable value and recognize the difference as a component of cost of goods sold in the period in which it occurs. The Company capitalizes inventory purchases of saleable product from approved suppliers while inventory purchases from suppliers prior to regulatory approval are included as a component of research and development expense. The Company expenses inventory identified for use as marketing samples when they are packaged. The average cost reflects the actual purchase price of Vascepa active pharmaceutical ingredient, or API.

Property, Plant and Equipment

The Company provides for depreciation and amortization using the straight-line method by charges to operations in amounts that depreciate the cost of the fixed asset over its estimated useful life. The estimated useful lives, by asset classification, are as follows:

Asset Classification	Useful Lives
Computer equipment and software	3 - 5 years
Furniture and fixtures	5 years
Leasehold improvements	Lesser of useful life or lease term

Upon retirement or sale of assets, the cost of the assets disposed and the related accumulated depreciation are removed from the condensed consolidated balance sheet and any resulting gain or loss is credited or expensed to operations. Repairs and maintenance costs are expensed as incurred.

Long-Lived Asset Impairment

The Company reviews its long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. Recoverability of these assets is determined by comparing the forecasted undiscounted net cash flows of the operation to which the assets relate to their carrying amount. If impairment is indicated, the assets are written down to fair value. Fair value is determined based on discounted forecasted cash flows or appraised values, depending on the nature of the assets.

Intangible Asset, net

Intangible asset, net consists of a milestone payment paid to the former shareholders of Laxdale Limited related to the 2004 acquisition of the rights to Vascepa, which is the result of Vascepa receiving marketing approval for the first indication and is amortized over its estimated useful life on a straight-line basis. See Note 6—Commitments and Contingencies for further information regarding other obligations related to the acquisition of Laxdale Limited.

Costs for Patent Litigation and Legal Proceedings

Costs for patent litigation or other legal proceedings are expensed as incurred and included in selling, general and administrative expenses.

Research and Development Costs

The Company charges research and development costs to operations as incurred. Research and development expenses are comprised of costs incurred by the Company in performing research and development activities, including: salary and benefits; stock-based compensation expense; laboratory supplies and other direct expenses; contractual services, including clinical trial and pharmaceutical development costs; commercial supply investment in its drug candidates; and infrastructure costs, including facilities costs and depreciation expense. In addition, research and development costs include the costs of product supply received from suppliers when such receipt by the Company is prior to regulatory approval of the supplier.

Selling, General and Administrative Costs

The Company charges selling, general and administrative costs to operations as incurred. Selling, general and administrative costs include salaries and benefits, stock-based compensation expense, and costs of programs and infrastructure necessary for the general conduct of the Company’s business, including those incurred as a result of the commercialization of Vascepa in the United States as well as co-promotion fees accrued under the agreement with Kowa Pharmaceuticals America, Inc.

Income Taxes

Deferred tax assets and liabilities are recognized for the future tax consequences of differences between the carrying amounts and tax bases of assets and liabilities and operating loss carryforwards and other attributes using enacted rates expected to be in effect when those differences reverse. Valuation allowances are provided against deferred tax assets that are not more likely than not to be realized.

The Company provides reserves for potential payments of tax to various tax authorities or does not recognize tax benefits related to uncertain tax positions and other issues. Tax benefits for uncertain tax positions are based on a determination of whether a tax benefit taken by the Company in its tax filings or positions is more likely than not to be realized, assuming that the matter in question will be decided based on its technical merits. The Company’s policy is to record interest and penalties in the provision for income taxes.

The Company regularly assesses its ability to realize deferred tax assets. Changes in historical earnings performance and future earnings projections, among other factors, may cause the Company to adjust its valuation allowance on deferred tax assets, which would impact the Company's income tax expense in the period in which it is determined that these factors have changed.

Excess tax benefits and deficiencies that arise upon vesting or exercise of share-based payments are recognized as an income tax benefit and expense, respectively, in the condensed consolidated statement of operations. Excess income tax benefits and deficiencies are classified in cash flows from operating activities and cash paid to taxing authorities arising from the withholding of shares from employees are classified as cash flows from financing activities.

The Company's and its subsidiaries' income tax returns are periodically examined by various tax authorities. The Company is currently under audit by the United States Internal Revenue Service (IRS) for the years 2013 to 2014. Although the outcome of tax

audits is always uncertain and could result in significant cash tax payments, the Company does not believe the outcome of these audits will have a material adverse effect on its consolidated financial position or results of operations.

Derivative Instruments

Derivative financial liabilities are recorded at fair value, with gains and losses arising for changes in fair value recognized in the condensed consolidated statement of operations at each period end while such instruments are outstanding. If the Company issues shares to discharge the liability, the derivative financial liability is derecognized and common stock and additional paid-in capital are recognized on the issuance of those shares. Long-term debt redemption features are valued using probability-weighted models incorporating management estimates for potential change in control, and by determining the fair value of the debt with and without the change in control provision included.

Loss per Share

Basic net loss per share is determined by dividing net loss by the weighted average shares of common stock outstanding during the period. Diluted net loss per share is determined by dividing net loss by diluted weighted average shares outstanding. Diluted weighted average shares reflects the dilutive effect, if any, of potentially dilutive common shares, such as common stock options and warrants calculated using the treasury stock method and convertible notes using the “if-converted” method. In periods with reported net operating losses, all common stock options and warrants are deemed anti-dilutive such that basic net loss per share and diluted net loss per share are equal. However, in certain periods in which there is a gain recorded pursuant to the change in fair value of the warrant derivative liability, for diluted net loss per share purposes, the impact of such gains is reversed and the treasury stock method is used to determine diluted net loss per share.

The Company’s preferred stock is entitled to receive dividends on an as-if-converted basis in the same form as dividends actually paid on common shares. Accordingly, the preferred stock is considered a participating security and the Company is required to apply the two-class method to consider the impact of the preferred stock on the calculation of basic and diluted earnings per share. The Company is currently in a net loss position and is therefore not required to present the two-class method, however, in the event the Company is in a net income position, the two-class method must be applied by allocating all earnings during the period to common shares and preferred stock based on their contractual entitlements assuming all earnings were distributed.

The calculation of net loss and the number of shares used to compute basic and diluted net loss per share for the three and six months ended June 30, 2017 and 2016 are as follows:

	Three months ended June 30,		Six months ended June 30,	
In thousands	2017	2016	2017	2016
Net loss—basic and diluted	$(13,634)	$(13,354)	$(34,575)	$(43,125)
Weighted average shares outstanding—basic and diluted	270,725			