AMARIN CORP PLC\UK
Form 10-Q
November 01, 2018

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 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 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 every Interactive Data File required to be submitted 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 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	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

307,461,189 common shares were outstanding as of October 30, 2018, including 303,882,906 shares held as American Depositary Shares (ADSs), each representing one Ordinary Share, 50 pence par value per share and 358,685 Ordinary Shares. In addition, 28,931,746 ordinary share equivalents were issuable in exchange for outstanding preferred shares as of October 30, 2018, for a total of 336,392,935 ordinary shares and ordinary share equivalents outstanding as of October 30, 2018.

INDEX TO FORM 10-Q

PART I

AMARIN CORPORATION PLC

CONDENSED CONSOLIDATED BALANCE SHEETS

(Unaudited, in thousands, except share amounts)

	September 30, 2018	December 31, 2017
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 81,892	$ 73,637
Restricted cash	600	600
Accounts receivable, net	47,648	45,318
Other receivables	25,654	—
Inventory, net	43,673	30,260
Prepaid and other current assets	2,935	3,455
Total current assets	202,402	153,270
Property, plant and equipment, net	69	28
Other long-term assets	174	174
Intangible asset, net	7,642	8,126
TOTAL ASSETS	$ 210,287	$ 161,598
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current Liabilities:		
Accounts payable	$ 26,174	$ 25,155
Accrued expenses and other current liabilities	93,899	58,902
Current portion of exchangeable senior notes, net of discount	219	481
Current portion of long-term debt from royalty-bearing instrument	30,130	22,348
Deferred revenue, current	1,220	1,644
Total current liabilities	151,642	108,530
Long-Term Liabilities:		
Exchangeable senior notes, net of discount	29,159	28,992
Long-term debt from royalty-bearing instrument	53,924	70,834
Deferred revenue, long-term	19,736	17,192
Other long-term liabilities	8,652	1,150
Total liabilities	263,113	226,698
Commitments and contingencies (Note 6)		
Stockholders' Deficit:		
Series A Convertible Preferred Stock, £0.05 par, unlimited authorized; 289,317,460 shares issued and outstanding as of September 30, 2018 (equivalent to 28,931,746 ordinary shares upon future consolidation and redesignation at a 10:1 ratio); 328,184,640 shares issued and outstanding as of December 31, 2017 (equivalent to 32,818,464 ordinary shares upon future consolidation and redesignation at a 10:1 ratio)	21,850	24,364
Common stock, £0.50 par, unlimited authorized; 307,309,316 issued, 304,089,718 outstanding as of September 30, 2018; 272,719,044 issued, 271,022,011 outstanding as of December 31, 2017	232,646	208,768
Additional paid-in capital	1,057,408	977,866

Treasury stock; 3,219,598 shares as of September 30, 2018; 1,697,033 shares as of December 31, 2017	(9,867)	(4,229)
Accumulated deficit	(1,354,863)	(1,271,869)
Total stockholders' deficit	(52,826)	(65,100)
TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT	$ 210,287	$ 161,598

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 September 30,		Nine months ended September 30,	
	2018	2017	2018	2017
Product revenue, net	$54,973	$47,051	$151,286	$126,343
Licensing revenue	350	309	598	895
Total revenue, net	55,323	47,360	151,884	127,238
Less: Cost of goods sold	13,541	11,921	37,035	31,520
Gross margin	41,782	35,439	114,849	95,718
Operating expenses:				
Selling, general and administrative	49,960	33,194	147,310	98,910
Research and development	14,072	10,694	43,993	35,211
Total operating expenses	64,032	43,888	191,303	134,121
Operating loss	(22,250)	(8,449)	(76,454)	(38,403)
Interest expense, net	(2,163)	(2,401)	(6,188)	(7,097)
Other (expense) income, net	(58)	25	(134)	100
Loss from operations before taxes	(24,471)	(10,825)	(82,776)	(45,400)
(Provision for) benefit from income taxes	—	—	—	—
Net loss	$(24,471)	$(10,825)	$(82,776)	$(45,400)
Loss per share:				
Basic	$(0.08)	$(0.04)	$(0.28)	$(0.17)
Diluted	$(0.08)	$(0.04)	$(0.28)	$(0.17)
Weighted average shares:				
Basic	295,595	270,803	291,526	270,566
Diluted	295,595	270,803	291,526	270,566

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, 2017	328,184,640	272,719,044	(1,697,033)	$24,364	$208,768	$977,866	$(4,229)	$(1,271,869)	$(65,100)
Cumulative-effect adjustment	—	—	—	—	—	—	—	(218)	(218)
January 1, 2018	328,184,640	272,719,044	(1,697,033)	$24,364	$208,768	$977,866	$(4,229)	$(1,272,087)	$(65,318)
Issuance of common stock, net of transaction costs	—	20,616,438	—	—	14,635	55,372	—	—	70,007
Issuance of common stock under employee stock purchase plan	—	127,872	—	—	85	338	—	—	423
Conversion of Series A Convertible Preferred Stock, net	(38,867,180)	3,886,718	—	(2,514)	2,514	(39)	—	—	(39)
Exercise of stock options	—	5,439,239	—	—	3,589	12,905	—	—	16,494
Vesting of restricted stock units	—	4,520,005	(1,522,565)	—	3,055	(3,055)	(5,638)	—	(5,638)
Stock-based compensation	—	—	—	—	—	14,021	—	—	14,021
Loss for the period	—	—	—	—	—	—	—	(82,776)	(82,776)
September 30, 2018	289,317,460	307,309,316	(3,219,598)	$21,850	$232,646	$1,057,408	$(9,867)	$(1,354,863)	$(52,826)

See notes to condensed consolidated financial statements.

AMARIN CORPORATION PLC

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited, in thousands)

	Nine months ended September 30,	
	2018	2017
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$(82,776)	$(45,400)
Adjustments to reconcile loss to net cash used in operating activities:		
Depreciation and amortization	12	51
Stock-based compensation	14,032	10,471
Amortization of debt discount and debt issuance costs	1,687	1,736
Amortization of intangible asset	484	485
Changes in assets and liabilities:		
Accounts receivable, net	(2,330)	(14,625)
Other receivables	(25,654)	—
Inventory, net	(13,413)	(8,043)
Prepaid and other current assets	520	5,298
Other long-term assets	—	567
Accrued interest payable	(371)	(6,959)
Deferred revenue	1,902	1,604
Accounts payable and other current liabilities	36,005	23,670
Other long-term liabilities	7,502	448
Net cash used in operating activities	(62,400)	(30,697)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of equipment	(53)	(12)
Net cash used in investing activities	(53)	(12)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of exchangeable debt	—	30,000
Payment of debt issuance costs	—	(1,207)
Payment of transaction costs for conversion of preferred stock	(39)	—
Proceeds from issuance of common stock, net of transaction costs	70,007	—
Proceeds from issuance of common stock under employee stock purchase plan	423	—
Proceeds from exercise of stock options, net of transaction costs	16,494	451
Repurchase of exchangeable senior notes	—	(15,107)
Payment on long-term debt from royalty-bearing instrument	(10,539)	—
Taxes paid related to stock-based awards	(5,638)	(2,593)
Net cash provided by financing activities	70,708	11,544
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS AND RESTRICTED CASH	8,255	(19,165)
CASH AND CASH EQUIVALENTS AND RESTRICTED CASH, BEGINNING OF PERIOD	74,237	98,851
CASH AND CASH EQUIVALENTS AND RESTRICTED CASH, END OF PERIOD	$82,492	$79,686
Supplemental disclosure of cash flow information:		
Cash paid during the year for:		
Interest	$16,030	$12,536
Income taxes	$825	$1,186

See notes to condensed consolidated financial statements.

AMARIN CORPORATION PLC

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

For purposes of this Quarterly Report on Form 10-Q, 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 pharmaceutical 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 capsule size. 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 is also developing Vascepa for FDA approval of potential additional indications for use. In particular, the Company conducted 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, was designed to evaluate the efficacy of Vascepa in reducing major cardiovascular events in a high-risk patient population on statin therapy. The REDUCE-IT study topline results were made public in September 2018, and broader reporting of results is planned at the 2018 Scientific Sessions of the American Heart Association (AHA) on November 10, 2018 in Chicago, Illinois.

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, which, in connection with positive REDUCE-IT results, is currently being increased from approximately 170 sales professionals, including sales representatives and their managers, to a planned total of over 400 sales professionals, and through a co-promotion agreement with Kowa Pharmaceuticals America, Inc. Under this co-promotion agreement, which commenced in May 2014 and extends until the end of 2018, 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.

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, 2017, or the 2017 Form 10-K, filed with the SEC. The balance sheet amounts at December 31, 2017 in this report were derived from the Company's audited 2017 consolidated financial statements included in the 2017 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 nine months ended September 30, 2018 and 2017 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. Certain prior year balances related to beginning and ending cash and cash

equivalents and restricted cash in the condensed consolidated statements of cash flows have been conformed to the current year presentation.

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 September 30, 2018, the Company had current assets of $202.4 million, including cash and cash equivalents of $81.9 million, accounts receivable, net, of $47.6 million and other receivables of $25.7 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 American Depositary Shares ("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 September 30, 2018. On October 19, 2018, the Company announced that it exercised its option to mandatorily exchange the entirety of the 2017 Notes into ADSs. When completed on November 2, 2018, the mandatory exchange will result in extinguishment of the debt and issuance of an aggregate amount of 7,716,048 ADSs, subject to certain adjustments as provided in the 2017 Notes, such that the Company will have no outstanding debt or related interest obligations.

The Company believes its cash and cash equivalents will be sufficient to fund its projected operations through planned expansion of its sales force and the anticipated submission in early 2019 of a supplemental new drug application (sNDA) with the FDA based on REDUCE-IT study results. Depending on the level of cash generated from operations, and in light of the recently announced successful results of the REDUCE-IT study, additional capital may be required to support planned expansion of Vascepa promotion and potential Vascepa promotion beyond which the Company is currently executing. If additional capital is required and the Company is unable to obtain additional capital, the Company may be forced to delay, limit or eliminate certain promotional activities. 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

Effective January 1, 2018, the Company adopted Accounting Standards Codification, or ASC, Topic 606, Revenue from Contracts with Customers, using the modified retrospective transition method. Under this method, the Company revised its opening retained earnings balance with a cumulative-effect adjustment as of January 1, 2018. This standard applies to all contracts with customers except for contracts that are within the scope of other standards, such as leases, insurance, and financial instruments. Under Topic 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 Topic 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. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of Topic 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied. For a complete discussion of accounting for net product revenue and licensing revenue, see Note 9—Revenue Recognition.

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 significant credit losses.

The following table summarizes the impact of accounts receivable reserves on the gross trade accounts receivable balances as of September 30, 2018 and December 31, 2017:

In thousands	September 30, 2018	December 31, 2017
Gross trade accounts receivable	$ 62,727	$ 57,802

Trade allowances	(14,624)	(12,035)
Chargebacks	(455)	(449)
Accounts receivable, net	$ 47,648	$ 45,318

Other Receivables

Other receivables consist of amounts due from parties other than customers, such as amounts due from financial institutions resulting from the timing of stock option exercises which amounts were received shortly after period end and amounts due from licensing partners resulting from the achievement of milestones related to the Company's licensing agreements.

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, as well as license fees related to the Company's strategic collaboration with Mochida Pharmaceutical Co., Ltd.

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 payable to Kowa Pharmaceuticals America, Inc.

Income Taxes

On December 22, 2017, the U.S. enacted the Tax Cuts and Jobs Act (the “Act”) which instituted fundamental changes to the taxation of multinational corporations. The Act includes changes to the taxation of foreign earnings by implementing a dividend exemption system, expansion of the current anti-deferral rules, a minimum tax on low-taxed foreign earnings and new measures to deter base erosion. The Act also includes a permanent reduction in the corporate tax rate to 21%, repeal of the corporate alternative minimum tax, expensing of capital investment, and limitation of the deduction of interest expense. Furthermore, as part of the transition to the new tax system, a one-time transition tax is imposed on a U.S. shareholder's historical undistributed earnings of foreign affiliates. The Company is applying the guidance in SAB 118 when accounting for the enactment-date effects of the Act. As of December 31, 2017, the Company had recorded provisional amounts to account for the impact of tax effects of the Act related to the change in corporate tax rate from 34% to 21% and the changes to executive compensation deductibility. As of September 30, 2018, the Company has not completed its accounting for all of the tax effects of the Act. The Company will continue to make and refine its calculations as additional analysis is completed. The Company’s estimates may also be affected as it gains a more thorough understanding of the tax law. The Company will disclose the impact to the provisional amounts in the reporting period in which the accounting analysis is completed, which will not exceed one year from the date of enactment. Any changes are not expected to have an impact to the tax provision or condensed consolidated financial statements.

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. Deferred tax assets and liabilities are classified as non-current in the condensed consolidated balance sheets.

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, future earnings projections, and changes in tax laws and tax rates, 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 as 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 undergoing federal and state audits, including 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.

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 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 are deemed anti-dilutive such that basic net loss per share and diluted net loss per share are equal.

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 nine months ended September 30, 2018 and 2017 are as follows:

	Three months ended September 30,		Nine months ended September 30,	
In thousands	2018	2017	2018	2017
Net loss—basic and diluted	$(24,471)	$(10,825)	$(82,776)	$(45,400)
Weighted average shares outstanding—basic and diluted	295,595	270,803	291,526	270,566
Net loss per share—basic and diluted	$(0.08)	$(0.04)	$(0.28)	$(0.17)

For the three and nine months ended September 30, 2018 and 2017, the following potentially dilutive securities were not included in the computation of net loss per share because the effect would be anti-dilutive:

	Three months ended September 30,		Nine months ended September 30,	
In thousands	2018	2017	2018	2017
Stock options	21,037	23,631	21,037	23,631
Restricted stock and restricted stock units	9,634	11,887	9,634	11,887
Exchangeable senior notes (if converted)	7,716	7,716	7,716	7,716
Preferred stock (if converted)	28,932	32,818	28,932	32,818

Debt Instruments

Debt instruments are initially recorded at fair value, with coupon interest and amortization of debt issuance discounts recognized in the condensed consolidated statement of operations as interest expense each period in which such instruments are outstanding. The Company records debt issuance costs related to a recognized debt liability in the condensed consolidated balance sheets as a direct deduction from the carrying amount of that debt liability and amortized to interest expense using the effective interest method over the expected term of the related debt. Unamortized debt issuance costs related to the extinguishment of debt are expensed at the time the debt is extinguished and recorded in other (expense) income, net, in the condensed consolidated statements of operations. If the Company issues shares to discharge the liability, the debt obligation is derecognized and common stock and additional paid-in capital are recognized upon the issuance of those shares.

The 2017 Notes can only be settled in ADSs upon conversion. The terms of the 2017 Notes also allow for repurchase in cash by the Company at the option of the holders as well as redemption by the Company for cash at specified times. The conversion feature in the 2017 Notes qualifies for the exception from derivative accounting in accordance with ASC 815-40 and is therefore accounted for as part of the debt host. The conversion feature in the 2017 Notes will continue to be evaluated on a quarterly basis to determine if it still receives an exception from derivative accounting in accordance with ASC 815-40. The 2017 Notes were recognized at par of $30.0 million. The Company also recognized a $1.2 million discount related to placement agent fees and offering expenses. This discount is being amortized through interest expense over the expected term of the 2017 Notes, through the first optional put date in January 2022.

See Note 5—Debt for further discussion.

Stock-Based Compensation

Stock-based compensation cost is generally measured at the grant date, based on the fair value of the award, and is recognized as compensation expense over the requisite service period. For awards with performance conditions, if the achievement of the performance conditions is deemed probable, the Company recognizes compensation expense based on the fair value of the award over the estimated service period. The Company reassesses the probability of achievement of the performance conditions for such awards each reporting period.

The Company estimates the level of forfeitures expected to occur based on its historical data and records compensation cost only for those awards that are ultimately expected to vest.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to credit risk consist primarily of cash and cash equivalents and accounts receivable. The Company maintains substantially all of its cash and cash equivalents in financial institutions believed to be of high-credit quality.

A significant portion of the Company’s sales are to wholesalers in the pharmaceutical industry. The Company monitors the creditworthiness of customers to whom it grants credit terms and has not experienced any credit losses. The Company does not require

collateral or any other security to support credit sales. Three customers individually accounted for 10% or more of the Company's gross product sales. Customers A, B, and C accounted for 26%, 31%, and 31%, respectively, of gross product sales for the nine months ended September 30, 2018, and represented 37%, 33%, and 17%, respectively, of the gross accounts receivable balance as of September 30, 2018. Customers A, B, and C accounted for 28%, 27%, and 35%, respectively, of gross product sales for the nine months ended September 30, 2017 and represented 36%, 27%, and 24%, respectively, of the gross accounts receivable balance as of September 30, 2017. The Company has not experienced any significant write-offs of its accounts receivable.

Concentration of Suppliers

The Company has contractual freedom to source the API for Vascepa and has entered into supply agreements with multiple suppliers. The Company's supply of product for commercial sale and clinical trials is dependent upon relationships with third-party manufacturers and key suppliers.

The Company cannot provide assurance that its efforts to procure uninterrupted supply of Vascepa to meet market demand will continue to be successful or that it will be able to renew current supply agreements on favorable terms or at all. Significant alteration to or termination of the Company's current supply chain or its failure to enter into new and similar agreements in a timely fashion, if needed, could have a material adverse effect on its business, condition (financial and other), prospects or results of operations.

The Company currently has manufacturing agreements with three independent FDA-approved commercial API manufacturers and three independent FDA-approved commercial API encapsulators for Vascepa manufacturing. Each of these companies has qualified its manufacturing processes and is capable of manufacturing Vascepa. There can be no guarantee that these or other suppliers with which the Company may contract in the future to encapsulate API will remain qualified to manufacture the product to its specifications or that these and any future suppliers will have the manufacturing capacity to meet anticipated demand for Vascepa.

Foreign Currency

All subsidiaries use the U.S. dollar as the functional currency. Monetary assets and liabilities denominated in a foreign currency are remeasured into U.S. dollars at period-end exchange rates. Gains and losses from the remeasurement are included in other (expense) income, net in the condensed consolidated statements of operations. For transactions settled during the applicable period, gains and losses are included in other (expense) income, net in the condensed consolidated statements of operations. Certain amounts payable pursuant to supply contracts are denominated in currencies other than the U.S. dollar.

Fair Value of Financial Instruments

The Company provides disclosure of financial assets and financial liabilities that are carried at fair value based on the price that would be received upon sale of an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. Fair value measurements may be classified based on the amount of subjectivity associated with the inputs to fair valuation of these assets and liabilities using the following three levels:

Level 1—Inputs are unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access at the measurement date.

Level 2—Inputs include quoted prices for similar assets and liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active, inputs other than quoted prices that are observable for the asset or liability (i.e., interest rates, yield curves, etc.) and inputs that are derived principally from or corroborated by observable market data by correlation or other means (market corroborated inputs).

Level 3—Unobservable inputs that reflect the Company's estimates of the assumptions that market participants would use in pricing the asset or liability. The Company develops these inputs based on the best information available, including its own data.

The following tables present information about the Company's assets and liabilities as of September 30, 2018 and December 31, 2017 that are measured at fair value on a recurring basis and indicate the fair value hierarchy of the valuation techniques the Company utilized to determine such fair value:

	September 30, 2018			
In thousands	Total	Level 1	Level 2	Level 3
Asset:				
Cash equivalents—money market	$9,834	$9,834	$ —	$ —

	December 31, 2017			
In thousands	Total	Level 1	Level 2	Level 3
Asset:				
Cash equivalents—money market	$9,317	$9,317	$ —	$ —

The carrying amounts of cash, cash equivalents, accounts payable and accrued liabilities approximate fair value because of their short-term nature. The carrying amounts and the estimated fair values of debt instruments as of September 30, 2018 and December 31, 2017 are as follows:

	September 30, 2018		December 31, 2017	
In thousands	Carrying Value	Estimated Fair Value	Carrying Value	Estimated Fair Value
Current portion of long-term debt from royalty-bearing instrument, net of accrued interest	$29,460		$21,569	
Long-term debt from royalty-bearing instrument	53,924		70,834	
Total long-term debt from royalty-bearing instrument	$83,384	$83,200	$92,403	$88,000
2017 Notes	29,159	103,583	28,992	38,200

The estimated fair value of the long-term debt from royalty-bearing instrument pursuant to the December 2012 financing is calculated utilizing the same Level 3 inputs utilized in valuing the related derivative liability (see Derivative Liabilities below). The estimated fair value of the 2017 Notes is calculated based on Level 1 quoted bond prices or, in the absence of quoted bond prices, is calculated using a Level 3 binomial model. The carrying value of the 2017 Notes as of September 30, 2018 and December 31, 2017 includes a debt discount of $0.8 million and $1.0 million, respectively, which is being amortized as non-cash interest expense over the expected term of the 2017 Notes, through the first optional put date in January 2022.

Derivative Liabilities

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 Feature

The Company’s December 2012 royalty-bearing instrument financing arrangement (discussed in Note 5—Debt) contains a redemption feature whereby, upon a change of control, the Company would be required to repay $150.0 million, less any previously repaid amount. The Company determined this redemption feature to be an embedded derivative, which is carried at fair value and is classified as Level 3 in the fair value hierarchy due to the use of significant unobservable inputs. The fair value of the embedded derivative was calculated using a probability-weighted model incorporating management estimates of future revenues and for a potential change in control, and by determining the fair value of

the debt with and without the change in control provision included. The difference between the two was determined to be the fair value of the embedded derivative. The fair value of this derivative liability is remeasured at each reporting period, with changes in fair value recognized in the condensed consolidated statement of operations. As of September 30, 2018, the fair value of the derivative was determined to be nil, and the debt was valued by comparing debt issues of similar companies with (i) remaining terms of between 1.5 and 4.3 years, (ii) coupon rates of between 5.4% and 10.8% and (iii) market yields of between 7.0% and 12.0%. As of December 31, 2017, the fair value of the derivative was determined to be nil based on underlying assumptions, and the debt was valued by comparing debt issues of similar companies with (i) remaining terms of between 2.3 and 4.3 years, (ii) coupon rates of between 5.8% and 10.8% and (iii) market yields of between 10.2% and 18.4%. As such, the Company recognized no gain or loss on change in fair value of derivative liability for the nine months ended September 30, 2018. The Company also recognized no gain or loss on change in fair value of derivative liability for the nine months ended September 30, 2017.

Any changes in the assumptions used to value the derivative liabilities, including the probability of a change in control, could result in a material change to the carrying value of such liabilities.

Segment and Geographical Information

Operating segments are defined as components of an enterprise about which separate financial information is available that is evaluated on a regular basis by the chief operating decision-maker, or decision-making group, in deciding how to allocate resources to

an individual segment and in assessing performance of the segment. The Company currently operates in one business segment, which is the development and commercialization of Vascepa. A single management team that reports to the Company's chief decision-maker, who is the Chief Executive Officer, comprehensively manages the business. Accordingly, the Company does not have separately reportable segments.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board, or FASB, and are early adopted by the Company or adopted as of the specified effective date.

In May 2014, the FASB issued Accounting Standards Update ("ASU"), No. 2014-09, which amends the guidance for accounting for revenue from contracts with customers. This ASU supersedes the revenue recognition requirements in Accounting Standards Codification ("ASC") Topic 605, Revenue Recognition, and creates a new Topic 606, Revenue from Contracts with Customers. In 2015 and 2016, the FASB issued additional ASUs related to Topic 606 that delayed the effective date of the guidance and clarified various aspects of the new revenue guidance, including principal versus agent considerations, identifying performance obligations, and licensing, and they include other improvements and practical expedients. The Company adopted this standard effective January 1, 2018 using the modified retrospective transition method.

The Company, as a result of adopting Topic 606 on January 1, 2018, has adjusted its opening retained earnings and deferred revenue balances by $0.2 million. The adjustment relates solely to the Company's licensing revenues and the timing over which certain non-refundable upfront and milestone payments received from Eddingpharm (Asia) Macao Commercial Offshore Limited and HLS Therapeutics Inc. are recognized under Topic 606. No practical expedients associated with the adoption of Topic 606 were applied.

In May 2017, the FASB issued ASU No. 2017-09, Compensation—Stock Compensation: Scope of Modification Accounting. The amendments in ASU No. 2017-09 provide guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting in Topic 718. The Company adopted this standard effective January 1, 2018 and, in accordance with the ASU, will apply it prospectively. The Company does not expect it to have a material impact on the Company's condensed consolidated financial statements.

In January 2017, the FASB issued ASU No. 2017-01, Clarifying the Definition of a Business. The standard clarifies the definition of a business when evaluating whether transactions should be accounted for as acquisitions or disposals of assets or businesses. Under the provisions of this new standard, it is expected that more transactions will be accounted for as asset acquisitions rather than business acquisitions. The Company adopted this standard effective January 1, 2018 and, in accordance with the ASU, will apply it prospectively. The Company does not expect it to have a material impact on the Company's condensed consolidated financial statements.

In October 2016, the FASB issued ASU No. 2016-16, Income Taxes (Topic 740): Intra-Entity Transfers of Assets Other Than Inventory, which requires the recognition of income tax consequences of an intra-entity transfer of an asset, other than inventory, when the transfer occurs. The Company adopted this standard effective January 1, 2018, which had no impact on the Company's condensed consolidated financial statements.

In August 2016, the FASB issued ASU No. 2016-15, Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments, which is intended to reduce diversity in practice regarding how certain cash receipts and cash payments related to eight specific issues are presented and classified in the statement of cash flows. In November 2016, the FASB issued ASU No. 2016-18, Statement of Cash Flows (Topic 230): Restricted Cash, which requires that the statement of cash flows explain the change during the period in the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. The Company adopted this standard effective January 1, 2018 and, in accordance with the ASUs, applied them using a retrospective transition method to each period presented. Adoption of these ASUs did not have a material impact on the Company's

condensed consolidated financial statements.

In January 2016, the FASB issued ASU No. 2016-01, Financial Instruments—Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities. The new guidance is intended to improve the recognition and measurement of financial instruments by requiring separate presentation of financial assets and financial liabilities by measurement category and form of financial asset (i.e., securities or loans and receivables) within the balance sheet or the accompanying notes to the financial statements, eliminating the requirement for public business entities to disclose the method(s) and significant assumptions used to estimate the fair value that is required to be disclosed for financial instruments measured at amortized cost within the balance sheet, requiring public business entities to use the exit price notion when measuring the fair value of financial instruments for disclosure purposes, requiring equity investments (except those accounted for under the equity method of accounting, or those that result in consolidation of the investee) to be measured at fair value with changes in fair value recognized in net income, and requiring a reporting organization to present separately in other comprehensive income the portion of the total change in the fair value of a liability resulting from a change in the instrument-specific credit risk (also referred to as “own credit”) when the organization has

elected to measure the liability at fair value in accordance with the fair value option for financial instruments, among others. In February 2018, the FASB issued ASU No. 2018-03, Technical Corrections and Improvements to Financial Instruments—Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities, which is intended to clarify certain aspects of the guidance issued in ASU 2016-01. The Company adopted these standards effective January 1, 2018, which had no impact on the Company's condensed consolidated financial statements.

The Company also considered the following recent accounting pronouncements which were not yet adopted as of September 30, 2018:

In August 2018, the FASB issued ASU No. 2018-13, Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement, which eliminates, adds and modifies certain disclosure requirements for fair value measurements, including eliminating the requirement to disclose the amount of and reasons for transfers between Level 1 and Level 2 of the fair value hierarchy, and requiring disclosure of the range and weighted average used to develop significant unobservable inputs for Level 3 fair value measurements. The new guidance is effective for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years. Early adoption, either of the entire standard or only the provisions that eliminate or modify requirements, is permitted. The Company has evaluated the disclosure requirements of this standard and does not expect it to have a material impact on the Company's consolidated financial statements.

In June 2018, the FASB issued ASU No. 2018-07, Compensation—Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting, which is intended to simplify the accounting for share-based payments to nonemployees by aligning it with the accounting for share-based payments to employees, with certain exceptions. The new guidance is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. Early adoption is permitted. The Company has evaluated the accounting, transition and disclosure requirements of this standard and does not expect it to have a material impact on the Company's consolidated financial statements.

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842). The new guidance will require lessees to recognize a right-of-use asset and a lease liability for virtually all of their leases (other than leases that meet the definition of a short-term lease). The liability will be equal to the present value of lease payments. The asset will be based on the liability, subject to adjustment, such as for initial direct costs. Under the new guidance, lessor accounting is largely unchanged but certain targeted improvements were made to align, where necessary, lessor accounting with the lessee accounting model and Topic 606, Revenue from Contracts with Customers. The new lease guidance also simplified the accounting for sale and leaseback transactions primarily because lessees must recognize lease assets and lease liabilities and therefore, will no longer be provided with a source of off-balance sheet financing. The new guidance is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. Early adoption is permitted. The Company is currently evaluating the accounting, transition and disclosure requirements of the standard and cannot currently estimate the financial statement impact of adoption.

The Company believes that the impact of other recently issued but not yet adopted accounting pronouncements will not have a material impact on the Company's consolidated financial position, results of operations, and cash flows, or do not apply to the Company's operations.

(3) Intangible Asset

Intangible asset consists of the historical acquisition cost of certain technology rights for Vascepa and has an estimated weighted-average remaining useful life of 11.8 years. The carrying value as of September 30, 2018 and December 31, 2017 is as follows:

In thousands	September 30, 2018	December 31, 2017
Technology rights	$ 11,624	$ 11,624
Accumulated amortization	(3,982)	(3,498)
Intangible asset, net	$ 7,642	$ 8,126

(4) Inventory

The Company capitalizes its purchases of saleable inventory of Vascepa from suppliers that have been qualified by the FDA. Inventories as of September 30, 2018 and December 31, 2017 consist of the following:

In thousands	September 30, 2018	December 31, 2017
Raw materials	$ 8,709	$ 7,044
Work in process	11,597	10,844
Finished goods	23,655	12,372
Inventory	43,961	30,260
Inventory reserve	(288)	—
Inventory, net	$ 43,673	$ 30,260

(5) Debt

Long-Term Debt from Royalty-Bearing Instrument—December 2012 Financing

On December 6, 2012, the Company entered into a Purchase and Sale Agreement with BioPharma Secured Debt Fund II Holdings Cayman LP, or BioPharma. Under this agreement, the Company granted to BioPharma a security interest in future receivables associated with the Vascepa patent rights, in exchange for $100.0 million received at the closing of the agreement which occurred in December 2012. Under these terms, the Company continues to own all Vascepa intellectual property rights, however, such rights, as described below, could be used as collateral for repayment of the remaining unpaid balance under this agreement if the Company defaults on making required payments. In the agreement, the Company agreed to repay BioPharma up to $150.0 million with such repayment based on a portion of net revenues and receivables generated from Vascepa. On December 20, 2017, BioPharma assigned all rights under this agreement to CPPIB Credit Europe S.à r.l., or CPPIB.

As of September 30, 2018, the remaining amount to be repaid to CPPIB is $94.1 million. During the three and nine months ended September 30, 2018, the Company made repayments under the agreement of $5.3 million and $15.0 million, respectively, to CPPIB and an additional $5.5 million is scheduled to be paid in November 2018 for the third quarter of 2018. These payments were calculated based on the threshold limitation, as described below, as opposed to the scheduled quarterly repayments. Additional quarterly repayments, subject to the threshold limitation, are scheduled to be paid. All such payments reduce the remainder of the $150.0 million in aggregate payments to CPPIB.

These quarterly payments are subject to a quarterly threshold amount whereby, if a calculated threshold, based on quarterly Vascepa net revenues, is not achieved, the quarterly payment payable in that quarter can, at the Company's election, be reduced, with the reduction carried forward without interest for payment in a future period. The payment of any carried forward amount is subject to similarly calculated threshold repayment amounts based on Vascepa net revenue levels. Except upon a change of control in Amarin, the agreement does not expire until $150.0 million in aggregate has been repaid. Except in the event of the Company's default, there is no compounding of interest and no scheduled cliff payment due under this agreement. Rather, payment will be made, subject to the threshold limitation, until $150.0 million in aggregate has been repaid, including payments made previously. The Company can prepay an amount equal to $150.0 million less any previously repaid amount.

For each quarterly period since the inception of the debt, net revenues were below the contractual threshold amount such that cash payments were calculated for each period reflecting the optional reduction amount as opposed to the contractual threshold payment due for each quarterly period. In accordance with the agreement, quarterly differences between the calculated optional reduction amounts and the repayment schedule amounts were rescheduled for payment beginning in the second quarter of 2017. Any such deferred repayments will remain subject to continued

application of the quarterly ceiling in amounts due established by the calculated threshold limitation based on quarterly Vascepa net revenues. No additional interest expense or liability is incurred as a result of such deferred repayments. These estimates are reevaluated each reporting period by the Company and adjusted if necessary, prospectively.

The Company determined the redemption feature upon a change of control to be an embedded derivative requiring bifurcation. The fair value of the embedded derivative was calculated by determining the fair value of the debt with the change in control provision included and also without the change in control provision. The difference between the two fair values of the debt was determined to be the fair value of the embedded derivative, and upon closing the Company recorded a derivative liability of $14.6 million as a reduction to the note payable. The fair value of this derivative liability is remeasured at each reporting period, with changes in fair value recognized in the condensed consolidated statement of operations and any changes in the assumptions used in measuring the fair value of the derivative liability could result in a material increase or decrease in its carrying value. Based on current assumptions underlying the valuation, the Company recognized no gain or loss on change in fair value of derivative liability during the nine months ended September 30, 2018 and 2017.

As of September 30, 2018 and December 31, 2017, the carrying value of the royalty-bearing instrument, net of the unamortized debt discount and issuance costs, was $83.4 million and $92.4 million, respectively. During the nine months ended September 30, 2018, the Company recorded cash and non-cash interest expense of $4.3 million and $1.5 million, respectively, in connection with the royalty-bearing instrument. During the nine months ended September 30, 2017, the Company recorded $4.8 million and $1.6 million of cash and non-cash interest expense, respectively, in connection with the royalty-bearing instrument. The Company will periodically evaluate the remaining term of the agreement and the effective interest rate is recalculated each period based on the Company's most current estimate of repayment.

To secure the obligations under the agreement, the Company granted BioPharma, which it subsequently assigned to CPPIB, a security interest in the Company's patents, trademarks, trade names, domain names, copyrights, know-how and regulatory approvals related to the covered products, all books and records relating to the foregoing and all proceeds of the foregoing, referred to collectively as the collateral. If the Company (i) fails to deliver a payment when due and does not remedy that failure within a specific notice period, (ii) fails to maintain a first-priority perfected security interest in the collateral in the United States and does not remedy that failure after receiving notice of such failure or (iii) becomes subject to an event of bankruptcy, then CPPIB may attempt to collect the maximum amount payable by the Company under this agreement (after deducting any payments the Company has already made).

Under the agreement, the Company is restricted from paying dividends on its common shares, unless it has cash and cash equivalents in excess of a specified amount after such payment.

January 2012, May 2014, and November 2015 Exchangeable Senior Notes

In 2012, 2014 and 2015, the Company and its subsidiaries entered into a series of transactions pertaining to exchangeable notes. In January 2017, holders of the 3.5% exchangeable senior notes due 2032 (the "2012 Notes") exercised their option to put approximately

$15.0 million in aggregate principal amount of 2012 Notes to the Company for cash and, in March 2017, the Company redeemed the entirety of the remaining $0.1 million in aggregate principal amount of 2012 Notes, such that no 2012 Notes remained outstanding as of September 30, 2017. The carrying value of the related conversion option will remain in equity hereafter as a result of the repayment in full of the related debt instrument. As of September 30, 2018 and December 31, 2017, all debt issued in these transactions was exchanged or redeemed such that none remained outstanding.

January 2017 Exchangeable Senior Notes

On January 20, 2017, the Company and Corsicanto II DAC ("Corsicanto II"), a designated activity company formed under the laws of Ireland and a wholly owned subsidiary of the Company, entered into separate, privately negotiated purchase agreements with certain investors pursuant to which Corsicanto II issued and sold $30.0 million in aggregate principal amount of 3.5% exchangeable senior notes due 2047 (the "2017 Notes") at an issue price of 100%. The net proceeds from the offering were $28.8 million after deducting placement agent fees and offering expenses payable by the Company. The offering of the 2017 Notes closed on January 25, 2017. Corsicanto II has no assets, operations, revenues or cash flows other than those related to the issuance, administration and repayment of the 2017 Notes. On October 19, 2018, the Company announced that it exercised its option to mandatorily exchange the entirety of the 2017 Notes into ADSs upon satisfaction of the specified equity conditions as described below. When completed on November 2, 2018, the mandatory exchange will result in extinguishment of the debt and issuance of an aggregate amount of 7,716,048 ADSs, subject to certain adjustments as provided in the 2017 Notes, such that the Company will have no outstanding debt or related interest obligations.

The 2017 Notes were issued pursuant to an Indenture (the "Indenture") entered into by the Company, Corsicanto II and Wilmington Trust, National Association, as trustee (the "Trustee"). The 2017 Notes are the senior unsecured obligations

of Corsicanto II and are guaranteed by the Company. The 2017 Notes bear interest at a rate of 3.5% per annum from, and including, January 25, 2017, payable semi-annually in arrears on January 15 and July 15 of each year, beginning on July 15, 2017 and ending upon the 2017 Notes' maturity date of January 15, 2047, unless earlier repurchased, redeemed or exchanged.

At any time after the issuance of the 2017 Notes and prior to the close of business on the second business day immediately preceding January 15, 2047, holders may exchange their 2017 Notes for ADSs at their option and at the exchange rate described below. If prior to January 19, 2021, a make-whole fundamental change (as defined in the Indenture) occurs and a holder elects to exchange its 2017 Notes in connection with such make-whole fundamental change, such holder may be entitled to an increase in the exchange rate as described in the Indenture.

The initial exchange rate is 257.2016 ADSs per $1,000 principal amount of the 2017 Notes (equivalent to an initial exchange price of approximately $3.89 per ADS (the "Exchange Price")), subject to adjustment in certain circumstances. The initial exchange price for the 2017 Notes represents a premium of approximately 35% over the last reported sale price of $2.88 per share of the Company's ADSs on The NASDAQ Global Market on January 19, 2017. Upon exchange, the 2017 Notes are to be settled in ADSs. The exchange rate is subject to adjustment from time to time upon the occurrence of certain events, including, but not limited to, the payment of cash dividends. In the event of physical settlement, the 2017 Notes would be exchangeable into a total of 7,716,048 ADSs, subject to certain adjustments as provided in the Indenture. Based on the closing price of the Company's stock as of September 30, 2018, the value of the shares if converted on that date would exceed the principal amount of the 2017 Notes by $95.5 million.

Prior to January 19, 2021, Corsicanto II may not redeem the 2017 Notes at its option other than in connection with certain changes in the tax law of a relevant taxing jurisdiction that results in additional amounts (as defined in the Indenture) becoming due with respect to payments and/or deliveries on the 2017 Notes. On or after January 19, 2021, Corsicanto II may redeem for cash all or a portion of the 2017 Notes at a redemption price of 100% of the aggregate principal amount of the 2017 Notes to be redeemed, plus accrued and unpaid interest to, but not including, the redemption date. If a Fundamental Change (as defined in the Indenture) occurs, holders may require Corsicanto II to repurchase all or part of their 2017 Notes for cash at a Fundamental Change repurchase price equal to 100% of the aggregate principal amount of the 2017 Notes to be repurchased, plus accrued and unpaid interest to, but not including, the Fundamental Change repurchase date. In addition, holders of the 2017 Notes may require Corsicanto II to repurchase all or any portion of the 2017 Notes on January 19, 2022 for cash at a price equal to 100% of the aggregate principal amount of the 2017 Notes to be repurchased, plus accrued and unpaid interest to, but not including, the repurchase date.

Corsicanto II may elect at its option to cause all or any portion of the 2017 Notes to be mandatorily exchanged in whole or in part at any time prior to the close of business on the business day preceding January 15, 2047 if the Daily VWAP (as defined in the Indenture) equals or exceeds 130% of the Exchange Price then in effect (which quotient equals approximately $5.05 on the date hereof) for at least 20 VWAP Trading Days (as defined in the Indenture) in any 30 consecutive VWAP Trading Day period. Corsicanto II may only exercise its optional exchange rights upon satisfaction of specified equity conditions, including that the ADSs issuable upon exchange of the 2017 Notes be eligible for resale without registration by non-affiliates and listed on The NASDAQ Global Market, its related exchanges or the New York Stock Exchange. If Corsicanto II elects to exercise its optional exchange rights on or prior to January 19, 2021, each holder whose 2017 Notes are exchanged may upon exchange receive a specified number of additional ADSs as set forth in the Indenture.

The Indenture contains customary terms and covenants and events of default. If an event of default (other than certain events of bankruptcy, insolvency or reorganization involving Corsicanto II) occurs and is continuing, the Trustee by notice to Corsicanto II, or the holders of at least 25% in principal amount of the outstanding 2017 Notes by notice to Corsicanto II and the Trustee, may declare 100% of the principal of and accrued and unpaid interest, if any, on all of the 2017 Notes to be due and payable. Upon such a declaration of acceleration, such principal and accrued and unpaid interest, if any, will be due and payable immediately. Upon the occurrence of certain events of bankruptcy, insolvency or reorganization involving Corsicanto II, 100% of the principal of and accrued and unpaid interest, if any, on all of the 2017 Notes will become due and payable automatically. Notwithstanding the foregoing, the Indenture will provide that, to the extent Corsicanto II elects and for up to 360 days, the sole remedy for an event of default relating to certain failures by Corsicanto II or the Company, as the case may be, to comply with certain reporting covenants in the

Indenture consists exclusively of the right to receive additional interest on the 2017 Notes.

Corsicanto II agreed to use commercially reasonable efforts to procure the listing of the 2017 Notes on the Global Exchange Market operated under the supervision of the Irish Stock Exchange (or on another recognized stock exchange for the purposes of Section 64 of the Taxes Consolidation Act 1997 of Ireland and within the meaning of Section 1005 ITA 2007 of the United Kingdom) prior to July 15, 2017, which was the first interest payment date for the 2017 Notes.

The 2017 Notes were recorded at par of $30.0 million. In addition, the Company recorded a discount of $1.2 million in placement agent fees and offering expenses. Such costs are presented as a direct deduction from the debt liability on the condensed consolidated balance sheets. This discount is being amortized as interest expense over the estimated life of the 2017 Notes, through the first optional put date in January 2022. As of September 30, 2018 and December 31, 2017, the carrying value of the 2017 Notes, net of unamortized discount, was $29.2 million and $29.0 million, respectively.

Because the conversion option in the 2017 Notes receives an exception from derivative accounting and only requires gross physical settlement in shares, the embedded option does not require separate accounting and is therefore accounted for as part of the debt host

at amortized cost. In addition, the Company determined that the fundamental change redemption feature is clearly and closely related to the debt host in accordance with ASC 815-15 and therefore does not require bifurcation.

During the nine months ended September 30, 2018, the Company recognized interest expense of $1.0 million related to the 2017 Notes, of which $0.2 million represents non-cash interest and $0.8 million represents contractual coupon interest. During the nine months ended September 30, 2017, the Company recognized interest expense of $0.9 million related to the 2017 Notes, of which $0.1 million represents non-cash interest and $0.7 million represents contractual coupon interest. As of both September 30, 2018 and December 31, 2017, the Company had accrued interest of $0.2 million related to the 2017 Notes, which is presented as current portion of exchangeable senior notes, net of discount, on the condensed consolidated balance sheets. The Company made the contractual interest payments due on the 2017 Notes during the nine months ended September 30, 2018 and 2017 of $1.1 million and $0.5 million, respectively.

(6) Commitments and Contingencies

Litigation

In the ordinary course of business, the Company is from time to time involved in lawsuits, claims, investigations, proceedings, and threats of litigation relating to intellectual property, commercial arrangements and other matters. “Item 3. Legal Proceedings” of the Company’s Annual Report on Form 10-K for the fiscal year ended December 31, 2017 and “Item 1. Legal Proceedings” of the Company’s Quarterly Report on Form 10-Q for the quarters ended March 31, 2018 and June 30, 2018 include discussions of the Company’s current legal proceedings. There have been no material changes to the matters described in those disclosures as of the date of this filing.

Milestone and Supply Purchase Obligations

The Company entered into long-term supply agreements with multiple FDA-approved API suppliers and encapsulators. Certain supply agreements require annual minimum volume commitments by the Company and certain volume shortfalls may require payments for such shortfalls, as detailed below.

The Company entered into its initial Vascepa API supply agreement with Nisshin Pharma, Inc. (“Nisshin”) in 2010. In 2011, the Company entered into agreements with two additional suppliers, Chemport, Inc. (“Chemport”) and BASF (formerly Equateq Limited), for the supply of API. In 2012, the Company agreed to terms with a fourth API supplier, a consortium of companies led by Slanmhor Pharmaceutical, Inc. (“Slanmhor”). The API supply agreement with BASF terminated in February 2014. In July 2014, the Company terminated the supply agreement with Slanmhor and subsequently, in June 2015, entered into a new supply agreement with Finorga SAS (“Novasep”). These agreements included requirements for the suppliers to meet certain product specifications and qualify their materials and facilities with applicable regulatory authorities including the FDA. The Company has incurred certain costs associated with the qualification of product produced by these suppliers as described below.

Nisshin, Chemport and Novasep are currently the three manufacturers from which the Company purchases API. As of September 30, 2018, the Company has no royalty, milestone or minimum purchase commitments with Nisshin. In the ordinary course, pursuant to the results of the REDUCE-IT study, the Company is increasing its orders for API from these manufacturers while taking steps to help qualify at least one additional potential API manufacturer.

Chemport was approved by the FDA to manufacture API for commercial sale in April 2013 and the Company began purchasing commercial supply from Chemport in 2013. The agreement with Chemport contains a provision requiring the Company to pay Chemport in cash for any shortfall in the minimum purchase obligations. The Company began purchasing commercial supply from Novasep in 2015. API manufactured by Novasep was previously approved by the FDA in July 2014. The 2015 supply agreement with Novasep contains a provision requiring the Company to pay Novasep a certain cash remedy for any shortfall in the minimum purchase obligations. The Company continues to meet its contractual purchase obligations.

Under the 2004 share repurchase agreement with Laxdale Limited ("Laxdale"), upon receipt of marketing approval in Europe for the first indication for Vascepa (or first indication of any product containing Amarin Neuroscience Limited intellectual property acquired from Laxdale in 2004), the Company must make an aggregate stock or cash payment to the former shareholders of Laxdale (at the sole option of each of the sellers) of £7.5 million (approximately $9.8 million as of September 30, 2018). Also under the Laxdale agreement, upon receipt of a marketing approval in the United States or Europe for a further indication of Vascepa (or further indication of any other product using Amarin Neuroscience Limited intellectual property), the Company must make an aggregate stock or cash payment (at the sole option of each of the sellers) of £5 million (approximately $6.5 million as of September 30, 2018) for each of the two potential market approvals (i.e. £10 million maximum, or approximately $13.0 million as of September 30, 2018).

The Company has no provision for any of the obligations above since the amounts are either not probable or able to be estimated as of September 30, 2018.

(7) Equity

Preferred Stock

On March 5, 2015, the Company entered into a subscription agreement with four institutional investors (the "Purchasers"), including both existing and new investors, for the private placement of 352,150,790 restricted American Depositary Shares, each representing one (1) share of Amarin's Series A Convertible Preference Shares, par value £0.05 per share, in the capital of the Company ("Series A Preference Shares"), resulting in gross proceeds to the Company of $52.8 million. The closing of the private placement occurred on March 30, 2015.

For each restricted American Depositary Share, the Purchasers paid a negotiated price of $0.15 (equating to $1.50 on an as-if-converted-to-ordinary-shares basis), resulting in $52.8 million in aggregate gross proceeds to the Company, before deducting estimated offering expenses of approximately $0.7 million. The net proceeds are reflected as preferred stock in the accompanying condensed consolidated balance sheets.

Each ten (10) Series A Preference Shares may be consolidated and redesignated as one (1) ordinary share, par value £0.50 per share, in the capital of the Company, each ordinary share to be represented by American Depositary Shares ("ADSs"), provided that consolidation will be prohibited if, as a result, the holder of such Series A Preference Shares and its affiliates would beneficially own more than 4.99% of the total number of Amarin ordinary shares or ADSs outstanding following such redesignation (the "Beneficial Ownership Limitation"). By written notice to the Company, a holder may from time to time increase or decrease the Beneficial Ownership Limitation to any other percentage not in excess of 19.9% specified in such notice; provided that any such increase will not be effective until the sixty-first (61st) day after such notice is delivered to the Company. This consolidation and redesignation may be effected by a holder of Series A Preference Shares following the first to occur of the resale of the ADSs representing the ordinary shares being registered for resale under the Securities Act pursuant to an effective registration statement, following any sale of the ADSs representing the ordinary shares pursuant to Rule 144 under the Securities Act, or if such ADSs representing the ordinary shares are eligible for sale under Rule 144, following the expiration of the one-year holding requirement under Rule 144. During the year ended December 31, 2015, at the request of the holders, a portion of the Series A Preference Shares were consolidated and redesignated, resulting in the issuance of 6,283,333 ADSs.

Except as otherwise provided in the Series A Preference Share Terms or as required by applicable law, the Series A Preference Shares have no voting rights. However, as long as any Series A Preference Shares are outstanding, the Company cannot, without the approval of the holders of seventy-five percent (75%) of the then outstanding Series A Preference Shares, alter or change adversely the powers, preferences or rights attaching to the Series A Preference Shares or enter into any agreement with respect to the foregoing.

Holders of the Series A Preference Shares are entitled to receive, and the Company is required to pay, dividends (other than dividends in the form of ordinary shares) on the Series A Preference Shares equal (on an as-if-converted-to-ordinary-shares basis) to and in the same form as dividends (other than dividends in the form of ordinary shares) actually paid on ordinary shares when, as and if such dividends (other than dividends in the form of ordinary shares) are paid on the ordinary shares.

The restricted American Depositary Shares and Series A Preference Shares were sold in a transaction exempt from the registration requirements under the Securities Act of 1933, as amended (the "Securities Act"). The Company filed a registration statement with the SEC covering the resale of the restricted American Depositary Shares and the ADSs representing ordinary shares created by the consolidation and redesignation of the Series A Preference Shares (the "Registrable Securities") on April 9, 2015, which was declared effective by the SEC on May 1, 2015. In addition, the Company agreed to use its commercially reasonable best efforts to keep the registration, and any qualification, exemption or compliance under state securities laws which the Company determines to obtain, continuously effective, and to keep the Registration Statement free of any material misstatements or omissions, until the earlier of (a) March 11, 2017 or (b) the date on which all Registrable Securities held by Purchasers may be sold or transferred in compliance with Rule 144 under the Securities Act, without any volume or manner of sale restrictions.

The Series A Preference Shares contain a contingent beneficial conversion feature ("BCF") because they contain a conversion feature at a fixed rate that was in-the-money when issued. The BCF was recorded in the three months ended June 30, 2015 as a result of the related Form S-3 Registration Statement being declared effective, which represents the resolution of the contingency to convert the Series A Preference Shares. The BCF was recognized in stockholders' deficit and was measured by allocating a portion of the proceeds equal to the intrinsic value of that feature to additional paid-in capital. The effective purchase price of the ordinary shares into which the preferred shares are convertible was $1.50, which was used to compute the intrinsic value. The intrinsic value was calculated as the difference between the effective purchase price of the ordinary shares and the market value ($2.39 per share) on the date the preferred shares were issued, multiplied by the number of shares into which the preferred shares are convertible. The BCF resulting from the issuance of the Series A Preference Shares was determined to be $31.3 million. The BCF was recorded as a non-cash dividend to preferred shareholders through accumulated deficit, and was therefore reflected as an adjustment to net loss applicable to common shareholders for earnings per common share purposes in accordance with GAAP for the year ended December 31, 2015.

On March 30, 2015, in connection with the closing of the private placement, and pursuant to a pre-existing contractual right to participate in certain private placement transactions effected by the Company, the Company entered into a separate subscription

agreement with an existing investor, Sofinnova Venture Partners VII L.P. (Sofinnova), for the purchase of an additional $5.8 million of restricted American Depositary Shares, each representing one (1) share of the Company's Series A Preference Shares, at the same price per share and otherwise on substantially the same terms as the initial private placement (the "Second Private Placement"). In accordance with applicable marketplace rules of the NASDAQ Stock Market, the consummation of the Second Private Placement was conditioned upon approval by the Company's shareholders at a future meeting of the Company's shareholders. Such approval was received at the Company's Annual General Meeting of Shareholders on July 6, 2015 and as a result, the closing of the Second Private Placement occurred on July 10, 2015. The Company issued 38,867,180 restricted ADSs, each representing one Series A Preference Share, which could be consolidated and redesignated from time to time up to a maximum of 3,886,718 ordinary shares, each ordinary share to be represented by one ADS. For each restricted ADS, Sofinnova paid a negotiated price of $0.15 (equating to $1.50 on an as-if-converted-to-ordinary-shares basis) resulting in gross proceeds to the Company of $5.8 million. At the time of the transaction, Dr. James Healy was a member of the Company's Board and a managing general partner of Sofinnova Management VII, L.L.C., which is the general partner of Sofinnova. Dr. James Healy resigned as Director of the Company's Board effective December 20, 2016.

The Company filed another registration statement with the SEC covering the resale of these restricted American Depositary Shares and the ADSs representing ordinary shares created by the consolidation and redesignation of the Series A Preference Shares (the "Sofinnova Registrable Securities") on July 24, 2015, which was declared effective by the SEC on August 7, 2015. In addition, the Company agreed to use its commercially reasonable best efforts to keep the registration, and any qualification, exemption or compliance under state securities laws which the Company determines to obtain, continuously effective, and to keep the registration statement free of any material misstatements or omissions, until the earlier of (a) July 10, 2017 or (b) the date on which all Sofinnova Registrable Securities held by Sofinnova may be sold or transferred in compliance with Rule 144 under the Securities Act, without any volume or manner of sale restrictions.

The existence of this preferred stock purchase option was determined to be a derivative liability effective March 5, 2015, the date on which the private placement was initially subscribed. The fair value of this liability was calculated using a Black-Scholes model and was determined to be $0.9 million at inception and was charged to accumulated deficit as a deemed non-cash dividend to Sofinnova. The liability was then marked to fair value as of March 30, 2015, the date on which the Company executed a subscription agreement with Sofinnova, resulting in a charge of $0.9 million through gain (loss) on change in fair value of derivatives. The liability of $1.8 million was reclassified to permanent equity (additional paid-in capital) on such date. Subsequent to approval of the Second Private Placement at the Company's Annual General Meeting of Shareholders in July 2015, the Company recorded the remaining value of the BCF related to this share issuance as a non-cash dividend to preferred shareholders through accumulated deficit. The value of the BCF was determined on the same basis as the first private placement and amounted to $3.4 million less $1.8 million previously recorded for the preferred stock purchase option for a net non-cash charge of $1.6 million in the year ended December 31, 2015.

During the three months ended September 30, 2018, the Company issued 3,886,718 ADSs upon consolidation and redesignation of Series A Preference Shares at the request of the holder, such that a maximum of 28,931,746 ordinary shares remain issuable upon future consolidation and redesignation of the remaining Series A Preference Shares as of September 30, 2018, subject to certain adjustments for dilutive events.

Common Stock

On February 1, 2018, the Company completed a public offering of 19,178,082 ADSs, with each ADS representing one ordinary share of the Company. The Company also granted the underwriters a 30-day option to purchase an additional 2,876,712 ADSs, which was partially exercised on March 5, 2018 for issuance of 1,438,356 ADSs. The underwriters purchased the ADSs from the Company at a price of $3.41 per ADS after commission, resulting in net proceeds to the Company of approximately $70.0 million, after deducting estimated offering expenses payable by the Company. The stated uses of net proceeds in connection with this offering were as follows: to expand medical education and market

awareness initiatives, including, in advance of REDUCE-IT results being known, pilot testing of new promotional initiatives for potential broader application following REDUCE-IT results, to increase its inventory balances for incremental inventory build prior to REDUCE-IT results and for general corporate and working capital purposes.

Incentive Equity Awards

As of September 30, 2018, there were an aggregate of 21,036,913 stock options and 9,634,188 restricted stock units ("RSUs") outstanding, representing approximately 6% and 3%, respectively, of outstanding shares (including common and preferred shares) on a fully diluted basis.

During the nine months ended September 30, 2018 and 2017, the Company issued 5,439,239 and 259,195 shares, respectively, as a result of the exercise of stock options, resulting in gross and net proceeds of $16.5 million during the nine months ended September 30, 2018 and $0.5 million during the nine months ended September 30, 2017. The Company recorded a receivable of $23.2 million in other receivables on the condensed consolidated balance sheet as of September 30, 2018 representing the cost of shares plus taxes withheld due from financial institutions resulting from the timing of stock option exercises in late September 2018, which amounts were collected in early October 2018.

In September 2018, in connection with positive REDUCE-IT results, the Company issued 2,499,750 shares upon vesting of performance-based RSUs granted in 2015, of which 764,819 shares were retained as treasury shares as settlement of employee tax obligations.

On May 14, 2018, the Company granted a total of 190,034 RSUs and 286,536 stock options to members of the Company's Board of Directors under the Amarin Corporation plc Stock Incentive Plan (the "2011 Plan"). The RSUs vest in equal installments over a three-year period upon the earlier of the anniversary of the grant date or the Company's annual general meeting of shareholders in such anniversary year. The stock options vest in full upon the earlier of the one-year anniversary of the grant date or the Company's annual general meeting of shareholders in such anniversary year. Upon termination of service to the Company or upon a change of control, each Director shall be entitled to a payment equal to the fair market value of one share of Amarin common stock per award vested or granted, respectively, which is required to be made in shares.

On February 1, 2018, the Company granted a total of 1,305,575 RSUs and 2,205,075 stock options to employees under the 2011 Plan. The RSUs vest annually over a three-year period and the stock options vest monthly over a four-year period.

On May 15, 2017, the Company granted a total of 91,504 RSUs and 131,575 stock options to members of the Company's Board of Directors under the 2011 Plan. The RSUs vest in equal installments over a three-year period upon the earlier of the anniversary of the grant date or the Company's annual general meeting of shareholders in such anniversary year. The stock options vest in full upon the earlier of the one-year anniversary of the grant date or the Company's annual general meeting of shareholders in such anniversary year. Upon termination of service to the Company or upon a change of control, each Director shall be entitled to a payment equal to the fair market value of one share of Amarin common stock per award vested or granted, respectively, which is required to be made in shares.

On May 15, 2017, October 2, 2017, and March 12, 2018, the Company granted a total of 2,310,000 RSUs, 220,000 RSUs, and 970,000 RSUs, respectively, to employees under the 2011 Plan that vest over three years commencing after REDUCE-IT results upon the achievement of certain regulatory and sales performance conditions associated with the REDUCE-IT clinical trial and subsequent revenue growth.

On February 1, 2017, the Company granted a total of 1,575,000 RSUs and 2,642,500 stock options to employees under the 2011 Plan. The RSUs vest annually over a three-year period and the stock options vest over a four-year period. During the nine months ended September 30, 2018, the Company issued 506,679 common shares related to the vesting of these RSUs, of which 183,828 shares were retained as treasury shares as settlement of employee tax obligations.

(8) Co-Promotion Agreement

On March 31, 2014, the Company entered into a Co-Promotion Agreement (the "Agreement") with Kowa Pharmaceuticals America, Inc. related to the commercialization of Vascepa® (icosapent ethyl) capsules in the United States. Under the terms of the Agreement, Amarin granted to Kowa Pharmaceuticals America, Inc. the right to be the sole co-promoter, together with the Company, of Vascepa in the United States during the term. The initial term of the Agreement extends until the end of 2018. The Agreement was amended on July 25, 2017 to reflect evolving promotional needs, including refinement of target lists.

During the term, Kowa Pharmaceuticals America, Inc. and Amarin have agreed to use commercially reasonable efforts to promote, detail and optimize sales of Vascepa in the United States. The performance requirements include a negotiated minimum number of details to be delivered by each party in the first and second position, and the use of a negotiated number of minimum sales representatives from each party. Kowa Pharmaceuticals America, Inc. has agreed to bear the costs incurred for its sales force associated with the commercialization of Vascepa and to pay for certain incremental costs associated with the use of its sales force, such as sample costs and costs for promotional and marketing materials. Amarin will continue to recognize all revenue from sales of Vascepa and will use commercially

reasonable efforts to maintain a minimum amount of inventory of Vascepa for use in the United States.

In exchange for Kowa Pharmaceuticals America, Inc.'s co-promotional services, Kowa Pharmaceuticals America, Inc. is entitled to a quarterly co-promotion fee based on aggregate Vascepa gross margin that varies during the term. The percentage of aggregate Vascepa gross margin earned by Kowa Pharmaceuticals America, Inc. was, as amended, approximately eighteen percent (18%) in 2017, partially offset by certain other refinements. During 2018, which is the last year of the Agreement, as amended, the Company is incurring expense for both the annual co-promotion fee, which in 2018 is calculated as eighteen-and-a-half percent (18.5%) of Vascepa gross margin, plus accrual for co-promotion tail payments which are calculated as a percentage of the 2018 co-promotion fee. Assuming Kowa Pharmaceuticals America, Inc. fulfills its obligations in accordance with the terms of the Agreement, as amended, after expiration of the Agreement, Kowa Pharmaceuticals America, Inc. is eligible to receive up to three years of co-promotion tail payments equal to declining percentages of the co-promotion fee amount earned in the final year of the Agreement with the sum of the three years of co-promotion tail payments totaling less than the co-promotion fee amount earned in the final year of the agreement.

This co-promotion tail payment obligation is being accrued by the Company in 2018. As of September 30, 2018 and December 31, 2017, the Company accrued $10.8 million and nil, respectively, related to such co-promotion tail payments.

As of September 30, 2018 and December 31, 2017, the Company had a net payable of $18.0 million and $8.3 million, respectively, to Kowa Pharmaceuticals America, Inc. representing co-promotion fees, net of reimbursable amounts incurred for samples and other marketing expenses, and accrual for co-promotion tail payments payable to Kowa Pharmaceuticals America, Inc.

(9) Revenue Recognition

The Company sells Vascepa principally to a limited number of major wholesalers, as well as selected regional wholesalers and specialty pharmacy providers in the United States, 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 addition to distribution agreements with Distributors, the Company enters into arrangements with health care providers and payors that provide for government-mandated and/or privately-negotiated rebates, chargebacks and discounts with respect to the purchase of the Company's product.

Revenues from product sales are recognized when the Distributor obtains control of the Company's product, which occurs at a point in time, typically upon delivery to the Distributor. Payments from Distributors are generally received 30-60 days from date of sale. 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. The Company calculates gross product revenues generally based on the wholesale acquisition cost that the Company charges its Distributors for Vascepa.

Reserves for Variable Consideration

Revenues from product sales are recorded at the net sales price (transaction price), which includes estimates of variable consideration for which reserves are established and which result from (a) trade allowances, such as invoice discounts for prompt pay and distributor fees, (b) estimated government and private payor rebates and chargebacks and discounts, such as Medicaid reimbursements, (c) reserves for expected product returns and (d) estimated costs of incentives that are offered within contracts between the Company and its Distributors, health care providers, payors and other indirect customers relating to the Company's sales of its product. These reserves are based on the amounts earned or to be claimed on the related sales and are classified as reductions of accounts receivable (if the amount is payable to the Distributor) or as a current liability (if the amount is payable to a party other than a Distributor). Where appropriate, these estimates take into consideration a range of possible outcomes which are probability-weighted for relevant factors such as the Company's historical experience, current contractual and statutory requirements, specific known market events and trends, industry data and forecasted customer buying and payment patterns. Overall, these reserves reflect the Company's best estimates of the amount of consideration to which it is entitled based on the terms of the contract. The amount of variable consideration which is included in the transaction price may be constrained, and is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. Actual amounts of consideration ultimately received may differ from the Company's estimates. If actual results in the future vary from the Company's estimates, the Company adjusts these estimates, which would affect net product revenue and earnings in the period such variances become known.

Trade Allowances: The Company generally provides invoice discounts on Vascepa sales to its Distributors for prompt payment and 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 historical data,

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, Medicare, 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 these reserves based upon a range of possible outcomes that are probability-weighted for the estimated payor mix. These reserves are recorded in the same period the revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability, which is included in accrued expenses and other current liabilities on the condensed consolidated balance sheets. For Medicare, the Company also estimates the number of patients in the prescription drug coverage gap for whom the Company will owe an additional liability under the Medicare Part D program. 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. The Company's liability for these rebates consists of invoices received for claims from prior quarters that have not been paid or for which an invoice has not yet been received, estimates of claims for the current quarter, and estimated future claims that will be made for product that has been recognized as revenue, but remains in the distribution channel inventories at the end of each reporting period.

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 1-gram and 0.5-gram size capsules is currently four years and three years, respectively, after being 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. These reserves are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability which is included in accrued expenses and other current liabilities on the condensed consolidated balance sheets.

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. These reserves are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability which is included in accrued expenses and other current liabilities on the condensed consolidated balance sheets. 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 nine months ended September 30, 2018 and 2017:

In thousands	Trade Allowances	Rebates, Chargebacks and Discounts	Product Returns	Other Incentives	Total
Balance as of December 31, 2017	$ 12,035	$ 32,064	$ 1,887	$ 2,107	$ 48,093
Provision related to current period sales	30,814	128,905	812	14,636	175,167
Provision related to prior period sales	(660)	(836)	—	(69)	(1,565)
Credits/payments made for current period sales	(15,908)	(76,015)	—	(15,038)	(106,961)
Credits/payments made for prior period sales	(11,657)	(29,594)	(69)	(2,297)	(43,617)
Balance as of September 30, 2018	$ 14,624	$ 54,524	$ 2,630	$ (661)	$ 71,117

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	24,780	87,499	1,496	10,796	124,571
Provision related to prior period sales	(297)	(841)	—	(82)	(1,220)
Credits/payments made for current period sales	(11,061)	(62,014)	(391)	(8,834)	(82,300)
Credits/payments made for prior period sales	(3,107)	(16,722)	(24)	(1,770)	(21,623)
Balance as of September 30, 2017	$ 14,058	$ 28,837	$ 1,940	$ 1,791	$ 46,626

Licensing Revenue

The Company enters into licensing agreements which are within the scope of Topic 606, Revenue from Contracts with Customers, under which it licenses certain rights to Vascepa for uses that are currently commercialized and under development by the Company. The terms of these arrangements typically include payment to the Company of one or more of the following: non-

refundable, up-front license fees; development, regulatory and commercial milestone payments; payments for manufacturing supply services the Company provides through its contract manufacturers; and royalties on net sales of licensed products. Each of these payments results in licensing revenues.

In determining the appropriate amount of revenue to be recognized as it fulfills its obligations under each of its agreements, the Company performs the following steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation.

In determining performance obligations, management evaluates whether the license is distinct from the other performance obligations with the collaborative partner based on the consideration of the relevant facts and circumstances for each arrangement. Factors considered in the determination of 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.

Licenses of intellectual property: If the license to the Company’s intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenues from non-refundable, up-front fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. For licenses that are bundled with other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front fees. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

Milestone Payments: At the inception of each arrangement that includes development, regulatory and commercial milestone payments, the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the control of the Company or licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. The Company evaluates factors such as the scientific, clinical, regulatory, commercial and other risks that must be overcome to achieve the respective milestone as well as the level of effort and investment required. The transaction price is then allocated to each performance obligation on a relative stand-alone selling price basis, for which the Company recognizes revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, the Company re-evaluates the probability of achievement of such development, regulatory and commercial milestones and any related constraint, and if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect licensing revenues and earnings in the period of adjustment.

The Company receives payments from its customers based on billing schedules established in each contract. Up-front payments and fees are recorded as deferred revenue upon receipt or when due, and may require deferral of revenue recognition to a future period until the Company performs its obligations under these arrangements. Amounts are recorded as accounts receivable when the Company’s right to consideration is unconditional. The Company does not assess whether a contract has a significant financing component if the expectation at contract inception is such that the

period between payment by the customer and the transfer of the promised goods or services to the customer will be one year or less.

(10) Development, Commercialization and Supply Agreements
In-licenses

Mochida Pharmaceutical Co., Ltd.

In June 2018, the Company entered into a collaboration with Mochida Pharmaceutical Co., Ltd. (“Mochida”) related to the development and commercialization of drug products and indications based on the active pharmaceutical ingredient in Vascepa, the omega-3 acid, EPA (eicosapentaenoic acid). Among other terms in the agreement, the Company obtained an exclusive license to certain Mochida intellectual property to advance the Company’s interests in the United States and certain other territories and the parties will collaborate to research and develop new products and indications based on EPA for the Company’s commercialization in the United States and certain other territories. The potential new product and indication opportunities contemplated under this agreement are currently in early stages of development.

Upon closing of the collaboration agreement, the Company made a non-refundable, non-creditable upfront payment of approximately $2.7 million, which was recorded in research and development expense in the condensed consolidated statement of operations for the nine months ended September 30, 2018. In addition, the agreement provides for the Company to pay milestone payments upon the

achievement of certain product development milestones and royalties on net sales of future products arising from the collaboration, if any.

Out-licenses

Eddingpharm (Asia) Macao Commercial Offshore Limited

In February 2015, the Company entered into a Development, Commercialization and Supply Agreement (the "DCS Agreement") with Eddingpharm (Asia) Macao Commercial Offshore Limited ("Eddingpharm") related to the development and commercialization of Vascepa in Mainland China, Hong Kong, Macau and Taiwan, or the "China Territory." Under the terms of the DCS Agreement, the Company granted to Eddingpharm an exclusive (including as to the Company) license with right to sublicense to develop and commercialize Vascepa in the China Territory for uses that are currently commercialized and under development by the Company based on the Company's MARINE, ANCHOR and REDUCE-IT clinical trials of Vascepa.

Under the DCS Agreement, Eddingpharm is solely responsible for development and commercialization activities in the China Territory and associated expenses. The Company provides development assistance and is responsible for supplying finished and later bulk drug product at defined prices under negotiated terms. The Company retains all Vascepa manufacturing rights. Eddingpharm agreed to certain restrictions regarding the commercialization of competitive products globally and the Company agreed to certain restrictions regarding the commercialization of competitive products in the China Territory.

The Company and Eddingpharm agreed to form a joint development committee to oversee regulatory and development activities for Vascepa in the China Territory in accordance with a negotiated development plan and to form a separate joint commercialization committee to oversee Vascepa commercialization activities in the China Territory. Development costs are paid by Eddingpharm to the extent such costs are incurred in connection with the negotiated development plan or otherwise incurred by Eddingpharm. Eddingpharm is responsible for preparing and filing regulatory applications in all countries of the China Territory at Eddingpharm's cost with the Company's assistance. The DCS Agreement also contains customary provisions regarding indemnification, supply, record keeping, audit rights, reporting obligations, and representations and warranties that are customary for an arrangement of this type.

The term of the DCS Agreement expires, on a product-by-product basis, upon the later of (i) the date on which such product is no longer covered by a valid claim under a licensed patent in the China Territory, or (ii) the twelfth (12th) anniversary of the first commercial sale of such product in Mainland China. The DCS Agreement may be terminated by either party in the event of a bankruptcy of the other party and for material breach, subject to customary cure periods. In addition, at any time following the third anniversary of the first commercial sale of a product in Mainland China, Eddingpharm has the right to terminate the DCS Agreement for convenience with twelve months' prior notice. Neither party may assign or transfer the DCS Agreement without the prior consent of the other party, provided that the Company may assign the DCS Agreement in the event of a change of control transaction.

Upon closing of the DCS Agreement, the Company received a non-refundable $15.0 million up-front payment. In March 2016, Eddingpharm submitted its clinical trial application ("CTA") with respect to the MARINE indication for Vascepa to the Chinese regulatory authority. Following the CTA submission, the Company received a non-refundable $1.0 million milestone payment. In March 2017, the CTA was approved by the Chinese regulatory authority, and in December 2017, Eddingpharm commenced a pivotal clinical trial aimed to support the regulatory approval of the first indication of Vascepa in a patient population with severe hypertriglyceridemia in Mainland China.

In addition to the non-refundable, up-front and regulatory milestone payments described above, the Company is entitled to receive certain regulatory and sales-based milestone payments of up to an additional $153.0 million as well as tiered double-digit percentage royalties on net sales of Vascepa in the China Territory escalating to the high teens.

The regulatory milestone events relate to the submission and approval of certain applications to the applicable regulatory authority, such as a clinical trial application, clinical trial exemption, or import drug license application. The amounts to be received upon achievement of the regulatory milestone events relate to the submission and approval for three indications, and range from $2.0 million to $15.0 million for a total of $33.0 million. The sales-based milestone events occur when annual aggregate net sales of Vascepa in the territory equals or exceeds certain specified thresholds, and range from $5.0 million to $50.0 million for a total of $120.0 million. Each such milestone payment shall be payable only once regardless of how many times the sales milestone event is achieved. Each such milestone payment is non-refundable and non-creditable against any other milestone payments.

The Company assessed this arrangement in accordance with Topic 606 and concluded that the contract counterparty, Eddingpharm, is a customer. The Company identified the following performance obligations at the inception of the DCS Agreement: (1) the exclusive license to develop and commercialize Vascepa in the China Territory for uses that are currently commercialized and under development by the Company, (2) the obligation to participate in various steering committees, (3) ongoing development and

regulatory assistance, and (4) manufacture and supply of commercial product. Based on the analysis performed, the Company concluded that the identified performance obligations are not distinct and therefore a combined performance obligation.

The transaction price includes the $15.0 million up-front consideration received and the $1.0 million milestone payment received related to the successful submission of the CTA for the MARINE indication. None of the other clinical or regulatory milestones have been included in the transaction price, as all milestone amounts were fully constrained. As part of its evaluation of the constraint, the Company considered numerous factors, including that receipt of the milestones is outside the control of the Company and contingent upon success in future clinical trials and the licensee's efforts. Any consideration related to sales-based milestones (including royalties) will be recognized when the related sales occur as they were determined to relate predominantly to the license granted to Eddingpharm and therefore have also been excluded from the transaction price. The Company will re-evaluate the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur.

During the nine months ended September 30, 2018 and 2017, the Company recognized $0.1 million and $0.9 million, respectively, as licensing revenue related to the up-front and milestone payments received in connection with the Eddingpharm agreement. Through September 30, 2018 and December 31, 2017, the Company has recognized $2.8 million and $3.1 million, respectively, as licensing revenue under the DCS Agreement concurrent with the support provided by Amarin to Eddingpharm in achieving the combined performance obligation, which in the Company's judgment is the best measure of progress towards satisfying the performance obligation. The remaining transaction price of $13.2 million and $12.9 million is recorded in deferred revenue as of September 30, 2018 and December 31, 2017, respectively, on the condensed consolidated balance sheets and will be recognized as revenue over the remaining period of 16 years.

Biologix FZCo

In March 2016, the Company entered into an agreement with Biologix FZCo ("Biologix"), a company incorporated under the laws of the United Arab Emirates, to register and commercialize Vascepa in several Middle Eastern and North African countries. Under the terms of the distribution agreement, the Company granted to Biologix a non-exclusive license to use its trademarks in connection with the importation, distribution, promotion, marketing and sale of Vascepa in the Middle East and North Africa territory. Upon closing of the agreement, the Company received a non-refundable up-front payment, which will be recognized as revenue over 10 years commencing upon first marketing approval of Vascepa in the territory. The Company is entitled to receive all payments based on total product sales and pays Biologix a service fee in exchange for its services, whereby the service fee represents a percentage of gross selling price which is subject to a minimum floor price.

In March 2018 and July 2018, the Company received approval for Vascepa as a prescription medication for use in Lebanon and United Arab Emirates, respectively, as an adjunct to diet to reduce triglyceride levels in adult patients with severe hypertriglyceridemia.

HLS Therapeutics, Inc.

In September 2017, the Company entered into an agreement with HLS Therapeutics Inc. ("HLS"), a company incorporated under the laws of Canada, to register, commercialize and distribute Vascepa in Canada. Under the agreement, HLS will be responsible for regulatory and commercialization activities and associated costs. The Company is responsible for providing assistance towards local filings, supplying finished product under negotiated supply terms, maintaining intellectual property, and continuing the development and funding of REDUCE-IT-related activities.

Upon closing of the agreement, the Company received one-half of a non-refundable $5.0 million up-front payment, and received the remaining half on the six-month anniversary of the closing. Following achievement of the

REDUCE-IT trial primary endpoint, which was announced in September 2018, the Company is entitled to receive a non-refundable $2.5 million milestone payment which is recorded in other receivables on the condensed consolidated balance sheet as of September 30, 2018. In addition to the non-refundable, up-front and regulatory milestone payments just described, the Company is entitled to receive certain regulatory and sales-based milestone payments of up to an additional $57.5 million, as well as tiered double-digit royalties on net sales of Vascepa in Canada.

The Company assessed this arrangement in accordance with Topic 606 and concluded that the contract counterparty, HLS, is a customer. The Company identified the following performance obligations at the inception of the contract: (1) license to HLS to develop, register, and commercialize Vascepa in Canada, (2) support general development and regulatory activities, (3) participate in various steering committees, and (4) manufacture and provide finished form of product. Based on the analysis performed, the Company concluded that the identified performance obligations in the agreement are not distinct and therefore a combined performance obligation.

The transaction price includes the $5.0 million up-front consideration and the $2.5 million milestone related to the achievement of the REDUCE-IT trial primary endpoint. None of the other regulatory milestones have been included in the transaction price, as all of the remaining regulatory milestone amounts were fully constrained. As part of its evaluation of the constraint, the Company considered numerous factors, including that receipt of the milestones is outside the control of the Company and contingent upon the licensee's efforts. Any consideration related to sales-based milestones (including royalties) will be recognized when the related sales occur as they were determined to relate predominantly to the license granted to HLS and therefore have also been excluded from the transaction price. The Company will re-evaluate the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur.

During the nine months ended September 30, 2018 and 2017, the Company recognized $0.5 million and less than $0.1, respectively, as licensing revenue related to up-front and milestone payments received in connection with the HLS agreement. Through September 30, 2018 and December 31, 2017, the Company has recognized $0.7 million and $0.1 million, respectively, as licensing revenue under the agreement concurrent with the support provided by Amarin to HLS in achieving the performance obligation, which in the Company's judgment is the best measure of progress towards satisfying the combined performance obligation. The remaining transaction price of $6.8 million and $4.9 million is recorded in deferred revenue as of September 30, 2018 and December 31, 2017, respectively, on the condensed consolidated balance sheets and will be recognized as revenue over the remaining period of 12 years.

The following table presents changes in the balances of the Company's contract assets and liabilities during the nine months ended September 30, 2018:

In thousands	Balance at Beginning of Period	Additions	Deductions	Balance at End of Period
Nine months ended September 30, 2018:				
Contract assets	$ —	$ —	$ —	$ —
Contract liabilities:				
Deferred revenue	$ 19,054	$ 2,500	$ (598)	$ 20,956

During the nine months ended September 30, 2018, the Company recognized the following revenues as a result of changes in the contract asset and contract liability balances in the respective periods:

In thousands	Nine Months Ended September 30, 2018
Revenue recognized in the period from:	
Amounts included in contract liability at the beginning of the period	$ 405
Performance obligations satisfied in previous periods	$ 193

(11)Subsequent Events

The Company has evaluated subsequent events from September 30, 2018 through the date of the issuance of these condensed consolidated financial statements.

On October 19, 2018, the Company announced that it exercised its option to mandatorily exchange the entirety of the 2017 Notes into ADSs. Refer to January 2017 Exchangeable Senior Notes in Note 5—Debt for further discussion.

29

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. These forward-looking statements reflect our plans, estimates and beliefs. These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements. In some cases, you can identify forward-looking statements by terms such as "anticipates," "believes," "continue," "could," "estimates," "expects," "intends," "may," "plans," "potential," "projects," "should," "would" and similar expressions intended to identify forward-looking statements. Forward-looking statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. Because of these risks and uncertainties, the forward-looking events and circumstances discussed in this report may not transpire. We discuss many of these risks in Part I, Item 1A under the heading "Risk Factors" of our Annual Report on Form 10-K for the fiscal year ended December 31, 2017 and below under Part II, Item IA, "Risk Factors".

Given these uncertainties, you should not place undue reliance on these forward-looking statements. Also, forward-looking statements represent our estimates and assumptions only as of the date of this document. You should read this document with the understanding that our actual future results may be materially different from what we expect. Except as required by law, we do not undertake any obligation to publicly update or revise any forward-looking statements contained in this report, whether as a result of new information, future events or otherwise.

Overview

We are a pharmaceutical company with expertise in lipid science focused on the commercialization and development of therapeutics to improve cardiovascular health.

Our 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. This FDA-approved indication for Vascepa, known as the MARINE indication, is based primarily on the successful results from the MARINE study of Vascepa in this approved patient population. In considering this approval, FDA also reviewed the successful results from our study of Vascepa in patients with high triglyceride levels (TG >200 mg/dL and <500 mg/dL) who are also on statin therapy for elevated low-density lipoprotein cholesterol, or LDL-C, levels which condition we refer to as mixed dyslipidemia or persistently high triglycerides. This study is known as the ANCHOR study. Safety data from both the MARINE and ANCHOR studies are reflected in FDA-approved labeling for Vascepa. In January 2013, we began selling and marketing Vascepa in the United States based on the FDA-approved MARINE indication. In August 2015, we began communicating promotional information beyond the MARINE indication to healthcare professionals in the United States based on the federal court declaration described below. In March 2016, we reached agreement with the FDA and U.S. government under which they agreed to be bound by the terms of the August 2015 judicial declaration. Vascepa is available in the United States by prescription only.

We sell Vascepa principally to a limited number of major wholesalers, as well as selected regional wholesalers and specialty pharmacy providers, or collectively, our Distributors or our customers, that in turn resell Vascepa to retail pharmacies for subsequent resale to patients and healthcare providers. We market Vascepa in the United States through our direct sales force. In March 2014, we entered into a co-promotion agreement in the United States with Kowa Pharmaceuticals America, Inc. under which Kowa Pharmaceuticals America, Inc. began to co-promote Vascepa in conjunction with its promotion of its primary product, a branded statin for patients with high cholesterol, which commenced in May 2014 and extends until the end of 2018. Prior to REDUCE-IT results topline announcement in September 2018, our direct sales force consisted of approximately 170 sales professionals, including sales representatives and their managers. We are currently increasing the size of our sales force to a planned total of over 400 sales professionals in the United States in connection with positive REDUCE-IT results and expanding our

promotion of Vascepa.

In February 2015, we entered into an exclusive agreement with Eddingpharm (Asia) Macao Commercial Offshore Limited, or Eddingpharm, to develop and commercialize Vascepa capsules in Mainland China, Hong Kong, Macau and Taiwan, or the China Territory. In March 2016, we entered into an agreement with Biologix FZCo, or Biologix, to register and commercialize Vascepa in countries within the Middle East and North Africa. In September 2017, we entered into an agreement with HLS Therapeutics Inc., or HLS, to register, commercialize and distribute Vascepa in Canada.

In June 2018, we entered into a collaboration with Mochida Pharmaceutical Co., Ltd., or Mochida, related to development and potential subsequent commercialization of drug products and indications based on the active pharmaceutical ingredient in Vascepa, the omega-3 acid, EPA (eicosapentaenoic acid). The potential new product and indication opportunities contemplated under this agreement are currently in early stages of development.

We continue to assess other collaboration opportunities to maximize the value of the Vascepa franchise globally.

Triglycerides are the main constituent of body fat in humans. Hypertriglyceridemia refers to a condition in which patients have high levels of triglycerides in the bloodstream. It is estimated that greater than one in four adults in the United States, or more than 50 million people, have elevated triglyceride levels. This data is based upon the most recent review of patient demographics, including the impact of patients on statin therapy, as published in the Journal of Clinical Lipidology in April 2018. Many patients with high triglyceride levels also have diabetes and other lipid level abnormalities such as high cholesterol. The patient condition of having more than one lipid level abnormality is referred to as mixed dyslipidemia. According to The American Heart Association Scientific Statement on Triglycerides and Cardiovascular Disease (2011), triglycerides provide important information as a marker associated with the risk for heart disease and stroke, especially when an individual also has low high-density lipoprotein cholesterol, or HDL-C (often referred to as “good” cholesterol), and elevated levels of LDL-C (often referred to as “bad” cholesterol). Guidelines for the management of very high triglyceride levels suggest that reducing triglyceride levels is the primary goal in patients to reduce the risk of acute pancreatitis. The effect of Vascepa on cardiovascular mortality and morbidity, or the risk for pancreatitis, in patients with hypertriglyceridemia has not been determined.

We recently announced topline results of the REDUCE-IT (Reduction of Cardiovascular Events with EPA—Intervention Trial) cardiovascular outcomes study of Vascepa, which we started in December 2011. REDUCE-IT, a multinational, prospective, randomized, double-blind, placebo-controlled study, is the first prospective cardiovascular outcomes study of any drug in a population of patients who, despite stable statin therapy, have elevated triglyceride levels. The REDUCE-IT study, since its inception in 2011, was conducted based on a special protocol assessment, or SPA, agreement with the FDA. In REDUCE-IT, cardiovascular event rates for patients on stable statin therapy plus 4 grams per day of Vascepa were compared to cardiovascular event rates for patients on stable statin therapy plus placebo. In 2016, we completed patient enrollment and randomization of 8,175 individual patients into the REDUCE-IT study, exceeding the 8,000 patients targeted for the trial. Since patient enrollment commenced in 2011, over 35,000 patient years of study experience were accumulated in the REDUCE-IT study. The REDUCE-IT study topline results were made public in September 2018, and broader reporting of results is planned at the 2018 Scientific Sessions of the American Heart Association (AHA) on November 10, 2018 in Chicago, Illinois. Based on the final positive results of REDUCE-IT, we plan to seek additional indicated uses for Vascepa in the United States and to continue to develop Vascepa commercially in major markets around the world.

In the successful Phase 3 MARINE and ANCHOR clinical trials, Vascepa was studied at a daily dose of 2 grams and 4 grams. We sought approval of Vascepa at the more efficacious 4-gram dose for use in each patient population. These trials demonstrated favorable results in their respective patient populations, particularly with the 4-gram dose of Vascepa, in reducing triglyceride levels without increasing LDL-C levels in the MARINE trial and with a statistically significant decrease in LDL-C levels in the ANCHOR trial, in each case, relative to placebo. These trials also showed favorable results, particularly with the 4-gram dose of Vascepa, in other important lipid and inflammation biomarkers, including apolipoprotein B (apo B), non-high-density lipoprotein cholesterol (non-HDL-C), total-cholesterol (TC), very low-density lipoprotein cholesterol (VLDL-C), lipoprotein-associated phospholipase A2 (Lp-PLA2), and high sensitivity C-reactive protein (hs-CRP). In these trials, the most commonly reported adverse reaction (incidence >2% and greater than placebo) in Vascepa-treated patients was arthralgia (joint pain) (2.3% for Vascepa vs. 1.0% for placebo).

In April 2015, we received a Complete Response Letter, or CRL, from the FDA in response to our supplemental new drug application, or sNDA, that sought approval of Vascepa for use in patients with mixed dyslipidemia, based on the successful ANCHOR study. The CRL followed an October 2013 rescission by the FDA of a special protocol assessment, or SPA, agreement and three failed attempts by us to appeal that rescission at FDA. The FDA has acknowledged the success of the ANCHOR study, which met all primary and secondary endpoints. However, FDA determined that there were insufficient data to conclude that drug-induced changes in serum triglycerides could be recognized by the FDA as a valid surrogate for reducing cardiovascular risk in the ANCHOR population for the purpose of regulatory approval of a drug targeted at a triglyceride-lowering indication in this population. The FDA has acknowledged that the standard of proof required by the FDA for approval of a new drug indication is higher than that generally used to inform patient treatment guidelines and that used by physicians in clinical practice. The FDA did not

determine that the drug-induced effects of Vascepa, which go beyond triglyceride-lowering, would not actually reduce cardiovascular risk in this population and the FDA encouraged us to complete the REDUCE-IT outcomes study. Based on our communications with the FDA, we expect that the FDA's review and analysis of our final positive results from the REDUCE-IT outcomes study will be required for FDA-approved label expansion for Vascepa. We anticipate submitting an sNDA to the FDA in early 2019 based on the positive results of the REDUCE-IT study.

In May 2015, we and a group of independent physicians filed a lawsuit in federal court to permit us to promote to healthcare professionals the use of Vascepa in patients with mixed dyslipidemia so long as the promotion is truthful and non-misleading. This use reflects recognized medical practice but is not covered by current FDA-approved labeling for the drug. Historically, FDA has considered promotion of drug uses not covered by FDA-approved labeling to be illegal off-label promotion, even if such promotion is truthful and non-misleading. In August 2015, we were granted preliminary relief in the form of a declaratory judgment in this lawsuit. The court declaration permits us to promote to healthcare professionals the FDA-reviewed and agreed effects of Vascepa demonstrated in the ANCHOR clinical trial and presentation of the current state of scientific research related to the potential of Vascepa to reduce the risk of cardiovascular disease including through use of peer-reviewed scientific publications of available data.

In August 2015, we began to communicate promotional information beyond the MARINE indication to healthcare professionals in the United States as permitted by this court declaration and, in March 2016, the parties obtained court approval of negotiated settlement terms under which the FDA and the U.S. government agreed to be bound by the court's conclusions from the August 2015 declaration that we may engage in truthful and non-misleading speech promoting the off-label use of Vascepa and that certain statements and disclosures that we proposed to make to healthcare professionals were truthful and non-misleading. In September 2018, in connection with the public release of topline REDUCE-IT results, we commenced communications to healthcare professionals which were intended to ensure we meet our continuing obligation to update healthcare professionals regarding off-label use of Vascepa to ensure that our communications remain truthful and non-misleading, which we believe is consistent with the federal court approved settlement under Amarin Pharma, Inc. et al. v. United States Food and Drug Administration et al., 119 F.Supp.3d 196, 236 (S.D.N.Y. 2015). While we believe we are now permitted under applicable law to more broadly promote Vascepa, the FDA-approved labeling for Vascepa did not change as a result of this litigation and settlement, and neither government nor other third-party coverage or reimbursement to pay for the off-label use of Vascepa promoted under the court declaration was required.

Commercialization – United States

We commenced the commercial launch of 1-gram size Vascepa capsules in the United States in January 2013. We commenced sales and shipments of Vascepa at that time to our network of U.S.-based wholesalers. Prior to REDUCE-IT results topline announcement in September 2018, our direct sales force consisted of approximately 170 sales professionals, including sales representatives and their managers. We are currently increasing the size of our sales force to a planned total of over 400 sales professionals in connection with positive REDUCE-IT results and expanding our promotion of Vascepa. Commencing in May 2014, in addition to Vascepa promotion by our sales representatives, Kowa Pharmaceuticals America, Inc. began co-promoting Vascepa in conjunction with its promotion of its primary product, a branded statin for patients with high cholesterol. We also employ various medical affairs and marketing personnel to support our commercialization of Vascepa.

In October 2016, in addition to the original 1-gram capsule size for Vascepa, we introduced a smaller 0.5-gram capsule size, the first and only 0.5-gram prescription omega-3 alternative available on the market, for the subset of patients who prefer a smaller capsule. The FDA-approved dosing for Vascepa continues to be 4 grams per day, and, as expected, the majority of new and existing patients taking Vascepa continue to be prescribed the 1-gram size Vascepa capsule.

Under our co-promotion agreement with Kowa Pharmaceuticals America, Inc., both parties have agreed to use commercially reasonable efforts to promote, detail and optimize sales of Vascepa in the United States and have agreed to specific performance requirements detailed in the related agreement. The performance requirements include a negotiated minimum number of sales details to be delivered by each party in the first and second position, the use of a negotiated number of minimum sales representatives from each party, and the achievement of minimum levels of Vascepa revenue in 2015 and beyond. First position refers to when a sales representative's primary purpose in detailing is related to Vascepa, while second position refers to when a sales representative's primary purpose in detailing is to promote another product, but they also devote time in the same sales call to promote Vascepa. Kowa Pharmaceuticals America, Inc. has also agreed to bear the costs incurred for its sales force associated with the commercialization of Vascepa and to pay for certain incremental costs associated with the use of its sales force, such as sample costs and costs for promotional and marketing materials. We will continue to recognize all revenue from sales of Vascepa. In exchange for Kowa Pharmaceuticals America, Inc.'s co-promotional services, Kowa Pharmaceuticals America, Inc. is entitled to a quarterly co-promotion fee based on a percentage of aggregate Vascepa gross margin that varies during the term. The percentage of aggregate Vascepa gross margin earned by Kowa Pharmaceuticals America, Inc. was, as amended, approximately eighteen percent (18%) in 2017, partially offset by certain other refinements. During 2018, which is the last year of the agreement, as amended, we are incurring expense for both the annual co-promotion fee, which in 2018 is calculated as eighteen-and-a-half percent (18.5%) of Vascepa gross margin, plus accrual for co-promotion tail payments which are calculated as a percentage of the 2018 co-promotion fee. Assuming Kowa

Pharmaceuticals America, Inc. fulfills its obligations in accordance with the terms of the agreement, as amended, after expiration of the agreement, Kowa Pharmaceuticals America, Inc. is eligible to receive up to three years of co-promotion tail payments equal to declining percentages of the co-promotion fee amount earned in the final year of the agreement with the sum of the three years of co-promotion tail payments totaling less than the co-promotion fee amount earned in the final year of the agreement.

Based on monthly compilations of data provided by a third party, Symphony Health, the estimated number of normalized total Vascepa prescriptions for the three months ended September 30, 2018 was approximately 458,000 compared to 430,000, 391,000 and 384,000 in the three months ended June 30, 2018, March 31, 2018 and September 30, 2017, respectively. According to data from another third party, IQVIA, the estimated number of normalized total Vascepa prescriptions for the three months ended September 30, 2018 was approximately 457,000 compared to 430,000, 392,000 and 374,000 in the three months ended June 30, 2018, March 31, 2018 and September 30, 2017, respectively. Normalized total prescriptions represent the estimated total number of Vascepa prescriptions dispensed to patients, calculated on a normalized basis (i.e., one month’s supply, or total capsules dispensed multiplied by the number of grams per capsule divided by 120 grams). Inventory levels at wholesalers tend to fluctuate based on seasonal factors, prescription trends and other factors.

The data reported above is based on information made available to us from third-party resources and may be subject to adjustment and may overstate or understate actual prescriptions. Timing of shipments to wholesalers, as used for revenue recognition purposes, and timing of prescriptions as estimated by these third parties may differ from period to period. Although we believe these data are prepared on a period-to-period basis in a manner that is generally consistent and that such results can be generally indicative of current prescription trends, these data are based on estimates and should not be relied upon as definitive. While we expect to be able to grow Vascepa revenues over time, no guidance should be inferred from the operating metrics described above. We also anticipate that such sales growth will be inconsistent from period to period. We believe that investors should view the above-referenced operating metrics with caution, as data for this limited period may not be representative of a trend consistent with the results presented or otherwise predictive of future results. Seasonal fluctuations in pharmaceutical sales, for example, may affect future prescription trends of Vascepa, as could changes in prescriber sentiment, quarterly changes in Distributor purchases, and other factors. We believe investors should consider our results over several quarters, or longer, before making an assessment about potential future performance.

The commercialization of pharmaceutical products is a complex undertaking, and our ability to effectively and profitably commercialize Vascepa will depend in part on our ability to generate market demand for Vascepa through education, marketing and sales activities, our ability to achieve market acceptance of Vascepa, our ability to generate product revenue and our ability to receive adequate levels of reimbursement from third-party payers. See “Risk Factors—Risks Related to the Commercialization and Development of Vascepa.”

In August 2015, we and our co-promotion partner began communicating promotional information beyond MARINE clinical trial data to targeted healthcare professionals. Such qualified communications are being made pursuant to the August 2015 federal district court declaration and related March 2016 settlement allowing truthful and non-misleading promotion of the FDA-reviewed and agreed effects of Vascepa demonstrated in the ANCHOR clinical trial and presentation of the current state of scientific research related to the potential of Vascepa to reduce the risk of cardiovascular disease including through use of peer-reviewed scientific publications of available data. In September 2018, in connection with the public release of topline REDUCE-IT results, we commenced communications to healthcare professionals which were intended to ensure we meet our continuing obligation to update healthcare professionals regarding off-label use of Vascepa to ensure that our communications remain truthful and non-misleading, which we believe is consistent with the federal court approved settlement under Amarin Pharma, Inc. et al. v. United States Food and Drug Administration et al., 119 F.Supp.3d 196, 236 (S.D.N.Y. 2015).

Commercialization – Outside the United States

In February 2015, we announced an exclusive agreement with Eddingpharm to develop and commercialize Vascepa capsules in what we refer to as the China Territory, consisting of the territories of Mainland China, Hong Kong, Macau and Taiwan, for uses that are currently commercialized and under development by us in the United States based on the MARINE, ANCHOR and REDUCE-IT clinical trials of Vascepa. Under the agreement, Eddingpharm is responsible for development and commercialization activities in the China Territory and associated expenses. We will provide development assistance and be responsible for supplying the product. Terms of the agreement include up-front and milestone payments to us of up to $169.0 million, including a non-refundable $15.0 million up-front payment received at closing and a non-refundable milestone payment of $1.0 million received upon successful submission of a clinical trial application, or CTA, with respect to the MARINE indication for Vascepa to the Chinese regulatory authority in March 2016. In March 2017, the CTA was approved by the Chinese regulatory authority and, in December 2017, Eddingpharm commenced a pivotal clinical trial aimed to support the regulatory approval of the first indication of Vascepa in a patient population with severe hypertriglyceridemia in Mainland China. We are also entitled to receive future regulatory and sales-based milestone payments of up to an additional $153.0 million. The regulatory milestone events relate to the submission and approval of certain applications to the applicable regulatory authority, such as a clinical trial application, clinical trial exemption, or import drug license application. The amounts to be received upon achievement of the regulatory milestone events relate to the submission and approval for three indications, and range from $2.0 million to $15.0 million for a total of $33.0 million. The sales-based milestone events occur when annual aggregate net sales of Vascepa in the territory equals or exceeds certain specified thresholds, and range from $5.0 million to $50.0 million for a total of $120.0 million. Eddingpharm will also pay us tiered double-digit percentage royalties on net sales of Vascepa in the China Territory escalating to the high teens. We will supply finished product to Eddingpharm under negotiated terms.

In March 2016, we entered into an agreement with Biologix FZCo, or Biologix, to register and commercialize Vascepa in several Middle Eastern and North African countries. Under the terms of the distribution agreement, we granted to Biologix a non-exclusive license to use our trademarks in connection with the importation, distribution, promotion, marketing and sale of Vascepa in the Middle East and North Africa territory. Upon closing of the agreement, we received a non-refundable up-front payment, which will be recognized as revenue over 10 years commencing upon first marketing approval of Vascepa in the territory. We receive all payments based on total product sales and pay Biologix a service fee in exchange for its services, whereby the service fee represents a percentage of gross selling price which is subject to a minimum floor price. In March 2018 and July 2018, we received approval for Vascepa as a prescription medication for use in Lebanon and United Arab Emirates, respectively, as an adjunct to diet to reduce triglyceride levels in adult patients with severe hypertriglyceridemia.

In September 2017, we entered into an agreement with HLS to register, commercialize and distribute Vascepa in Canada. Under the agreement, HLS will be responsible for regulatory and commercialization activities and associated costs. We will be responsible for providing assistance towards local filings, supplying finished product under negotiated supply terms, maintaining intellectual property, and continuing the development and funding of REDUCE-IT-related activities. Terms of the agreement include up-front and milestone payments to us of up to $65.0 million. These payments include a non-refundable $5.0 million up-front payment received in two equal installments, the first of which was received at closing with the second received upon the six-month anniversary of the closing, as well as a non-refundable milestone payment of $2.5 million received upon achievement of the REDUCE-IT trial primary endpoint. In addition to the non-refundable, up-front payment, we are entitled to receive certain regulatory and sales-based milestone payments of up to an additional $57.5 million, the timing and achievability of which cannot be determined at least until discussions with Canadian regulatory authorities have commenced, as well as tiered double-digit royalties on net sales of Vascepa in Canada.

We continue to assess other partnership opportunities for licensing Vascepa to partners outside of the United States.

Research and Development

REDUCE-IT is the first prospective cardiovascular outcomes study of any drug in a population of patients who, despite stable statin therapy, have elevated triglyceride levels. REDUCE-IT is a multinational, prospective, randomized, double-blind, placebo-controlled study designed to assess the cumulative effect on the rate of cardiovascular events for patients treated with Vascepa as an add-on to statin therapy compared to the corresponding rate of cardiovascular events for patients treated with placebo on top of statin therapy. REDUCE-IT was not designed to demonstrate that lowering triglycerides alone in the study population is sufficient to lower the rate of major adverse cardiovascular events compared to placebo. Rather, it was designed to test the hypothesis that the clinical effects of Vascepa, including, but not limited to, its impact on triglyceride lowering, are effective in lowering the rate of major adverse cardiovascular events compared to placebo in patients who despite statin therapy have risk factors for cardiovascular disease, including elevated triglyceride levels. Based on the final positive results of REDUCE-IT, we plan to seek additional indications for Vascepa beyond the indications studied in the ANCHOR or MARINE trials.

In 2016, we completed patient enrollment and randomization of 8,175 individual patients into the REDUCE-IT study, exceeding the 8,000 patients targeted for the trial.

The REDUCE-IT study topline study results were made public in September 2018, and broader reporting of results is planned at the 2018 Scientific Sessions of the American Heart Association (AHA) on November 10, 2018 in Chicago, Illinois.

The REDUCE-IT study, since its inception in 2011, was conducted based on a SPA agreement with the FDA. Since patient enrollment commenced in 2011, over 35,000 patient years of study experience were accumulated in the REDUCE-IT study. Our scientific rationale for the REDUCE-IT study was supported by (i) epidemiological data that suggests elevated triglyceride levels correlate with increased cardiovascular disease risk, (ii) genetic data that suggests triglyceride and/or triglyceride-rich lipoproteins (as well as low-density lipoprotein cholesterol (LDL cholesterol), known as bad cholesterol) are independently in the causal pathway for cardiovascular disease and (iii) clinical data that suggest substantial triglyceride reduction in patients with elevated baseline triglyceride levels correlates with reduced cardiovascular risk. Our scientific rationale for the REDUCE-IT study was also supported by research on the putative cardioprotective effects of EPA as presented in scientific literature. It is possible that the effects of EPA may be due not to a single mode of action, such as triglyceride lowering, but rather to multiple mechanisms working together. Studies in the scientific literature explore potentially beneficial effects of EPA on multiple atherosclerosis processes, including endothelial function, oxidative stress, foam cell formation, inflammation/cytokines, plaque formation/progression, platelet aggregation, thrombus formation, and plaque rupture. The REDUCE-IT study was needed to determine the clinical benefit of Vascepa therapy in statin-treated patients with controlled levels of LDL cholesterol, elevated triglyceride levels and other cardiovascular risk factors.

In June 2018, we entered into a multi-faceted collaboration with Mochida related to the development and commercialization of drug products and indications based on the active pharmaceutical ingredient in Vascepa, the omega-3 acid, EPA. Among other terms in the agreement, we obtained an exclusive license to certain Mochida intellectual property to advance our interests in the United States and certain other territories and the parties will collaborate to research and develop new products and indications based on EPA for our commercialization in the United States and certain other territories. The potential new product and indication opportunities contemplated under this agreement are currently in early stages of development. Upon closing of the collaboration agreement, we are required to make a non-refundable, non-creditable upfront payment of approximately $2.7 million. In addition, the agreement provides for milestone payments from us upon the achievement of certain product development milestones and royalties on net sales of future products arising from the collaboration, if any. We expect that expenditures related to research and development activities for product candidates under the collaboration agreement will be immaterial in 2018 and less than $5.0 million in 2019.

Commercial and Clinical Supply

We manage our supply chain internally but rely on contract manufacturers in each step of our commercial and clinical product supply, namely, active pharmaceutical ingredient, or API, manufacturing, encapsulation, packaging and supply-related logistics. Our approach to product supply seeks to mitigate risk of supply interruption and maintain an environment of cost competition and supply chain diversification. API for Vascepa is manufactured by three independent FDA-approved suppliers: Nisshin Pharma, Inc., or Nisshin, Finorga SAS, or Novasep, and Chemport, Inc., or Chemport. We encapsulate Vascepa through three independent FDA-approved commercial API encapsulators: Patheon, Inc. (formerly Banner Pharmacaps, now part of Thermo Fisher Scientific), Catalent Pharma Solutions, and Capsugel Plöermel SAS, (now a Lonza company), or Capsugel. The amount of supply we seek to purchase in future periods will depend on the level of growth of Vascepa revenues and minimum purchase commitments with certain suppliers. While our current supply chain is scalable, we continue efforts to expand, diversify and further enhance it.

Financial Position

We believe that our cash and cash equivalents of $81.9 million as of September 30, 2018 will be sufficient to fund our projected operations through planned expansion of our sales force and the anticipated submission in early 2019 of a supplemental new drug application (sNDA) with the FDA based on REDUCE-IT study results. Depending on the

level of cash generated from operations, and in light of the recently announced successful results of the REDUCE-IT study, additional capital may be required to support planned expansion of Vascepa promotion and potential Vascepa promotion beyond which we are currently executing. If additional capital is required and we are unable to obtain additional capital, we may be forced to delay, limit or eliminate certain promotional activities. We anticipate that quarterly net cash outflows in future periods will be variable.

Financial Operations Overview

Product Revenue, net. All of our product revenue is derived from product sales of 1-gram and 0.5-gram size capsules of Vascepa, net of allowances, discounts, incentives, rebates, chargebacks and returns. We sell product to a limited number of major wholesalers, as well as selected regional wholesalers and specialty pharmacy providers, or collectively, our Distributors or our customers, who resell the product to retail pharmacies for purposes of their reselling the product to fill patient prescriptions. We commenced our commercial launch of 1-gram size Vascepa capsules in the United States in January 2013, and introduced a smaller 0.5-gram capsule size in October 2016. Revenues from product sales are recognized when the Distributor obtains control of our product, which occurs at a point in time, typically upon delivery to the Distributor.

Licensing revenue. Licensing revenue currently consists of revenue attributable to receipt of up-front, non-refundable payments and milestone payments related to license and distribution agreements for Vascepa outside the United States. We recognize revenue from licensing arrangements as we fulfill the performance obligations under each of the agreements.

Cost of Goods Sold. Cost of goods sold includes the cost of API for Vascepa on which revenue was recognized during the period, as well as the associated costs for encapsulation, packaging, shipment, supply management, quality assurance, insurance, and other indirect manufacturing, logistics and product support costs. The cost of the API included in cost of goods sold reflects the average cost method of inventory valuation and relief. This average cost reflects the actual purchase price of Vascepa API.

Selling, General and Administrative Expense. Selling, general and administrative expense consists primarily of salaries and other related costs, including stock-based compensation expense, for personnel in our sales, marketing, executive, business development, finance and information technology functions, as well as co-promotion fees payable to Kowa Pharmaceuticals America, Inc. Other costs primarily include facility costs and professional fees for accounting, consulting and legal services.

Research and Development Expense. Research and development expense consists primarily of fees paid to professional service providers in conjunction with independent monitoring of our clinical trials and acquiring and evaluating data in conjunction with our clinical trials, fees paid to independent researchers, costs of qualifying contract manufacturers, services expenses incurred in developing and testing products and product candidates, salaries and related expenses for personnel, including stock-based compensation expense, costs of materials, depreciation, rent, utilities and other facilities costs. In addition, research and development expenses include the cost to support current development efforts, costs of product supply received from suppliers when such receipt by us is prior to regulatory approval of the supplier, as well as license fees related to our strategic collaboration with Mochida Pharmaceutical Co., Ltd. We expense research and development costs as incurred.

Interest and Other (Expense) Income, Net. Interest expense consists of interest incurred under lease obligations, interest incurred under our December 2012 royalty-bearing instrument financing arrangement, and interest incurred under our 3.5% exchangeable notes. Interest expense under our royalty-bearing instrument financing arrangement is calculated based on an estimated repayment schedule. Interest expense under our exchangeable notes includes the amortization of the conversion option related to our exchangeable debt, the amortization of the related debt discounts and debt obligation coupon interest. Interest income consists of interest earned on our cash and cash equivalents. Other (expense) income, net, consists primarily of foreign exchange losses and gains.

(Provision for) Benefit from Income Taxes. (Provision for) benefit from income taxes, deferred tax assets and liabilities, and reserves for unrecognized tax benefits reflect management’s best assessment of estimated future taxes to be paid. We are subject to income taxes in both the United States and foreign jurisdictions. In applying the estimated annual effective tax rate approach prescribed under ASC 740-270 and based on present evidence and conclusions around the realizability of deferred tax assets, we determined that any tax benefit related to the pretax losses generated

during the three and nine months ended September 30, 2018 and 2017 is neither more likely than not to be realized in the current year nor realizable as a deferred tax asset at the end of the year. Therefore, the appropriate amount of income tax benefit to recognize during the three and nine months ended September 30, 2018 and 2017 is zero.

Critical Accounting Policies and Significant Judgments and Estimates

Our discussion and analysis of our financial condition and results of operations is based on our condensed consolidated financial statements and notes, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenue and expenses. On an ongoing basis, we evaluate our estimates and judgments, including those related to derivative financial liabilities. We base our estimates on historical experience and on various market-specific and other relevant assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. Estimates are assessed each period and updated to reflect current information. A summary of our significant accounting policies is contained in Note 2 to our condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q. A summary of our critical accounting policies, significant judgments and estimates is presented in Part II, Item 7 of our Annual Report on Form 10-K for the year ended December 31, 2017. There were no material changes to our critical accounting policies, significant judgments and estimates during the nine months ended September 30, 2018, other than as set forth below.

Revenue Recognition—In accordance with GAAP, under Accounting Standards Codification (“ASC”) Topic 606, Revenue from Contracts with Customers, which we adopted on a modified retrospective basis effective January 1, 2018, we recognize revenue when our Distributors obtain control of promised goods or services, in an amount that reflects the consideration which we expect to receive in exchange for those goods or services. To determine revenue recognition for arrangements that we determine are within the scope of Topic 606, we perform the following five steps: (i) identify the contract(s) with a Distributor; (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) we satisfy a performance obligation. We apply the five-step model to contracts only when it is probable that we will collect the consideration we are entitled to in exchange for the goods or services we transfer to the Distributor. At contract inception, once the contract is determined to be within the scope of Topic 606, we assess the goods or services promised within each contract, determine those that are performance obligations and assess whether each promised good or service is distinct. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied. For a complete discussion of our accounting for net product revenue and licensing revenues, see Note 2—Significant Accounting Policies.

We sell Vascepa principally to a limited number of Distributors that in turn resell Vascepa to retail pharmacies that subsequently resell it to patients and healthcare providers. We began recognizing revenue from the sale of Vascepa following our commercial launch in the United States in January 2013. Prior to 2013, we recognized no revenue from Vascepa sales. In accordance with GAAP, we recognize revenue when the Distributor obtains control of our product, which occurs at a point in time, typically upon delivery to the Distributor. We recognized net product revenues of $151.3 million and $126.3 million based on sales to Distributors during the nine months ended September 30, 2018 and 2017, respectively.

We have written contracts with our Distributors, and transfer of control typically occurs upon delivery of our product to the Distributor. We evaluate the creditworthiness of each of our 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. We calculate gross product revenues based on the wholesale acquisition cost that we charge our Distributors for Vascepa. We estimate our net product revenues by deducting from our 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. The gross to net deductions are estimated based on available actual information, historical data, known trends, and levels of inventory in the distribution channel. We rely on resale data provided by our Distributors as well as

prescription data provided by Symphony Health and IQVIA in estimating the level of inventory held in the distribution channel. A hypothetical 5% change in estimated aggregate bottles of channel inventory would result in a change of less than 1% in net product revenues reported during each of the nine months ended September 30, 2018 and 2017.

When evaluating licensing arrangements, we perform the following steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) we satisfy each performance obligation. In determining performance obligations, we evaluate whether the license is distinct from the other performance obligations with the collaborative partner based on the consideration of the relevant facts and circumstances for each arrangement. Factors considered in the determination of 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 us.

If the license to our intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, we recognize revenues from non-refundable, up-front fees allocated to the license when the license is transferred to the

Distributor and the Distributor is able to use and benefit from the license. For licenses that are bundled with other promises, we utilize judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front fees. We evaluate the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition.

At the inception of each arrangement that includes development, regulatory and commercial milestone payments, we evaluate whether the milestones are considered probable of being reached and estimate the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within our control or the control of the licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. We evaluate factors such as the scientific, clinical, regulatory, commercial and other risks that must be overcome to achieve the respective milestone as well as the level of effort and investment required. The transaction price is then allocated to each performance obligation on a relative stand-alone selling price basis, for which we recognize revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, we re-evaluate the probability of achievement of such development, regulatory and commercial milestones and any related constraint, and if necessary, adjust its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect licensing revenues and earnings in the period of adjustment.

We receive payments from our customers based on billing schedules established in each contract. Up-front payments and fees are recorded as deferred revenue upon receipt or when due and may require deferral of revenue recognition to a future period until we perform our obligations under these arrangements. Amounts are recorded as accounts receivable when our right to consideration is unconditional. We do not assess whether a contract has a significant financing component if the expectation at contract inception is such that the period between payment by the customer and the transfer of the promised goods or services to the customer will be one year or less.

Recent Accounting Pronouncements

For a discussion of recent accounting pronouncements, see Note 2—Significant Accounting Policies in the accompanying Notes to Condensed Consolidated Financial Statements included in Item 1 of this Quarterly Report on Form 10-Q for additional information.

Results of Operations

Comparison of Three Months Ended September 30, 2018 and September 30, 2017

Product Revenue, net. We recorded net product revenue of $55.0 million and $47.1 million during the three months ended September 30, 2018 and 2017, respectively, an increase of $7.9 million, or 17%. This increase in revenue was driven primarily by an increase in estimated normalized total Vascepa prescriptions in the United States. Based on data provided by Symphony Health and IQVIA, estimated normalized total Vascepa prescriptions in the United States increased by approximately 74,000 and 83,000, respectively, over the three months ended September 30, 2017, representing growth of 19% and 22%, respectively.

All of our product revenue in the three months ended September 30, 2018 and 2017 was derived from product sales of 1-gram and 0.5-gram size capsules of Vascepa, net of allowances, discounts, incentives, rebates, chargebacks and returns. The FDA-approved dosing for Vascepa continues to be 4 grams per day and, as expected, the majority of new and existing patients taking Vascepa continue to be prescribed the 1-gram size Vascepa capsules. Timing of shipments to wholesalers, as used for revenue recognition, and timing of prescriptions as estimated by third-party sources such as Symphony Health and IQVIA may differ from period to period.

During the quarters ended September 30, 2018 and 2017, our net product revenue included adjustment for co-pay mitigation rebates provided by us to commercially insured patients. Such rebates are intended to offset the differential for patients of Vascepa not covered by commercial insurers at the time of launch on Tier 2 for formulary purposes, resulting in higher co-pay amounts for such patients. Our cost for these co-payment mitigation rebates during the quarters ended September 30, 2018 and 2017 was up to $70 per 30-day prescription filled and, beginning in March 2017, included up to $140 per 90-day prescription filled. Since launch, certain third-party payors have added Vascepa to their Tier 2 coverage, which results in lower co-payments for patients covered by these third-party payors. In connection with such Tier 2 coverage, we have agreed to pay customary rebates to these third-party payors on the resale of Vascepa to patients covered by these third-party payors.

As is typical for the pharmaceutical industry, the majority of Vascepa sales are to major commercial wholesalers which then resell Vascepa to retail pharmacies.

Licensing Revenue. Licensing revenue during the three months ended September 30, 2018 and 2017 was $0.4 million and $0.3 million, respectively. Licensing revenue relates to the amortization of amounts received in connection with a Vascepa licensing agreement for the China Territory, specifically a $15.0 million up-front payment received in February 2015 and a $1.0 million

milestone payment achieved in March 2016, as well as amortization of amounts received in connection with a Vascepa licensing agreement for Canada, specifically a $5.0 million up-front payment which was received upon closing of the agreement in September 2017 and a $2.5 million milestone payment that was receivable following achievement of the REDUCE-IT trial primary endpoint in September 2018. The up-front and milestone payments are being recognized over the estimated period in which we are required to provide regulatory and development support pursuant to the agreements. The amount of licensing revenue is expected to vary from period to period based on timing of milestones achieved and changes in estimates of the timing and level of support required. We do not anticipate significant revenues from international sources in 2018.

Cost of Goods Sold. Cost of goods sold during the three months ended September 30, 2018 and 2017 was $13.5 million and $11.9 million, respectively, an increase of $1.6 million, or 14%. Cost of goods sold includes the cost of API for Vascepa on which revenue was recognized during the period, as well as the associated costs for encapsulation, packaging, shipment, supply management, insurance and quality assurance. The cost of the API included in cost of goods sold reflects the average cost of API included in inventory. This average cost reflects the actual purchase price of Vascepa API.

The API included in the calculation of the average cost of goods sold during the quarters ended September 30, 2018 and 2017 was sourced from three API suppliers. These suppliers compete with each other based on cost, consistent quality, capacity, timely delivery and other factors. In the future, we may see the average cost of supply change based on numerous potential factors including increased volume purchases, continued improvement in manufacturing efficiency, the mix of purchases made among suppliers, currency exchange rates and other factors. We currently anticipate API average cost in 2018 to be similar to 2017. The average cost may be variable from period to period depending upon the timing and quantity of API purchased from each supplier.

Our gross margin on product sales for each of the three months ended September 30, 2018 and 2017 was 75%.

Selling, General and Administrative Expense. Selling, general and administrative expense for the three months ended September 30, 2018 and 2017 was $50.0 million and $33.2 million, respectively, an increase of $16.8 million, or 51%. Selling, general and administrative expenses for the three months ended September 30, 2018 and 2017 are summarized in the table below:

	Three months ended September 30,	
In thousands	2018	2017
Selling, general and administrative expense (1)	$33,200	$24,295
Co-promotion fees (2)	11,157	5,928
Non-cash stock-based compensation expense (3)	5,603	2,971
Total selling, general and administrative expense	$49,960	$33,194

(1) Selling, general and administrative expense, excluding co-promotion fees and non-cash compensation charges for stock compensation, for the three months ended September 30, 2018 and 2017 was $33.2 million and $24.3 million, respectively, an increase of $8.9 million, or 37%. This increase is due primarily to increased promotional activities, including commercial spend in preparation for successful REDUCE-IT results (announced on September 24, 2018), including costs for pilot direct-to-consumer activities of approximately $5 million.

(2) Co-promotion fees payable to Kowa Pharmaceuticals America, Inc. for the three months ended September 30, 2018 and 2017 were $11.2 million and $5.9 million, respectively, an increase of $5.2 million, or 88%. The increase is due primarily to an accrual for co-promotion tail payments of $3.9 million in the third quarter of 2018 as well as

an increase in gross margin on product sales, upon which the co-promotion fees are calculated for the third quarter of 2018 compared to the same period in 2017.

(3) Non-cash stock-based compensation expense for each of the three months ended September 30, 2018 and 2017 was $5.6 million and $3.0 million, respectively, an increase of $2.6 million, or 89%. Non-cash stock-based compensation expense represents the estimated costs associated with equity awards issued to internal staff supporting our selling, general and administrative functions.

Research and Development Expense. Research and development expense for the three months ended September 30, 2018 and 2017 was $14.1 million and $10.7 million, respectively, an increase of $3.4 million, or 32%. Research and development expenses for the three months ended September 30, 2018 and 2017 are summarized in the table below:

	Three months ended September 30,	
In thousands	2018	2017
REDUCE-IT study (1)	$9,414	$7,696
Regulatory filing fees and expenses (2)	419	442
Internal staffing, overhead and other (3)	3,191	2,032
Research and development expense, excluding non-cash expense	13,024	10,170
Non-cash stock-based compensation expense (4)	1,048	524
Total research and development expense	$14,072	$