UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the quarterly period ended June 30, 2020
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.)**
77 Sir John Rogerson's Quay, Block C, Grand Canal Docklands	**Dublin 2, Ireland**
(Address of Principal Executive Offices)	**(Zip Code)**

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

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of each exchange on which registered
American Depositary Shares (ADS(s)), each ADS representing the right to receive one (1) Ordinary Share of Amarin Corporation plc	AMRN	NASDAQ Stock Market LLC

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 (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). YES ☒ 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 ☒

388,673,381 common shares were outstanding as of July 31, 2020, including 388,472,048 shares held as American Depositary Shares (ADSs), each representing one Ordinary Share, 50 pence par value per share and 201,333 Ordinary Shares. In addition, 2,385,078 ordinary share equivalents were issuable in exchange for outstanding preferred shares as of July 31, 2020, for a total of 391,058,459 ordinary shares and ordinary share equivalents outstanding as of July 31, 2020.

INDEX TO FORM 10-Q

		Page
	PART I – Financial Information	
Item 1.	Financial Statements (unaudited):	
	Condensed Consolidated Balance Sheets as of June 30, 2020 and December 31, 2019	3
	Condensed Consolidated Statements of Operations for the three and six months ended June 30, 2020 and 2019	4
	Condensed Consolidated Statement of Changes in Stockholders' Equity (Deficit) for the six months ended June 30, 2020 and 2019	5
	Condensed Consolidated Statements of Cash Flows for the six months ended June 30, 2020 and 2019	6
	Notes to Condensed Consolidated Financial Statements	7
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	25
Item 3.	Quantitative and Qualitative Disclosures about Market Risk	40
Item 4.	Controls and Procedures	40
	PART II – Other Information	
Item 1.	Legal Proceedings	42
Item 1A.	Risk Factors	42
Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds	84
Item 6.	Exhibits	85
SIGNATURES		86

AMARIN CORPORATION PLC
CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited, in thousands, except share amounts)

	June 30, 2020	December 31, 2019
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 214,007	$ 644,588
Restricted cash	3,913	3,907
Short-term investments	336,273	—
Accounts receivable, net	124,985	116,430
Inventory	124,844	76,769
Prepaid and other current assets	23,589	13,311
Total current assets	827,611	855,005
Property, plant and equipment, net	2,316	2,361
Long-term investments	61,039	—
Operating lease right-of-use asset	8,291	8,511
Other long-term assets	1,074	1,074
Intangible asset, net	14,538	15,258
TOTAL ASSETS	$ 914,869	$ 882,209
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 86,757	$ 49,950
Accrued expenses and other current liabilities	168,549	139,826
Debt from royalty-bearing instrument	22,455	50,130
Deferred revenue, current	5,706	2,342
Total current liabilities	283,467	242,248
Long-Term Liabilities:		
Deferred revenue, long-term	14,507	18,504
Long-term operating lease liability	9,311	9,443
Other long-term liabilities	4,821	3,751
Total liabilities	312,106	273,946
Commitments and contingencies (Note 6)		
Stockholders' Equity:		
Series A Convertible Preferred Stock, £0.05 par, unlimited authorized; 51,603,780 shares issued and outstanding as of June 30, 2020 (equivalent to 5,160,378 ordinary shares upon future consolidation and redesignation at a 10:1 ratio) and 289,317,460 shares issued and outstanding as of December 31, 2019 (equivalent to 28,931,746 ordinary shares upon future consolidation and redesignation at a 10:1 ratio)	7,166	21,850
Common stock, £0.50 par, unlimited authorized; 391,589,312 issued, 385,847,517 outstanding as of June 30, 2020; 365,014,893 issued, 360,103,901 outstanding as of December 31, 2019	285,672	269,173
Additional paid-in capital	1,787,492	1,764,317
Treasury stock; 5,741,795 shares as of June 30, 2020; 4,910,992 shares as of December 31, 2019	(50,252)	(35,900)
Accumulated deficit	(1,427,315)	(1,411,177)
Total stockholders' equity	602,763	608,263
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 914,869	$ 882,209

See notes to condensed consolidated financial statements.

AMARIN CORPORATION PLC
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited, in thousands, except per share amounts)

	Three months ended June 30,		Six months ended June 30,	
	2020	2019	2020	2019
Product revenue, net	$ 133,724	$ 100,366	$ 285,928	$ 173,097
Licensing and royalty revenue	1,593	426	4,382	973
Total revenue, net	135,317	100,792	290,310	174,070
Less: Cost of goods sold	28,797	22,770	63,604	39,910
Gross margin	106,520	78,022	226,706	134,160
Operating expenses:				
Selling, general and administrative	92,395	73,406	226,332	145,039
Research and development	9,969	7,130	20,247	14,372
Total operating expenses	102,364	80,536	246,579	159,411
Operating income (loss)	4,156	(2,514)	(19,873)	(25,251)
Interest income (expense), net	151	789	1,359	(908)
Other income (expense), net	108	(95)	17	(92)
Income (loss) from operations before taxes	4,415	(1,820)	(18,497)	(26,251)
Income tax benefit	—	—	2,359	—
Net income (loss)	$ 4,415	$ (1,820)	$ (16,138)	$ (26,251)
Earnings (loss) per share:				
Basic	$ 0.01	$ (0.01)	$ (0.04)	$ (0.08)
Diluted	$ 0.01	$ (0.01)	$ (0.04)	$ (0.08)
Weighted average shares:				
Basic	384,663	330,863	373,300	329,793
Diluted	399,664	330,863	373,300	329,793

See notes to condensed consolidated financial statements.

AMARIN CORPORATION PLC
CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY
(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, 2019	**289,317,460**	**365,014,893**	**(4,910,992)**	**$ 21,850**	**$ 269,173**	**$ 1,764,317**	**$ (35,900)**	**$ (1,411,177)**	**$ 608,263**
Exercise of stock options	—	412,465	—	—	269	1,037	—	—	1,306
Vesting of restricted stock units	—	1,951,448	(759,832)	—	1,274	(1,274)	(13,831)	—	(13,831)
Stock-based compensation	—	—	—	—	—	10,591	—	—	10,591
Net Loss	—	—	—	—	—	—	—	(20,553)	(20,553)
March 31, 2020	**289,317,460**	**367,378,806**	**(5,670,824)**	**$ 21,850**	**$ 270,716**	**$ 1,774,671**	**$ (49,731)**	**$ (1,431,730)**	**$ 585,776**
Issuance of common stock under employee stock purchase plan	—	123,608	—	—	76	772	—	—	848
Conversion of Series A Convertible Preferred Stock, net	(237,713,680)	23,771,368	—	(14,684)	14,684	(238)	—	—	(238)
Exercise of stock options	—	148,290	—	—	92	260	—	—	352
Vesting of restricted stock units	—	167,240	(70,971)	—	104	(104)	(521)	—	(521)
Stock-based compensation	—	—	—	—	—	12,131	—	—	12,131
Net Income	—	—	—	—	—	—	—	4,415	4,415
June 30, 2020	**51,603,780**	**391,589,312**	**(5,741,795)**	**$ 7,166**	**$ 285,672**	**$ 1,787,492**	**$ (50,252)**	**$ (1,427,315)**	**$ 602,763**

	Preferred Shares	Common Shares	Treasury Shares	Preferred Stock	Common Stock	Additional Paid-in Capital	Treasury Stock	Accumulated Deficit	Total
December 31, 2018	**289,317,460**	**329,110,863**	**(3,260,850)**	**$ 21,850**	**$ 246,663**	**$ 1,282,762**	**$ (10,413)**	**$ (1,388,532)**	**$ 152,330**
Exercise of stock options	—	3,838,739	—	—	2,496	12,960	—	—	15,456
Vesting of restricted stock units	—	1,416,124	(526,708)	—	929	(929)	(9,080)	—	(9,080)
Stock-based compensation	—	—	—	—	—	6,596	—	—	6,596
Net Loss	—	—	—	—	—	—	—	(24,431)	(24,431)
March 31, 2019	**289,317,460**	**334,365,726**	**(3,787,558)**	**$ 21,850**	**$ 250,088**	**$ 1,301,389**	**$ (19,493)**	**$ (1,412,963)**	**$ 140,871**
Issuance of common stock under employee stock purchase plan	—	47,358	—	—	30	807	—	—	837
Exercise of stock options	—	619,404	—	—	396	1,492	—	—	1,888
Vesting of restricted stock units	—	116,937	(54,057)	—	74	(74)	(1,040)	—	(1,040)
Stock-based compensation	—	—	—	—	—	8,351	—	—	8,351
Net Loss	—	—	—	—	—	—	—	(1,820)	(1,820)
June 30, 2019	**289,317,460**	**335,149,425**	**(3,841,615)**	**$ 21,850**	**$ 250,588**	**$ 1,311,965**	**$ (20,533)**	**$ (1,414,783)**	**$ 149,087**

See notes to condensed consolidated financial statements.

AMARIN CORPORATION PLC
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited, in thousands)

	Six months ended June 30,	
	2020	**2019**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (16,138)	$ (26,251)
Adjustments to reconcile loss to net cash provided by (used in) operating activities:		
Depreciation and amortization	296	6
Amortization of investments	33	—
Stock-based compensation	22,722	14,766
Amortization of debt discount and debt issuance costs	490	878
Amortization of intangible asset	720	323
Changes in assets and liabilities:		
Accounts receivable, net	(8,555)	(28,875)
Inventory	(48,075)	11,534
Prepaid and other current assets	(10,273)	(4,158)
Other long-term assets	—	(928)
Interest receivable	(1,312)	—
Accrued interest payable	(240)	(81)
Deferred revenue	(633)	(973)
Accounts payable and other current liabilities	65,530	14,765
Other long-term liabilities	1,159	(3,186)
Net cash provided by (used in) operating activities	5,724	(22,180)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Sale and maturities of securities	131,440	—
Purchases of securities	(527,479)	—
Purchases of furniture, fixtures and equipment	(251)	(801)
Net cash used in investing activities	(396,290)	(801)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock, net of transaction costs	848	837
Proceeds from exercise of stock options, net of transaction costs	1,658	17,344
Payment of transaction costs for conversion of preferred stock	(238)	—
Payment on debt from royalty-bearing instrument	(27,925)	(12,533)
Taxes paid related to stock-based awards	(14,352)	(10,120)
Net cash used in financing activities	(40,009)	(4,472)
NET DECREASE IN CASH AND CASH EQUIVALENTS AND RESTRICTED CASH	(430,575)	(27,453)
CASH AND CASH EQUIVALENTS AND RESTRICTED CASH, BEGINNING OF PERIOD	648,495	250,727
CASH AND CASH EQUIVALENTS AND RESTRICTED CASH, END OF PERIOD	$ 217,920	$ 223,274
Supplemental disclosure of cash flow information:		
Cash paid during the year for:		
Interest	$ 1,193	$ 14,982
Income taxes	$ 20	$ 71
Supplemental disclosure of non-cash transactions:		
Initial recognition of operating lease right-of-use asset	$ —	$ 8,995

See 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, or Amarin, or the Company, is a pharmaceutical company focused on the commercialization and development of therapeutics to improve cardiovascular health and reduce cardiovascular risk.

The Company’s lead product, VASCEPA® (icosapent ethyl), was first approved by the U.S. Food and Drug Administration, or FDA, in July 2012 for use as an adjunct to diet to reduce triglyceride, or TG, levels in adult patients with severe ($\geq$500 mg/dL) hypertriglyceridemia. On December 13, 2019, the FDA approved a new indication and label expansion for VASCEPA based on the landmark results of our cardiovascular outcomes trial, REDUCE-IT®, or Reduction of Cardiovascular Events with EPA – Intervention Trial. VASCEPA is the first and only drug approved by the FDA as an adjunct to maximally tolerated statin therapy for reducing persistent cardiovascular risk in select high risk patients. VASCEPA is available in the United States, or the U.S., 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. VASCEPA is also available for sale by prescription only in Canada, Lebanon and the United Arab Emirates through collaborations and is also in development in other jurisdictions.

The Company, since inception, has devoted substantial resources to research and development efforts, most significantly, the development and conduct of a long-term cardiovascular outcomes study of VASCEPA, REDUCE-IT. The Company announced topline results from REDUCE-IT on September 24, 2018. On November 10, 2018, the Company presented primary results of REDUCE-IT at the 2018 Scientific Sessions of the American Heart Association, or AHA, and the results were concurrently published in *The New England Journal* of *Medicine*. REDUCE-IT met its primary endpoint demonstrating a 25% relative risk reduction, or RRR, to a high degree of statistical significance ($p<0.001$), in first occurrence of major adverse cardiovascular events, or MACE, in the intent-to-treat patient population with use of VASCEPA 4 grams/day as compared to placebo. REDUCE-IT also showed a 26% RRR in its key secondary composite endpoint of cardiovascular death, heart attacks and stroke ($p<0.001$). On March 18, 2019, the Company publicly presented the total cardiovascular events results, and the method of calculating such events, of the REDUCE-IT study at the American College of Cardiology’s, or ACC, 68th Annual Scientific Session and such results and methods were concurrently published in the *Journal of the American College of Cardiology.*

The FDA granted Priority Review designation to the Company’s March 2019 supplemental new drug application, or sNDA, seeking an expanded indication for VASCEPA in the United States based on the positive results of the REDUCE-IT study. In November 2019, the FDA held an Endocrinologic and Metabolic Drugs Advisory Committee, or EMDAC, meeting to review the REDUCE-IT sNDA. The EMDAC voted unanimously (16-0) to recommend approval of an indication and label expansion for VASCEPA to reduce cardiovascular events in high-risk patients based on the REDUCE-IT results. On December 13, 2019, the FDA approved a new indication and related label expansion based on REDUCE-IT. Reflecting the robust results of the clinical development program for VASCEPA, no additional post-approval clinical study or other special post-approval requirement (as often seen with other drug approvals) was requested by the FDA in conjunction with its approval of VASCEPA.

In the United States, 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 in the United States through its direct sales force. Prior to the REDUCE-IT results topline announcement in September 2018, the Company’s commercialization of VASCEPA was somewhat limited. Subsequent to learning the positive cardiovascular outcomes results of the REDUCE-IT study, the Company increased its promotional efforts. Based on the positive REDUCE-IT results, in early 2019, the Company increased the size of its sales force to approximately 440 sales professionals, including approximately 400 sales representatives. As a result of the FDA’s newly approved indication and label expansion, in early 2020 the Company completed the expansion of its direct sales force to approximately 900 sales professionals, including 800 sales representatives. In addition to promotion of VASCEPA in the United States, based on REDUCE-IT, the Company has increased focus on expansion of the Company’s development efforts for VASCEPA to major markets outside the United States. The Company currently has strategic collaborations to develop and commercialize VASCEPA in select territories outside the United States. The Company operates in one business segment.

On March 30, 2020, the United States District Court for the District of Nevada, or the Nevada Court, ruled in favor of two generic companies in Amarin’s patent litigation related to its abbreviated new drug applications, or ANDAs, that seek FDA approval for sale of generic versions of VASCEPA. On May 22, 2020, one of the two generic companies, Hikma Pharmaceutical USA Inc., or Hikma, received FDA approval to market its generic version of VASCEPA. To date, Hikma has not launched a generic version of VASCEPA. The Company disagrees with the Nevada Court’s decision that its patents are invalid and is vigorously pursuing an appeal. If generic

companies determine to launch generic versions of icosapent ethyl in the United States, such competition could have a material and adverse impact on our revenues and our operations.

VASCEPA is not yet known to most healthcare professionals and generics companies rarely invest in product or disease state related market education. Furthermore, VASCEPA is relatively expensive to manufacture and already sold at an affordable price as documented by third-party analysis such that saving, if any, on the price of generic VASCEPA is likely to come at the expense of reduced market education and development. Thus, the Company believes that the launch of a generic version of VASCEPA in the United States at this early stage in the life cycle of VASCEPA is potentially harmful to patient care and discourages new product development, including for identifying and pursuing additional indications that could be treated with VASCEPA.

Geographies outside the United States in which VASCEPA is sold and under regulatory review are not subject to this U.S. patent litigation and judgment. No similar litigation involving potential generic versions of VASCEPA is pending outside the United States. VASCEPA is currently available by prescription in Canada, Lebanon and the United Arab Emirates. In Canada, VASCEPA has the benefit of eight years of data protection afforded through Health Canada (until the end of 2027), in addition to separate patent protection with expiration dates that could extend into 2039. Amarin is pursuing additional regulatory approvals for VASCEPA in Europe, China and the Middle East. In China and the Middle East, Amarin is pursuing such regulatory approvals and subsequent commercialization of VASCEPA with commercial partners. In Europe, Amarin is preparing to self-launch VASCEPA, although it may engage commercialization partners for certain of the smaller countries of Europe. Ten to eleven years of market protection is anticipated due to regulatory exclusivity in the European Union subject to an approval recommendation by the European Medicines Agency, or EMA, in early 2021 and associated European Community, or EC, approval expected promptly thereafter, in addition to pending patent protection that could extend into 2039.

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 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, 2019, or the 2019 Form 10-K, filed with the SEC. The balance sheet amounts at December 31, 2019 in this report were derived from the Company's audited 2019 consolidated financial statements included in the 2019 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, or GAAP, requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. The results of operations for the three and six months ended June 30, 2020 are not necessarily indicative of the results for the entire fiscal year or any future period. Certain numbers presented throughout this document may not add precisely to the totals provided due to rounding. Absolute and percentage changes are calculated using the underlying amounts in thousands. The 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.

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 well as the current global pandemic, COVID-19.

As of June 30, 2020, the Company had Current assets of $827.6 million, including Cash and cash equivalents of $214.0 million, Short-term investments of $336.3 million, Accounts receivable, net, of $125.0 million and Inventory of $124.8 million. In addition, as of June 30, 2020, the Company has Long-term investments of $61.0 million. The Company's condensed consolidated balance sheets also include a royalty-bearing instrument which is expected to be fully paid during 2020 based on projected VASCEPA net revenues. As of June 30, 2020, the Company had no other debt outstanding.

(2) Significant Accounting Policies

Revenue Recognition

In accordance with Accounting Standards Codification, or ASC, Topic 606, *Revenue from Contracts with Customers*, the Company 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.

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. All customer accounts are actively managed and no losses in excess of amounts reserved are currently expected; however, the Company is monitoring the potential negative impact of COVID-19 on the Company's customers' ability to meet their financial obligations.

The following table summarizes the impact of accounts receivable reserves on the gross trade accounts receivable balances as of June 30, 2020 and December 31, 2019:

In thousands	June 30, 2020	December 31, 2019
Gross trade accounts receivable	$ 173,186	$ 149,567
Trade allowances	(36,826)	(29,261)
Chargebacks	(10,430)	(3,876)
Allowance for doubtful accounts	(945)	—
Accounts receivable, net	$ 124,985	$ 116,430

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.

Income Taxes

Deferred tax assets and liabilities are recognized for the future tax consequences of differences between the carrying amounts and tax bases of assets and liabilities and operating loss carryforwards and other tax 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 sheet.

The Company provides reserves for potential payments of tax to various tax authorities and 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 income tax provision, as applicable.

The Company regularly assesses its ability to realize deferred tax assets. Changes in historical earnings performance, future earnings projections, and changes in tax laws, 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 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, including the Internal Revenue Service, or IRS, and states. The IRS began an examination of the Company's 2018 U.S. income tax return in the first quarter of 2020. 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 this audit will have a material adverse effect on its consolidated financial position or results of operations.

Earnings (Loss) per Share

Basic net earnings (loss) per share is determined by dividing net income (loss) by the weighted average shares of common stock outstanding during the period. Diluted net earnings (loss) per share is determined by dividing net income (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 preferred stock 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 income position for the three months ended June 30, 2020 and therefore the two-class method must be applied for this period by allocating all earnings during the period to common shares and preferred stock based on their contractual entitlements assuming all earnings are distributed. The Company is in a net loss position for all other periods presented below and is therefore not required to apply the two-class method for those other periods.

The calculation of net income (loss) and the number of shares used to compute basic and diluted net earnings (loss) per share for the three and six months ended June 30, 2020 and 2019 are as follows:

	Three months ended June 30,		Six months ended June 30,	
In thousands	2020	2019	2020	2019
Net income (loss)—basic and diluted	$ 4,415	$ (1,820)	$ (16,138)	$ (26,251)
Weighted average shares outstanding—basic	384,663	330,863	373,300	329,793
Effect of dilutive securities:				
Stock options	6,372	—	—	—
Restricted stock and restricted stock units	1,640	—	—	—
Preferred stock, if converted	6,989	—	—	—
Weighted average shares outstanding—diluted	399,664	330,863	373,300	329,793
Net income (loss) per share—basic	$ 0.01	$ (0.01)	$ (0.04)	$ (0.08)
Net income (loss) per share—diluted	$ 0.01	$ (0.01)	$ (0.04)	$ (0.08)

For the three and six months ended June 30, 2020 and 2019, the following potentially dilutive securities were not included in the computation of net earnings (loss) per share because the effect would be anti-dilutive or because performance criteria were not yet met for awards contingent upon such measures:

In thousands	Three months ended June 30, 2020	Three months ended June 30, 2019	Six months ended June 30, 2020	Six months ended June 30, 2019
Stock options	6,131	16,585	17,178	16,585
Restricted stock and restricted stock units	4,842	9,315	7,572	9,315
Preferred stock, if converted	—	28,932	5,160	28,932

Stock options are anti-dilutive during periods of net earnings when the exercise price of the stock options exceeds the market price of the underlying shares on the last day of the reporting period. Restricted stock and restricted stock units are anti-dilutive during periods of net earnings when underlying performance-based vesting requirements were not achieved as of the last day of the reporting period.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to credit risk consist primarily of cash and cash equivalents, short-term and long-term investments, and accounts receivable. The Company maintains substantially all of its cash and cash equivalents, and short-term and long-term investments, 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 25%, 37%, and 29%, respectively, of gross product sales for the six months ended June 30, 2020, and represented 32%, 38%, and 23%, respectively, of the gross accounts receivable balance as of June 30, 2020. Customers A, B, and C accounted for 24%, 37%, and 29%, respectively, of gross product sales for the six months ended June 30, 2019 and represented 38%, 32%, and 22%, respectively, of the gross accounts receivable balance as of June 30, 2019. The Company has not experienced any significant write-offs of its accounts receivable. All customer accounts are actively managed and no losses in excess of amounts reserved are currently expected; however, the Company is monitoring the potential negative impact of COVID-19 on the Company's customers' ability to meet their financial obligations.

Concentration of Suppliers

The Company has contractual freedom to source the API for VASCEPA and to procure other services supporting its supply chain 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 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 disruption or termination of the Company's current supply chain, including as a result of COVID-19, or the Company's 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 multiple independent FDA-approved API manufacturers and several independent FDA-approved API encapsulators and packagers for VASCEPA manufacturing. Each of these companies has qualified and validated 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 manufacture VASCEPA or VASCEPA API will remain qualified to do so to the Company's specifications or that these and any future suppliers will have the manufacturing capacity to meet anticipated demand for VASCEPA.

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 estimated fair value of the Company's assets and liabilities as of June 30, 2020 and December 31, 2019 and indicate the fair value hierarchy of the valuation techniques the Company utilized to determine such fair value:

	June 30, 2020			
In thousands	Total	Level 1	Level 2	Level 3
Asset:				
Money Market Fund	$ 78,795	$ 78,795	$ —	$ —
U.S. Treasury Shares	65,626	65,626	—	—
Corporate Bonds	231,022	—	231,022	—
Commercial Paper	102,281	—	102,281	—
Repo Securities	12,000	—	12,000	—
Asset Backed Securities	11,605	—	11,605	—
Certificate of Deposit	6,121	—	6,121	—
Agency Securities	4,925	—	4,925	—
Total	$ 512,375	$ 144,421	367,954	$ —

	December 31, 2019			
In thousands	Total	Level 1	Level 2	Level 3
Asset:				
Money Market Fund	$ 10,078	$ 10,078	$ —	$ —

The carrying amount of the Company's cash and cash equivalents approximates fair value because of their short-term nature. The cash and cash equivalents consists of cash, deposits with banks and short-term highly liquid money market instruments with remaining maturities at the date of the purchase of 90 days or less.

The Company's held-to-maturity investments are stated at amortized cost, which approximates fair value. The Company does not intend to sell these investment securities and the contractual maturities are not greater than 24 months. Those with maturities greater than 90 days and less than twelve months are included in short-term investments on its condensed consolidated balance sheet. Those with remaining maturities in excess of twelve months are included in long-term investments on its condensed consolidated balance sheet.

Unrealized gains or losses on held-to-maturity securities are not recognized until maturity, except other-than-temporary unrealized losses which are recognized in earnings in the period incurred. The Company evaluates securities with unrealized losses to determine whether such losses are other than temporary. Interest on investments is reported in interest income. The unrealized gain for the six months ended June 30, 2020 and 2019 was $1.3 million and nil, respectively.

The carrying amounts of accounts payable and accrued liabilities approximate fair value because of their short-term nature. The carrying amounts and the estimated fair values of debt from royalty-bearing instrument as of June 30, 2020 and December 31, 2019 are as follows:

	June 30, 2020		December 31, 2019	
In thousands	Carrying Value	Estimated Fair Value	Carrying Value	Estimated Fair Value
Debt from royalty-bearing instrument	$ 22,266	$ 22,500	$ 49,702	$ 50,400

The estimated fair value of the debt from royalty-bearing instrument is calculated utilizing the same Level 3 inputs utilized in valuing the related derivative liability (see Derivative Liabilities below). The carrying value of the debt from royalty-bearing instrument is net of the unamortized debt discounts and issuance costs as of both June 30, 2020 and December 31, 2019. The carrying value of the debt from the royalty-bearing instrument as of June 30, 2020 approximates fair value because the instrument is expected to be fully paid during 2020 based on projected VASCEPA net revenues.

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 June 30, 2020, 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 1.4 and 6.8 years, (ii) coupon rates of between 6.0% and 11.5% and (iii) market yields of between 6.1% and 17.6%. As of December 31, 2019, 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 1.9 and 7.3 years, (ii) coupon rates of between 6.0% and 11.5% and (iii) market yields of between 5.2% and 16.8%. As such, the Company recognized no gain or loss on change in fair value of derivative liability for the six months ended June 30, 2020 and 2019.

Certain changes in the assumptions used to value the derivative liability, including the probability of a change in control, could potentially result in a change to the carrying value of such liability. Because the remaining amount due from this royalty-bearing instrument is fixed and anticipated to be fully paid before the end of 2020, any change in the value of this derivative liability will not have any impact on the Company's aggregate cash payment obligation from this instrument regardless of any potential change in the carrying value of such liability.

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 November 2018, the FASB issued ASU No. 2018-18, Collaborative Arrangements (Topic 808), Clarifying the Interaction between Topic 808 and Topic 606, which clarified that in collaborative arrangements where the counterparty is a customer for a good or service that is a distinct unit of account is required to be accounted for under ASC 606. The Company adopted this standard effective January 1, 2020, which did not have an impact on the Company's condensed consolidated financial statements.

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 Company adopted this standard effective January 1, 2020, which did not have a material impact on the Company's condensed consolidated financial statements.

In June 2016, the FASB issued ASU No. 2016-13, Financial Instruments – Credit Losses (Topic 326), Measurement of Credit Losses on Financial Instruments, which requires earlier recognition of credit losses on loans and other financial instruments held by entities, including trade receivables. The new standard requires entities to measure all expected credit losses for financial assets held at each reporting date based on historical experience, current conditions, and reasonable and supportable forecasts. The Company adopted this standard effective January 1, 2020, which did not have a material impact on the Company's condensed consolidated financial statements.

The Company also considered the following recent accounting pronouncement which was not yet adopted as of June 30, 2020:

In December 2019, the FASB issued ASU No. 2019-12, Income Taxes (Topic 740), Simplifying the Accounting for Income Taxes, which simplifies the accounting for income taxes by eliminating certain exceptions to the guidance in ASC 740 related to the approach for intraperiod tax allocation, the methodology for calculating income taxes in an interim period, the recognition of deferred tax liabilities for outside basis differences, among other simplifications. The new guidance is effective for fiscal years beginning after December 15, 2020, including interim periods within those fiscal years. Early adoption of all amendments in the same period is permitted. The Company is currently evaluating the impact that this standard will have on the Company's condensed consolidated financial statements.

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 condensed 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. Upon approval by FDA on December 13, 2019 of a new indication of VASCEPA, a milestone for £5 million was achieved, which resulted in the Intangible asset increasing by $8.5 million. The Intangible asset has an estimated weighted-average remaining useful life of 10.1 years. The carrying value as of June 30, 2020 and December 31, 2019 is as follows:

In thousands	June 30, 2020	December 31, 2019
Technology rights	$ 20,081	$ 20,081
Accumulated amortization	(5,543)	(4,823)
Intangible asset, net	$ 14,538	$ 15,258

(4) Inventory

The Company capitalizes its purchases of saleable inventory of VASCEPA from suppliers that have been qualified by the FDA. Inventories as of June 30, 2020 and December 31, 2019 consist of the following:

In thousands	June 30, 2020	December 31, 2019
Raw materials	$ 29,122	$ 19,455
Work in process	30,056	12,031
Finished goods	65,666	45,283
Total inventory	$ 124,844	$ 76,769

(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 June 30, 2020, the remaining amount to be repaid to CPPIB is $23.0 million. During the three and six months ended June 30, 2020, the Company made repayments under the agreement of $15.2 million and $29.4 million, respectively, to CPPIB and an additional $13.4 million is scheduled to be paid in August 2020 for the second quarter of 2020. These payments, as well as additional quarterly repayments scheduled in the future, are calculated as 10% of VASCEPA net product revenues. All such payments reduce the remainder of the $150.0 million in aggregate payments to CPPIB. Except upon a change of control in Amarin, the agreement does not expire until $150.0 million in aggregate has been repaid. The Company can prepay the net remaining amount at any time.

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 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 six months ended June 30, 2020 and 2019.

As of June 30, 2020 and December 31, 2019, the carrying value of the royalty-bearing instrument, net of the unamortized debt discount and issuance costs, was $22.3 million and $49.7 million, respectively. During the six months ended June 30, 2020, the Company recorded cash and non-cash interest expense of $1.3 million and $0.5 million, respectively, in connection with the royalty-bearing instrument. During the six months ended June 30, 2019, the Company recorded $2.4 million and $0.9 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.

(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. Refer to Item 1 Legal Proceedings of this Quarterly Report on Form 10-Q below for a discussion of the Company's current legal proceedings.

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.

These agreements include 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.

Pursuant to the supply agreements, there is a total of approximately $146.0 million that is potentially payable over the term of such agreements based on minimum purchase obligations. The Company continues to meet its contractual purchase obligations.

Under the 2004 share repurchase agreement with Laxdale Limited or 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 $9.2 million as of June 30, 2020). Also under the Laxdale agreement, upon receipt of a marketing approval in 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 $6.2 million as of June 30, 2020) for the potential market approval.

The Company has no provision for any of the obligations above since the amounts are either not paid or payable as of June 30, 2020.

(7) Equity

Preferred Stock

On March 5, 2015, the Company entered into a subscription agreement with four institutional investors, or 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, or 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, or 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 9.9% (increased from 4.99% effective March 2020) of the total number of Amarin ordinary shares or ADSs outstanding following such redesignation, or 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.

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, or 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, or 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.

During April 2020, at the request of certain holders, 237,713,680 Series A Preference Shares were consolidated and redesignated, resulting in the issuance of 23,771,368 ordinary shares. As of June 30, 2020, a total of 300,547,010 Series A Preference Shares had been consolidated and redesignated at the request of holders, resulting in the issuance of 30,054,701 ADSs, such that a maximum of 5,160,378 ordinary shares remained issuable upon future consolidation and redesignation of the remaining Series A Preference Shares as of June 30, 2020, subject to certain adjustments for dilutive events.

During July 2020, at the request of certain holders, 27,753,000 Series A Preference Shares were consolidated and redesignated, resulting in the issuance of 2,775,300 ordinary shares. Following this consolidation and redesignation of these shares in July 2020, a maximum of 2,385,078 ordinary shares remain issuable upon future consolidation and redesignation of the remaining Series A Preference Shares, subject to certain adjustments for dilutive events.

Common Stock

On March 16, 2020, the Company's Board of Directors, upon the recommendation of the Remuneration Committee and based on input from Radford, part of the Rewards Solutions practice of Aon Plc, as independent external compensation consultants to the Company's Remuneration Committee, adopted, subject to shareholder approval, the Amarin Corporation plc 2020 Stock Incentive Plan, or the 2020 Plan, which was subsequently approved by the Company's shareholders on July 13, 2020 at the Annual General Meeting of Shareholders. The 2020 Plan is intended to be the successor to the Amarin Corporation plc 2011 Stock Option Plan, as amended, or the 2011 Plan, which was set to expire on July 12, 2021. The maximum number of the Company's ordinary shares of £0.50 each or equivalent ADSs to be issued under the 2020 Plan shall not exceed the sum of (i) 20,000,000 shares and (ii) the number

of shares that remain available for grant under the 2011 Plan as of the date the 2020 Plan is approved by the Company's shareholders. The number of shares remaining under the 2011 Plan is approximately 2,634,440. The award of stock options (both incentive and non-qualified stock options), restricted stock units, and certain limited unrestricted share awards are permitted. The 2020 Plan will be administered by the Remuneration Committee of the Board of Directors and will expire on July 13, 2030.

During the six months ended June 30, 2020 and 2019, in addition to ordinary shares issued as described in *Preferred Stock* above and in *Incentive Equity Awards* below, the Company issued 123,608 and 47,358 ordinary shares, respectively, under the Amarin Corporation plc 2017 Employee Stock Purchase Plan.

Incentive Equity Awards

As of June 30, 2020, there were an aggregate of 17,177,729 stock options and 7,571,974 restricted stock units, or RSUs, outstanding under the 2011 Plan representing approximately 4% and 2%, respectively, of outstanding shares (including common and preferred shares) on a fully diluted basis.

During the six months ended June 30, 2020 and 2019, the Company issued 560,755 and 4,458,143 common shares, respectively, as a result of the exercise of stock options, resulting in gross and net proceeds of $1.7 million during the six months ended June 30, 2020 and $17.4 million during the six months ended June 30, 2019.

During the six months ended June 30, 2020 and 2019, the Company issued 1,143,934 and 1,533,061 common shares, respectively, related to the vesting of RSUs, of which 418,847 and 580,765 shares, respectively, were retained as treasury shares as settlement of employee tax obligations. During the six months ended June 30, 2020, in connection with the achievement of certain regulatory and sales performance conditions associated with the REDUCE-IT clinical trial and subsequent revenue growth, the Company issued 974,754 common shares upon vesting of performance-based RSUs granted in 2017 and 2018, of which 411,956 shares were retained as treasury shares as settlement of employee tax obligations. These performance-based RSUs will continue to vest ratably monthly through August 2021.

On June 1, 2020, the Company granted a total of 782,520 RSUs to employees under the 2011 Plan. The RSUs vest quarterly over a three-year period.

On March 2, 2020 and February 3, 2020, the Company granted a total of 821,950 RSUs and 1,875,000 stock options, respectively, to employees under the 2011 Plan. The RSUs vest annually over a three-year period and the stock options vest quarterly over a four-year period. Also on February 3, 2020, the Company granted a total of 1,253,400 RSUs to employees under the 2011 Plan that vest upon the achievement of specified sales performance conditions.

On May 20, 2019, the Company granted a total of 45,163 RSUs and 58,721 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.

Also on May 20, 2019, the Company granted an additional 20,000 RSUs to employees under the 2011 Plan that vest upon the achievement of a specified sales performance condition.

On February 1, 2019, the Company granted a total of 757,800 RSUs and 1,193,400 stock options to employees under the 2011 Plan. The RSUs vest annually over a three-year period and the stock options vest quarterly over a four-year period. Also on February 1, 2019, the Company granted a total of 580,000 RSUs to employees under the 2011 Plan that vest upon the achievement of a specified sales performance condition.

(8) Co-Promotion Agreement

On March 31, 2014, the Company entered into a Co-Promotion Agreement, or the Agreement, with Kowa Pharmaceuticals America, Inc. related to the commercialization of VASCEPA capsules in the United States. Under the terms of the Agreement, the Company 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 Agreement was amended on July 25, 2017 to reflect evolving promotional needs, including refinement of target lists. The Company and Kowa Pharmaceuticals America, Inc. intentionally designed the co-promotion to naturally end as of December 31, 2018 and mutually agreed not to renew the agreement.

During 2018, which was the last year of the Agreement, as amended, the Company incurred expense for co-promotion tail payments which are calculated as a percentage of the 2018 co-promotion fee, which was eighteen and a half percent (18.5%) of VASCEPA gross margin. The accrued tail payments are paid over three years with declining amounts each year. Kowa Pharmaceuticals America, Inc. is eligible to receive $17.8 million in co-promotion tail payments, the present value of which $16.6 million, was fully accrued as of December 31, 2018.

As of June 30, 2020 and December 31, 2019, a net payable to Kowa Pharmaceuticals America, Inc. of $6.5 million and $10.0 million, respectively, of which $4.6 million and $6.5 million, respectively, was classified as current on the condensed consolidated balance sheets, representing co-promotion fees, including accrual of the tail payments, net of reimbursable amounts incurred for samples and other marketing expenses.

(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 the 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 six months ended June 30, 2020 and 2019:

In thousands	Trade Allowances	Rebates, Chargebacks and Discounts	Product Returns	Other Incentives	Total
Balance as of December 31, 2019	**$ 29,261**	**$ 90,997**	**$ 4,579**	**$ 3,720**	**$ 128,557**
Provision related to current period sales	59,829	266,823	1,589	33,743	361,984
Provision related to prior period sales	—	(3,872)	—	—	(3,872)
Credits/payments made for current period sales	(23,197)	(152,965)	—	(29,897)	(206,059)
Credits/payments made for prior period sales	(29,067)	(85,622)	(191)	(3,721)	(118,601)
Balance as of June 30, 2020	**$ 36,826**	**$ 115,361**	**$ 5,977**	**$ 3,845**	**$ 162,009**

In thousands	Trade Allowances	Rebates, Chargebacks and Discounts	Product Returns	Other Incentives	Total
Balance as of December 31, 2018	**$ 19,495**	**$ 41,634**	**$ 2,948**	**$ 1,167**	**$ 65,244**
Provision related to current period sales	37,545	164,871	987	18,625	222,028
Provision related to prior period sales	—	—	—	—	—
Credits/payments made for current period sales	(19,203)	(98,452)	5	(16,687)	(134,337)
Credits/payments made for prior period sales	(19,325)	(41,363)	(471)	(1,199)	(62,358)
Balance as of June 30, 2019	**$ 18,512**	**$ 66,690**	**$ 3,469**	**$ 1,906**	**$ 90,577**

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

Licensing Revenue

The Company enters into licensing agreements which are within the scope of Topic 606, 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 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., or 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, or 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. 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.

In January 2020, we achieved certain milestones under the agreement, resulting in payment of $1.0 million to Mochida, which was recorded as Research and development expense on the condensed consolidated statement of operations.

Out-licenses

Eddingpharm (Asia) Macao Commercial Offshore Limited

In February 2015, the Company entered into a Development, Commercialization and Supply Agreement, or the DCS Agreement, with Eddingpharm (Asia) Macao Commercial Offshore Limited, or 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, or 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, and (3) ongoing development and regulatory assistance. 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 are 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 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 six months ended June 30, 2020 and 2019, the Company recognized $1.6 million and less than $0.1 million, respectively, as licensing revenue related to the up-front and milestone payments received in connection with the Eddingpharm agreement. From contract inception through June 30, 2020 and December 31, 2019, the Company recognized $4.6 million and $3.0 million, respectively, as licensing revenue under the DCS Agreement concurrent with the support provided by Amarin to Eddingpharm in achieving the combined development and regulatory performance obligation, which in the Company's judgment is the best measure of progress towards satisfying this performance obligation. The remaining transaction price of $11.3 million and $13.0 million is recorded in deferred revenue as of June 30, 2020 and December 31, 2019, respectively, on the condensed consolidated balance sheets and will be recognized as revenue over the remaining period of 14 years.

Biologix FZCo

In March 2016, the Company entered into an agreement with Biologix FZCo, or 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. VASCEPA was launched in Lebanon in June 2018 and in United Arab Emirates in February 2019, respectively.

The Company recognized net product revenue of nil and $0.3 million for the six months ended June 30, 2020 and 2019, respectively.

HLS Therapeutics, Inc.

In September 2017, the Company entered into an agreement with HLS Therapeutics Inc., or HLS, a company incorporated under the laws of Canada, to register, commercialize and distribute VASCEPA in Canada. Under the agreement, HLS is 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 received a non-refundable $2.5 million milestone payment. Following approval from Health Canada in December 2019, the Company received a non-refundable milestone payment of $2.5 million in February 2020. In addition, in January 2020 HLS obtained regulatory exclusivity from the Office of Patented Medicines and Liaison, or OPML, as a result the Company received a non-refundable $3.8 million milestone payment. In addition to the non-refundable, up-front and regulatory milestone payments just described, the Company is entitled to receive certain sales-based milestone payments of up to an additional $50.0 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, and (3) participate in various steering committees. 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, the $2.5 million milestone related to the achievement of the REDUCE-IT trial primary endpoint, the $2.5 million milestone related to obtaining approval from Health Canada and $3.8 million milestone related to obtaining regulatory exclusivity from the OPML. Any consideration related to sales-based milestones (including royalties) will be recognized when the related sales occur 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 six months ended June 30, 2020 and 2019, the Company recognized $2.7 million and $0.8 million, respectively, as licensing revenue related to up-front and milestone payments received in connection with the HLS agreement. From the contract's inception through June 30, 2020 and December 31, 2019, the Company has recognized $5.6 million and $2.9 million, respectively, as licensing revenue is recognized under the agreement concurrent with the support provided by Amarin to HLS in achieving this performance obligation, which in the Company's judgment is the best measure of progress towards satisfying the combined development and regulatory performance obligation. The remaining transaction price of $8.1 million and $7.1 million is recorded in deferred revenue as of June 30, 2020 and December 31, 2019, respectively, on the condensed consolidated balance sheets and will be recognized as revenue over the remaining period of 10 years.

The Company recognized net product revenue of $1.8 million and nil for the three months ended June 30, 2020 and 2019, respectively, and $8.5 million and nil for the six months ended June 30, 2020 and 2019, respectively.

The following table presents changes in the balances of the Company's contract assets and liabilities during the six months ended June 30, 2020 and 2019:

In thousands	Balance at Beginning of Period	Additions	Deductions	Balance at End of Period
Six months ended June 30, 2020:				
Contract assets	$ —	$ —	$ —	$ —
Contract liabilities:				
Deferred revenue	$ 20,846	$ 3,750	$ (4,382)	$ 20,213
Six months ended June 30, 2019:				
Contract assets	$ —	$ —	$ —	$ —
Contract liabilities:				
Deferred revenue	$ 20,710	$ —	$ (973)	$ 19,737

During the six months ended June 30, 2020 and 2019 date, 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	Six Months Ended June 30,	
Revenue recognized in the period from:	2020	2019
Amounts included in contract liability at the beginning of the period	$ 2,845	$ 973
Performance obligations satisfied in previous periods	$ 1,097	$ —

(11) Leases

The Company leases office space under operating leases. The lease liability is initially measured at the present value of the lease payments to be made over the lease term. Lease payments are comprised of the fixed and variable payments to be made by the Company to the lessor during the lease term minus any incentives or rebates or abatements receivable by the Company from the lessor or the owner. Payments for non-lease components do not form part of lease payments. The lease term includes renewal options only if these options are specified in the lease agreement and if failure to exercise the renewal option imposes a significant economic penalty for the Company. As there are no significant economic penalties, renewal cannot be reasonably assured and the lease terms for the office space do not include any renewal options. The Company has not entered into any leases with related parties. The Company accounts for short-term leases (i.e., lease term of 12 months or less) by making the short-term lease policy election and will not apply the recognition and measurement requirements of ASC 842.

The Company has determined that the rate implicit in the lease is not determinable and the Company does not have borrowings with similar terms and collateral. Therefore, the Company considered a variety of factors, including the Company's credit rating, observable debt yields from comparable companies with a similar credit profile and the volatility in the debt market for securities with similar terms, in determining that 11.5% was reasonable to use as the incremental borrowing rate for purposes of the calculation of lease liabilities and a change of 1% would not result in a material change to the Company's condensed consolidated financial statements.

On April 12, 2019 the Company entered into an Office Centre Sharing Agreement for office space in Dublin, Ireland effective May 1, 2019 was scheduled to terminate on April 30, 2020 and was extended for one additional year through April 30, 2021 and can continue to be extended automatically for successive one year periods. On July 4, 2019, the Company entered into an Office Centre Sharing Agreements effective October 1, 2019 for office space in Dublin, Ireland which terminates on September 30, 2020 and can be extended automatically for successive one year periods. These leases have been determined to be short-term leases and the Company is committed to making payments of $0.1 million during the next twelve months.

On February 5, 2019, the Company entered into a lease agreement for new office space in Bridgewater, New Jersey, or the Lease. The Lease commenced on August 15, 2019, or the Commencement Date, for an 11-year period, with two five-year renewal options. Subject to the terms of the Lease, Amarin will have a one-time option to terminate the agreement effective on the first day of the ninety-seventh month after the Commencement Date upon advance written notice and a termination payment specified in the Lease. Under the Lease, the Company pays monthly rent of approximately $0.1 million for the first year following the Commencement Date, and such rent will increase by a nominal percentage every year following the first anniversary of the Commencement Date. In addition, Amarin receives certain abatements subject to the limitations in the Lease. The operating lease liability is $10.4 million and $9.8 million and the operating lease right-of-use asset is $8.3 million and $8.5 million, as of June 30, 2020 and December 31, 2019, respectively. The lease expense for the three and six months ended June 30, 2020 is approximately $0.4 million and $0.8 million, respectively. The lease expense for the three and six months ended June 30, 2019 is approximately $0.4 million and $0.7 million, respectively.

The table below depicts a maturity analysis of the Company's undiscounted payments for its operating lease liabilities and their reconciliation with the carrying amount of lease liability presented in the statement of financial position as of June 30, 2020:

	Undiscounted lease payments ($000s)
Remainder of 2020	$ 390
2021	1,495
2022	1,776
2023	1,809
2024	1,843
2025 and thereafter	10,910
Total undiscounted payments	$ 18,223
Discount Adjustments	$ (7,811)
Current operating lease liability	$ 1,101
Long-term operating lease liability	$ 9,311

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," "predicts," "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, 2019 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 focused on the commercialization and development of therapeutics to improve cardiovascular, or CV, health and reduce CV risk.

Our lead product, VASCEPA® (icosapent ethyl) was first approved by the U.S. Food and Drug Administration, or FDA, for use as an adjunct to diet to reduce triglyceride, or TG, levels in adult patients with severe (TG ≥500 mg/dL) hypertriglyceridemia. On December 13, 2019, the FDA-approved a new indication and label expansion for VASCEPA based on the landmark results of our cardiovascular outcomes trial of VASCEPA, REDUCE-IT®, or Reduction of Cardiovascular Events with EPA – Intervention Trial. VASCEPA is the first and only drug approved by the FDA as an adjunct to maximally tolerated statin therapy for reducing persistent cardiovascular risk in select high risk-patients.

Since our inception, we have devoted substantial resources to our research and development efforts, most significantly our VASCEPA cardiovascular outcomes trial, REDUCE-IT. We announced topline results from REDUCE-IT on September 24, 2018. On November 10, 2018, we publicly presented primary results of the REDUCE-IT study at the 2018 Scientific Sessions of the American Heart Association, or AHA, and the results were concurrently published in *The New England Journal of Medicine*. REDUCE-IT met its primary endpoint demonstrating a 25% relative risk reduction, or RRR, to a high degree of statistical significance ($p<0.001$), in first occurrence of major adverse cardiovascular events, or MACE, in the intent-to-treat patient population with use of VASCEPA 4 grams/day as compared to placebo. REDUCE-IT also showed a 26% RRR in its key secondary composite endpoint of cardiovascular death, heart attacks and stroke ($p<0.001$). On March 18, 2019, we publicly presented the total cardiovascular events results, and the method of calculating such events, of the REDUCE-IT study at the American College of Cardiology's, or ACC, 68th Annual Scientific Session and such results and methods were concurrently published in the *Journal of the American College of Cardiology*. Included in such results were that VASCEPA reduced total events (first and subsequent events) by 30% compared to placebo, reflecting that for every 1,000 patients treated for five years with VASCEPA versus placebo in this trial, approximately 159 MACE would have been prevented with VASCEPA.

Based on REDUCE-IT results, several clinical treatment guidelines and position statements have been updated, including those listed below:

- In March 2019, the American Diabetes Association, or ADA, issued important updates to the Standard of Medical Care in Diabetes for 2019, including a recommendation for the use of icosapent ethyl in treating at-risk patients based on the results of the REDUCE-IT cardiovascular outcomes study.
- In August 2019, the AHA recognized the results of REDUCE-IT and recommended directing medical care away from unproven fish oil dietary supplements and to prescription drug therapy in patients with elevated TG levels.
- In September 2019, the National Lipid Association issued a position statement recognizing the cardiovascular risk-lowering effects of icosapent ethyl based on the REDUCE-IT results.
- In September 2019, the European Society of Cardiology and the European Atherosclerosis Society updated their Clinical Practice Guidelines for the Management of Dyslipidemias to incorporate findings from the REDUCE-IT study.
- In February 2020, the American Association of Clinical Endocrinologists and the American College of Endocrinology released a consensus statement on the comprehensive management of type 2 diabetes. The statement included new

guidance for managing patients with established or high risk for cardiovascular disease who have triglyceride levels between 135 – 499 mg/dL with icosapent ethyl which has proven benefits to prevent the next adverse cardiovascular event.

In October 2019, the Institute for Clinical and Economic Review, or ICER, released its final evidence report regarding clinical effectiveness and economic impacts on VASCEPA. ICER's report indicated that VASCEPA was cost effective across all of the non-profit organization's analyses, including its quality-adjusted life year metrics of <$50,000. The conclusion from the report is that VASCEPA easily meets "commonly cited thresholds for cost-effectiveness and therefore represents a high long-term value for money" based on the organization's value assessment framework. In addition, an independent academic, patient-level, cost-effectiveness analysis of icosapent ethyl led by Dr. William S. Weintraub, M.D., director of Outcomes Research with MedStar Cardiovascular Research Network, indicated that VASCEPA was projected to not only be cost-effective but also to reduce long-term health care costs in a majority of the scenarios analyzed.

The FDA granted Priority Review designation to our March 2019 supplemental new drug application, or sNDA, seeking an expanded indication for VASCEPA in the United States based on the positive results of the REDUCE-IT study. The FDA grants Priority Review designation to applications for drugs that, if approved, have the potential to offer significant improvements in the effectiveness and safety of the treatment of serious conditions. In November 2019, FDA held an Endocrinologic and Metabolic Drugs Advisory Committee, or EMDAC, meeting to review the REDUCE-IT sNDA. The EMDAC voted unanimously (16-0) to recommend approval of an indication and label expansion for VASCEPA to reduce cardiovascular events in high-risk patients based on the REDUCE-IT results. On December 13, 2019, the FDA approved a new indication and label expansion for VASCEPA capsules. VASCEPA is the first and only drug approved by the FDA as an adjunct to maximally tolerated statin therapy to reduce the risk of myocardial infarction, stroke, coronary revascularization, and unstable angina requiring hospitalization in adult patients with elevated TG levels (≥150 mg/dL) and either established cardiovascular disease or diabetes mellitus and two or more additional risk factors for cardiovascular disease.

On March 30, 2020, the United States District Court for the District of Nevada, or the Nevada Court, decided in favor of two generic companies in our patent litigation related to their abbreviated new drug applications, or ANDAs, that seek FDA approval for sale of generic versions of VASCEPA. On May 22, 2020, one of the two generic companies, Hikma Pharmaceutical USA Inc., or Hikma, received FDA approval to market its generic version of VASCEPA. To date, Hikma has not launched a generic version of VASCEPA. We disagree with the Nevada Court's decision that our patents are invalid and are vigorously pursuing an appeal. If generic companies determine to launch generic versions of icosapent ethyl in the United States, such competition could have a material and adverse impact on our revenues and our operations.

VASCEPA is not yet known to most healthcare professionals and generics companies rarely invest in product or disease state related market education. Furthermore, VASCEPA is relatively expensive to manufacture and already sold at an affordable price as documented by third-party analysis such that saving, if any, on the price of generic VASCEPA is likely to come at the expense of reduced market education and development. Thus, we believe that the launch of a generic version of VASCEPA in the United States at this early stage in the life cycle of VASCEPA is potentially harmful to patient care and discourages new product development, including identifying and pursuing additional indications that could be treated with VASCEPA.

Geographies outside the United States in which VASCEPA is sold and under regulatory review are not subject to this U.S. patent litigation and judgment. No similar litigation involving potential generic versions of VASCEPA is pending outside the United States. VASCEPA is currently available by prescription in Canada, Lebanon and the United Arab Emirates. In Canada, VASCEPA has the benefit of eight years of data protection afforded through Health Canada (until the end of 2027), in addition to separate patent protection with expiration dates that could extend into 2039. Amarin is pursuing additional regulatory approvals for VASCEPA in Europe, China and the Middle East. In China and the Middle East, Amarin is pursuing such regulatory approvals and subsequent commercialization of VASCEPA with commercial partners. In Europe, Amarin is preparing to self-launch VASCEPA, although it may engage commercialization partners for certain of the smaller countries of Europe. Ten to eleven years of market protection is anticipated due to regulatory exclusivity in the European Union subject to an approval recommendation by the European Medicines Agency, or EMA, near the end of 2020 and associated European Community, or EC, approval expected promptly thereafter, in addition to pending patent protection that could extend into 2039.

Commercialization

We commenced the commercial launch of VASCEPA through sales and shipments to our network of U.S.-based wholesalers in the United States in January 2013. We began selling and marketing 1-gram size VASCEPA capsules in January 2013, and in October 2016, introduced a smaller 0.5-gram capsule size. 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. VASCEPA is sold 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.

Prior to results of the REDUCE-IT study, we did not have cardiovascular outcomes data regarding the clinical effect of VASCEPA and a substantial portion of our resources were being spent on the REDUCE-IT study. As a result, our commercialization of VASCEPA was somewhat limited.

Prior to the REDUCE-IT results topline announcement in September 2018, our direct sales force consisted of approximately 170 sales professionals, including sales representatives and their managers. Based on the positive REDUCE-IT results, in early 2019, we increased the size of our sales team to approximately 440 sales professionals, including approximately 400 sales representatives. As a result of the FDA's newly approved indication and label expansion, our direct sales force was expanded to approximately 900 sales professionals, including approximately 800 sales representatives.

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 June 30, 2020 and 2019 was approximately 1,090,000 and 755,000, respectively. According to data from another third party, IQVIA, the estimated number of normalized total VASCEPA prescriptions for the three months ended June 30, 2020 and 2019 was approximately 1,007,000 and 683,000, 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.

Companies such as Symphony Health and IQVIA collect and report estimates of weekly, monthly, quarterly and annual prescription information. There is a limited amount of information available to such companies to determine the actual number of total prescriptions for prescription products like VASCEPA during such periods. Each vendor's estimates utilize a proprietary projection methodology and are based on a combination of data received from pharmacies and other distributors, and historical data when actual data is unavailable. Their calculations of changes in prescription levels between periods can be significantly affected by lags in data reporting from various sources or by changes in pharmacies and other distributors providing data. Such methods can from time to time result in significant inaccuracies in information when ultimately compared with actual results. These inaccuracies have historically been most prevalent and pronounced during periods of time of inflections upward or downward in rates of use. Further, data for a single and limited period may not be representative of a trend or otherwise predictive of future results. Data reported by Symphony Health and IQVIA is rarely identical. As such, the resulting conclusions from such sources should be viewed with caution. We are not responsible for the accuracy of these companies' information and Amarin does not receive prescription data directly from retail pharmacies.

We recognize revenue from product sales when the distributor obtains control of our product, which occurs at a point in time, typically upon delivery to the distributor. 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.

We also employ various medical affairs and marketing personnel to support our commercialization of VASCEPA. We expanded certain medical education and market awareness initiatives following the reporting of positive REDUCE-IT results in 2018. We began 2020 by taking steps to further expand promotion of VASCEPA, including direct to consumer advertising, as a result of the new indication and label expansion of VASCEPA approved by the FDA on December 13, 2019. In January 2020, we launched an educational campaign, *True To Your Heart*, to help people learn more about cardiovascular disease and how to better protect against persistent cardiovascular risk. At the start of 2020, we had intended to commence expanded promotion but cancelled such plans following the onset of COVID-19 and the prospects for a potential launch of generic versions of VASCEPA. We have restored most of that intended promotion and educational efforts which include the sponsorship of continuing medical education, social media-based communications, and advertisements on television and other forms of media.

On March 30, 2020, the Nevada Court ruled in favor of two generic companies in our patent litigation related to their ANDAs that seek FDA approval for sale of generic versions of VASCEPA. On May 22, 2020, one of the two generic companies, Hikma, received FDA approval to market its generic version of VASCEPA. To date, Hikma has not launched a generic version of VASCEPA. We disagree with the Nevada Court's decision that our patents are invalid and are vigorously pursuing an appeal. If generic companies

determine to launch generic versions of icosapent ethyl in the United States, such competition could have a material and adverse impact on our revenues and our operations.

VASCEPA is not yet known to most healthcare professionals and generics companies rarely invest in product or disease state related market education. Furthermore, VASCEPA is relatively expensive to manufacture and already sold at an affordable price as documented by third-party analysis such that saving, if any, on the price of generic VASCEPA is likely to come at the expense of reduced market education and development. Thus, we believe that the launch of a generic version of VASCEPA in the United States at this early stage in the life cycle of VASCEPA is potentially harmful to patient care and discourages new product development, including for identifying and pursuing additional indications that could be treated with VASCEPA.

Geographies outside the United States in which VASCEPA is sold and under regulatory review are not subject to this U.S. patent litigation and judgment. No similar litigation involving potential generic versions of VASCEPA is pending outside the United States. VASCEPA is currently available by prescription in Canada, Lebanon and the United Arab Emirates. In Canada, VASCEPA has the benefit of eight years of data protection afforded through Health Canada (until the end of 2027), in addition to separate patent protection with expiration dates that could extend into 2039. Amarin is pursuing additional regulatory approvals for VASCEPA in Europe, China and the Middle East. In China and the Middle East, Amarin is pursuing such regulatory approvals and subsequent commercialization of VASCEPA with commercial partners. In Europe, Amarin is preparing to self-launch VASCEPA, although it may engage commercialization partners for certain of the smaller countries of Europe. Ten to eleven years of market protection is anticipated due to regulatory exclusivity in the European Union subject to an approval recommendation by the European Medicines Agency, or EMA, near the end of 2020 and associated European Community, or EC, approval expected promptly thereafter, in addition to pending patent protection that could extend into 2039.

In addition to promotion of VASCEPA in the United States, based on REDUCE-IT, we have increased focus on expansion of our development efforts for VASCEPA to major markets outside the United States. We currently have strategic collaborations to develop and commercialize VASCEPA in select territories outside the United States.

China

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. Eddingpharm, with our support, is conducting a clinical trial of VASCEPA in China, which is evaluating the effect of VASCEPA on patients with very high triglyceride levels ($\geq$500 mg/dL). The results of this trial are expected to be announced before the end of 2020. After reviewing the results of this clinical study and consulting with regulatory authorities, our plans for seeking regulatory approval and reimbursement of VASCEPA in China will be updated.

Middle East and North Africa (MENA)

In March 2016, we entered into an agreement with Biologix, to register and commercialize VASCEPA in several Middle Eastern and North African countries. VASCEPA was launched in Lebanon in June 2018 and in United Arab Emirates in February 2019, respectively.

Canada

In September 2017, we entered into an agreement with HLS to register, commercialize and distribute VASCEPA in Canada. In March 2019, HLS received formal confirmation from Health Canada that the Canadian regulatory authority has granted priority review status for the upcoming New Drug Submission, which was filed in April 2019, for VASCEPA. In December 2019, HLS received formal confirmation from Health Canada that the Canadian regulatory authority has granted approval for VASCEPA to reduce the risk of cardiovascular events (cardiovascular death, non-fatal myocardial infarction, non-fatal stroke, coronary revascularization or hospitalization for unstable angina) in statin-treated patients with elevated triglycerides, who are at high risk of cardiovascular events due to: established cardiovascular disease, or diabetes, and at least one other cardiovascular risk factor. In January 2020 HLS obtained a regulatory exclusivity designation. Commercial launch in Canada began in February 2020 on a limited scale with subsequent expansion intended. An important step in growing the potential use of therapeutics in Canada, as is true in other countries, is gaining reimbursement coverage by the applicable payers. In July 2020, the Canadian Health Authorities recommended that patients with established cardiovascular diseases under certain conditions be reimbursed for VASCEPA. In addition, the Patented Medicines Price Review Boards review of VASCEPA's introductory price submission did not trigger the pricing investigation criteria. While coverage of patients with established cardiovascular disease represents a substantial portion of VASCEPA's approved label in Canada, HLS intends various initiatives to pursue expanding the Canadian Health Authorities recommendation to cover other patients at high risk for major adverse cardiovascular events beyond patients with established cardiovascular disease.

Europe

We are exploring potential development and commercial paths for VASCEPA throughout Europe.

In December 2019, we announced that the EMA validated the marketing authorization application seeking approval for VASCEPA. The validation confirms the submission is sufficiently complete for the EMA to begin its review. Review by the EMA of this application is active and together with associated EC review, expected promptly thereafter, is expected to be completed in early 2021. As we did in Canada, we are seeking an indication throughout Europe for VASCEPA targeting cardiovascular risk reduction based on the results of REDUCE-IT.

In parallel with EMA's review of our submission, we have been actively exploring the opportunity for VASCEPA commercialization in Europe. After extensive evaluation, we have determined self-launching VASCEPA in Europe, except perhaps in certain smaller countries of Europe, is the best path forward considering all factors. Such an approach avoids sharing the economic potential of VASCEPA with a third-party commercial partner and ensures that VASCEPA gets the highest level of priority and focus. Similar to our approach in launching VASCEPA in the United States, in Europe we intend to build a core team of experienced professionals and a highly capable sales team and plan to leverage third-party relationships for various support activities. Such activities are underway. In Europe, patients at high risk for cardiovascular disease tend, in comparison to the United States, to be treated more often by specialists, such as cardiologists rather than by physicians who are general practitioners. Pursuant to regulatory approval of VASCEPA in Europe, this greater concentration of at-risk patients being treated by specialists in Europe should allow for more efficient promotion of VASCEPA in Europe than in the United States. We have been active in preparing for reimbursement negotiations which we intend to commence on a country-by-country basis in Europe following anticipated approval of VASCEPA following the currently ongoing EMA review. In certain European countries, securing product reimbursement is a requisite to launching. In all countries securing adequate reimbursement is a requisite for commercial success of any therapeutic. The time required to secure reimbursement tends to vary from country to country and cannot be reliably predicted at this time. While we believe that we have strong arguments regarding the cost effectiveness of VASCEPA, the success of such reimbursement negotiations could have a significant impact on our ability to realize the commercial opportunity of VASCEPA in Europe.

Rest of World

We plan to also assess other potential partnership opportunities for licensing VASCEPA to partners in other parts of the world. While we believe that there is medical need and opportunity for VASCEPA elsewhere in the world, our current priorities are the geographies described above.

Research and Development

Since its inception in 2011, conduct of the REDUCE-IT cardiovascular outcomes study of VASCEPA has been the centerpiece of our research and development. Most of our other research and development during this period also pertained to VASCEPA, including study of the mechanism of action of the single active ingredient in VASCEPA, icosapent ethyl. The REDUCE-IT study was conducted based on a special protocol assessment, or SPA, agreement with the FDA. Based on the final positive results of REDUCE-IT, we sought additional indicated uses for VASCEPA in the United States and continued to pursue approval for VASCEPA around the world. We also anticipate continuing to publish additional details of the REDUCE-IT study to address scientific interest beyond the primary results of this study derived from the over 35,000 patient years of study experience which were accumulated in the REDUCE-IT study. The REDUCE-IT study topline results were made public in September 2018, and the primary results of the REDUCE-IT study were presented at the 2018 Scientific Sessions of the AHA on November 10, 2018 with such results concurrently published in *The New England Journal of Medicine*. The total (first and subsequent) cardiovascular events results of the REDUCE-IT study were presented at the American College of Cardiology's 68th Annual Scientific Session in March 2019 and concurrently published in the *Journal of the American College of Cardiology*. Potential additional research and development opportunities beyond REDUCE-IT will be prioritized after giving priority to securing regulatory approval for VASCEPA based on the REDUCE-IT results in various geographies internationally, including pursuit of approval for VASCEPA in Europe and in countries where we have commercialization partners for VASCEPA.

The FDA granted Priority Review designation to our March 2019 sNDA seeking an expanded indication for VASCEPA in the United States based on the positive results of the REDUCE-IT study. The FDA grants Priority Review designation to applications for drugs that, if approved, have the potential to offer significant improvements in the effectiveness and safety of the treatment of serious conditions when compared to standard applications. In November 2019, FDA held an EMDAC meeting to review the REDUCE-IT sNDA. The EMDAC voted unanimously (16-0) to recommend approval of an indication and label expansion for VASCEPA to reduce cardiovascular events in high-risk patients based on the REDUCE-IT results. On December 13, 2019, the FDA approved a new indication and related label expansion based on REDUCE-IT. VASCEPA is the first and only drug approved by the FDA as an adjunct to maximally tolerated statin therapy to reduce the risk of myocardial infarction, stroke, coronary revascularization, and unstable angina requiring hospitalization in adult patients with elevated TG levels (≥150 mg/dL) and either established cardiovascular disease or diabetes mellitus

and two or more additional risk factors for cardiovascular disease. Reflecting the robust results of the clinical development program for VASCEPA, no additional post-approval clinical study or other special post approval requirement (as often seen with other drug approvals) was requested by the FDA in conjunction with its approval of VASCEPA.

Based on our current understanding of the biological effects of a COVID-19 infection, including that patients at high risk of cardiovascular disease are at higher risk of mortality and severe effects from a COVID-19 infection, and based on data related to the mechanism of action and effects of VASCEPA in lowering cardiovascular risk in certain high-risk patients, we believe that VASCEPA could play a beneficial clinical role in helping patients infected by the virus. We are currently providing drug product and limited financial support to investigators in multiple pilot studies designed to better understand the potential of VASCEPA and this potentially beneficial role. If the results of these pilot studies are positive, we intend to evaluate whether additional study is appropriate. The clinical effects of VASCEPA are multi-factorial. Multiple mechanisms of action associated with VASCEPA from clinical and mechanistic studies support the rationale to study its effects in patients with the COVID-19 infection. Additional postulated mechanisms that might play a role in the use of VASCEPA in the patients infected with COVID-19 include potential antiviral/antimicrobial effects, fibrosis and cardiac damage mitigation in animal models and anti-inflammatory effects (acute) in pulmonary/lung tissue.

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. In addition, 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 made 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. In January 2020, we achieved certain milestones under the agreement, resulting in payment of $1.0 million to Mochida.

Commercial and Clinical Supply

We manage the manufacturing and supply of VASCEPA internally and have done so since we began clinical development of VASCEPA prior to the drug's marketing approval by FDA in 2012. We rely on contract manufacturers in each step of our commercial and clinical product supply chain. These steps include active pharmaceutical ingredient, or API, manufacturing, encapsulation of the API, product packaging and supply-related logistics. Our approach to product supply procurement is designed to mitigate risk of supply interruption and maintain an environment of cost competition through diversification of contract manufacturers at each stage of the supply chain and lack of reliance on any single supplier. We have multiple FDA-approved international API suppliers, encapsulators and packagers to support the VASCEPA commercial franchise. 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.

Impact of COVID-19

As the COVID-19 pandemic continues to spread and impact global populations and economies, we continue to evaluate its impact on patients, distributors, customers and our employees, as well as on our operations and the operations of our business partners and communities. Given the importance of supporting patients, we are diligently working with our suppliers, customers, distributors and other partners to provide patients with access to VASCEPA, while taking into account regulatory, institutional, and government guidance, policies and protocols. Given the uncertainties regarding the scope and impact of COVID-19 on our sales, supply, research and development efforts and operations, and on the operations of our customers, suppliers, distributors, other partners and patients, particularly as COVID-19 protocols and resources have restricted or discouraged patient access to hospitals, clinics, physicians' offices and other administration sites and caused a reprioritization of health care services, the impact of COVID-19 could materially impact our current performance and continue to represent a risk to our future performance.

Beginning in mid-March 2020, our ability to directly promote VASCEPA to healthcare professionals has been limited due to appropriate social distancing practices associated with COVID-19 and by patients electing to forego visiting their doctors for non-urgent medical examinations and/or choose to not get blood tests which test results provide information useful to the treatment of cardiovascular risk. Such impact has had a significant impact on slowing VASCEPA prescription and revenue growth. While COVID-19 continues to impact our promotion of VASCEPA, we see early signs of improvement. Our sales representatives are increasingly gaining access to educate healthcare professionals regarding VASCEPA. Such access remains variable and challenging due to COVID-19, yet we are optimistic that this improved access trend will increase and translate into increased levels of VASCEPA prescriptions and revenue. In July 2020 we launched our first television-based promotion of VASCEPA emphasizing that it is the first and only FDA approved drug for its indication. We anticipate that over time such promotion will increase awareness and usage of

VASCEPA, and could help mitigate challenges if social distancing protocols and other restrictions are reinforced, including in light of any resurgence of the infection in certain geographies. Data on increased product usage from similar promotion of other products suggests that the impact of television-based promotion can be positive and sustained but is rarely immediate in its effect.

Thus far, COVID-19 has not materially impacted our ability to secure and deliver supply of VASCEPA. And, thus far, COVID-19 is not known to have significantly impacted ongoing clinical trials of VASCEPA. Regarding regulatory review of VASCEPA in Europe, COVID-19 appears to have modestly slowed certain aspects of the review with the overall timeline for the review being completed by the EMA shifting from what was previously estimated as late 2020 into our current estimate of early 2021.

The ultimate impacts of COVID-19 on our business are unknown; however, we are actively monitoring the situation and may take precautionary and preemptive actions that we determine are in the best interests of our business. We cannot predict the effects that such actions may have on our business or on our financial results, in particular with respect to demand for or access to VASCEPA.

We believe that the overall morale of employees within Amarin is positive despite the challenges associated with COVID-19. While we have experienced modest employee turnover in recent months, the turnover level is generally consistent with the pre-COVID era. And, while in a period of social distancing we are intentionally slow in hiring replacements for our limited number of open positions resulting from such seemingly ordinary course turnover, it is our intention to fill such positions particularly as we witness our sales representatives increasingly able to resume direct interactions with healthcare professionals.

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. In the United States, 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. Outside of the United States, currently all our product revenue is derived from the sales of VASCEPA to our commercial partners based on the net price for VASCEPA established in our contracts with such partners. These commercial partners then resell the product in their agreed commercial territory. Revenues from product sales to our international commercial partners are recognized when the commercial partners obtain control of our product, which occurs at a point in time, typically upon delivery to the commercial partner. The net price of VASCEPA sold by us to our customers where we directly sell VASCEPA is generally significantly higher than the net price of VASCEPA that we sell to commercial partners who then incur the cost of promoting and reselling the product in their territories. As a result, even when the net price of VASCEPA to patients is similar in various parts of the world, our gross margin on sales is higher where we sell VASCEPA directly. Currently the majority of our products revenue is derived from direct sales of VASCEPA in the United States.

Licensing and royalty revenue. Licensing and royalty revenue currently consists of revenue attributable to receipt of up-front, non-refundable payments, milestone payments and sales-based 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. Our cost of goods sold is not materially impacted by whether we sell VASCEPA directly in a country or we sell VASCEPA to a commercial partner for resale in a country.

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. 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 our December 2012 royalty-bearing instrument financing arrangement, which is calculated based on an estimated repayment schedule. Interest income consists of interest earned on our cash and cash equivalents, as well as our short and long-term investments. Other (expense) income, net, consists primarily of foreign exchange losses and gains.

Income tax benefit. Income tax benefit, 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 guidance prescribed under ASC 740 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 for the three and six months ended June 30, 2020 and 2019 are not more likely than not to be realized. On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act, or CARES Act, was enacted in the United States. Among other provisions, the CARES Act allows businesses to carry back net operating losses arising in years 2018 to 2020 to the five prior tax years. We recorded an income tax benefit of nil million and $2.4 million for the three and six months ended June 30, 2020 as a result of these loss carrybacks and an income tax benefit of nil for the three and six months ended June 30, 2019.

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. 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 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, 2019. There were no material changes to our critical accounting policies, significant judgments and estimates during the six months ended June 30, 2020.

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.

Effects of Inflation

We believe the impact of inflation on operations has been minimal during the past three years.

Results of Operations

Comparison of Three Months Ended June 30, 2020 and June 30, 2019

Product revenue, net. We recorded net product revenue of $133.7 million and $100.4 million during the three months ended June 30, 2020 and 2019, respectively, an increase of $33.4 million, or 33%. This increase was driven primarily by volume of VASCEPA sales to our customers in the United States, as well as a modest increase in VASCEPA's net selling price in the United States. Orders by such customers were supported by an increase in estimated normalized total VASCEPA prescriptions in the United States, reflecting various factors including managed care improvements. Based on data provided by Symphony Health and IQVIA, estimated normalized total VASCEPA prescriptions in the United States increased by approximately 335,000 and 324,000, respectively, over the three months ended June 30, 2019, representing growth of 44% and 47%, respectively. The increase in net product revenue was also driven by VASCEPA sales to our commercial partners outside of the United States of approximately $1.8 million during the three months ended June 30, 2020 as compared to nil during the three months ended June 30, 2019.

All of our product revenue, net in the United States, in the three months ended June 30, 2020 and 2019 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 U.S. 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 June 30, 2020 and 2019, our Product revenue, net in the United States included adjustment for co-pay mitigation support provided by us for commercially insured patients. Such rebates are intended to offset a portion of the out-of-pocket expense that patients are required to pay for VASCEPA based upon the benefit of their insurances. Our cost for these co-payment support payments during the quarters ended June 30, 2020 and 2019 was up to $150 and $110, respectively per 30-day prescription filled and, up to $450 and $330, respectively per 90-day prescription filled.

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

In March 2020, COVID-19, or SARS-CoV-2, became widespread in the United States and other geographies around the globe. In recognition of guidance from public health officials, we announced on March 15, 2020 a temporary suspension of in-person promotional activities. In June 2020, we resumed sales force, field-based, face-to-face interactions with healthcare providers in a phased approach that is consistent with guidelines from local, state and government health officials in the United States. For a newly FDA-approved drug like VASCEPA to be prescribed, historically physicians need to have met with their patients for an examination and have received blood test results prior to prescribing the drug to the patient. Public reports from IQVIA showed patient visits to medical offices for non-emergency medical care were down approximately 70% in April 2020 during the height of the COVID-19 related social distancing. Also reported was a significant drop in the number of routine lab tests likely due to patients not seeking medical care for non-urgent medical needs and resources of the medical community shifting focus to address the COVID-19 pandemic. As a result, while VASCEPA prescription levels in the three months ended June 30, 2020 grew over the three months ended June 30, 2019, we witnessed a slowing of new patients being prescribed VASCEPA resulting in year over year growth in the three months ended June 30, 2020 which was considerably slower than the growth reported in the three months ended March 31, 2020 when we launched VASCEPA for its new cardiovascular indication. According to IQVIA data, in June 2020 the number of patient visits to health care providers and the number of lab tests increased meaningfully over the lows of April 2020 but remained below the volume levels reported prior to mid-March 2020 when the impact of COVID-19 began to significantly impact the United States. We cannot predict the duration of this pandemic and we cannot quantify the impact of COVID-19 on our business beyond June 30, 2020. We are confident that the patient need for VASCEPA remains high and that the slowing of VASCEPA growth in the three months ended June 30, 2020 was COVID-19 related. While we are optimistic that the worst of the COVID-19 impact is behind us regarding the levels of patients seeking ordinary course doctor visits and lab tests, we expect that COVID-19 will continue, at least in the near term, to impact the level of VASCEPA prescriptions and the degree and timing to which we can, if at all, reaccelerate VASCEPA growth, particularly if there are resurgences in the spread of the infection in various geographies and a reinforcement of social distancing and other protocols.

Licensing and royalty revenue. Licensing and royalty revenue during the three months ended June 30, 2020 and 2019 was $1.6 million and $0.4 million, respectively, an increase of $1.2 million, or 274%. Licensing and royalty revenue relates to the recognition of amounts received in connection with the following VASCEPA licensing agreements:

- Eddingpharm – a $15.0 million up-front payment received in February 2015 and a $1.0 million milestone payment achieved in March 2016
- HLS – a $5.0 million up-front payment which was received upon closing of the agreement in September 2017, a $2.5 million milestone payment that was received following achievement of the REDUCE-IT trial primary endpoint in September 2018, a $2.5 million milestone payment that was received following FDA approval of a new indication and label expansion in December 2019 and a $3.8 million milestone payment that was received as a result of obtaining a regulatory exclusivity designation in January 2020.

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.

As part of our licensing agreements with certain territories outside of the United States, we are entitled to a percentage of revenue earned based on sales by our partners. The royalty payments are being recognized as earned based on revenue recognized by our current partners.

Cost of goods sold. Cost of goods sold during the three months ended June 30, 2020 and 2019 was $28.8 million and $22.8 million, respectively, an increase of $6.0 million, or 26%. 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 June 30, 2020 and 2019 was sourced from multiple 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 2020 to be similar to or modestly lower than 2019. The average cost may be variable from period to period depending upon the timing and quantity of API purchased from each supplier.

Our overall gross margin on product sales for each of the three months ended June 30, 2020 and 2019 was 78% and 77%, respectively. The increase in gross margin on product sales is driven by gross margin on U.S. product sales of 79%, partially offset by the gross margin on product sales to our partners outside the U.S. which was based on contractually agreed upon terms with our commercial partners in those territories which partners incur the costs of promoting and selling the product in their territories. During the three months ended June 30, 2019, there were no product sales to our partners outside the U.S. to impact gross margin levels.

Selling, general and administrative expense. Selling, general and administrative expense for the three months ended June 30, 2020 and 2019 was $92.4 million and $73.4 million, respectively, an increase of $19.0 million, or 26%. Selling, general and administrative expenses for the three months ended June 30, 2020 and 2019 are summarized in the table below:

	Three months ended June 30,	
In thousands	**2020**	**2019**
Selling expense (1)	$ 64,601	$ 52,838
General and administrative expense (2)	17,434	13,726
Non-cash stock-based compensation expense (3)	10,360	6,842
Total selling, general and administrative expense	$ 92,395	$ 73,406

(1) Selling expense for the three months ended June 30, 2020 and 2019 was $64.6 million and $52.8 million, respectively, an increase of $11.8 million, or 22%. This increase is primarily due to increased personnel costs related to the sales force expansion from approximately 440 sales professionals, including approximately 400 sales representatives, in 2019 to approximately 900 sales professionals, including approximately 800 sales representatives, offset by a decrease in direct to consumer promotion due to the temporary suspension of such marketing activities following the ANDA patent litigation ruling in the United States, with such spending restored in June 2020.

(2) General and administrative expense for the three months ended June 30, 2020 and 2019 was $17.4 million and $13.7 million, respectively, an increase of $3.7 million, or 27%. This increase is primarily a result of an increase in personnel and related costs as well as insurance premiums.

(3) Non-cash stock-based compensation expense for the three months ended June 30, 2020 and 2019 was $10.4 million and $6.8 million, respectively, an increase of $3.5 million, or 51%. Non-cash stock-based compensation expense represents the estimated costs associated with equity awards issued to personnel supporting our selling, general and administrative functions. The increase is due primarily to an increase in the number of employees receiving equity awards as a result of the growth of our sales force and an increase in the underlying fair value of the equity awards.

We continuously evaluate all of our spending commitments and priorities, including the impact of the pending ANDA patent litigation and COVID-19 and as we work to increase revenue from VASCEPA. We currently plan to spend approximately $80.0 million in education and promotion in 2020 to increase awareness of VASCEPA as the only U.S. FDA-approved drug for lowering the risk of heart attacks, strokes, and other major adverse cardiovascular events in high risk patients beyond statin therapy. We plan to adjust our level of education and promotional activities based on various factors, including whether any generic company takes the risk of launching a generic version of VASCEPA during the patent litigation appeal process and the amount of any product launched.

Research and development expense. Research and development expense for the three months ended June 30, 2020 and 2019 was $10.0 million and $7.1 million, respectively, an increase of $2.8 million, or 40%. Research and development expenses for the three months ended June 30, 2020 and 2019 are summarized in the table below:

	Three months ended June 30,	
In thousands	**2020**	**2019**
REDUCE-IT study (1)	$ 3,769	$ 2,055
Regulatory filing fees and expenses (2)	777	227
Internal staffing, overhead and other (3)	3,652	3,807
Research and development expense, excluding non-cash Expense	8,198	6,089
Non-cash stock-based compensation expense (4)	1,771	1,041
Total research and development expense	$ 9,969	$ 7,130

The increase in research and development expenses for the quarter ended June 30, 2020, as compared to the prior year period, is primarily due to timing of REDUCE-IT and related costs.

(1) In September 2018, we announced landmark positive topline results of the REDUCE-IT cardiovascular outcomes trial. The increase in expenses is primarily driven by costs beyond the conduct of the study, including costs to further analyze samples collected from REDUCE-IT patients and to support various publications and scientific presentations relating to REDUCE-IT.

(2) The regulatory filing fees in each of the quarters ended June 30, 2020 and 2019 included annual FDA fees for maintaining manufacturing sites. Such fees primarily represent fees for qualification of new suppliers, including increasing capacity capabilities, and fees for sites used for the manufacture of product used in the REDUCE-IT clinical outcomes study.

(3) Internal staffing, overhead and other research and development expenses primarily relate to the costs of our personnel employed to manage research, development and regulatory affairs activities and related overhead costs including consulting and other professional fees that are not allocated to specific projects. Also included are costs related to qualifying suppliers and costs associated with supporting various other investigations, including work in collaboration with Mochida and pilot studies regarding VASCEPA and COVID-19.

(4) Non-cash stock-based compensation expense represents the estimated costs associated with equity awards issued to personnel supporting our research and development and regulatory functions.

We are in the process of evaluating all of our spending commitments and priorities on research and development activities. Our research and development expenses may be variable in the coming quarters as we advance analysis of samples collected from REDUCE-IT patients, consider potential investigator initiatives involving VASCEPA and cardiovascular risk mitigation in COVID-19 patients, support international regulatory review of VASCEPA, particularly in Europe, and adjust to the potential impact of the launch of generic versions of VASCEPA in the United States.

Interest income (expense), net. Net interest income (expense) for the three months ended June 30, 2020 and 2019 was $0.2 million and $0.8 million, respectively, a decrease of $0.6 million, or 81%. Net interest income for the three months ended June 30, 2020 and 2019 is summarized in the table below:

	Three months ended June 30,	
In thousands	**2020**	**2019**
Debt from royalty-bearing instrument (1):		
Cash interest	$ (496)	$ (1,156)
Non-cash interest	(201)	(431)
Total debt from royalty-bearing instrument interest expense	(697)	(1,587)
Other interest expense	(93)	(155)
Total interest expense	(790)	(1,742)
Interest income (2)	941	2,531
Total interest income (expense), net	$ 151	$ 789

(1) Cash and non-cash interest expense related to the December 2012 royalty-bearing instrument for the three months ended June 30, 2020 and 2019 was $0.7 million and $1.6 million, respectively. These amounts reflect the fact that our VASCEPA net revenue levels have not been, and during these periods were not assumed to be, high enough to support repayment in accordance with the contractual repayment schedule without the optional reduction which is allowed to be elected by us if the threshold revenue levels are not achieved. To date, our revenues have been below the contractual threshold amount each quarter such that each payment reflects the calculated optional reduction amount as opposed to the contractual threshold payments for each quarterly period.

(2) Interest income for the three months ended June 30, 2020 and 2019 was $0.9 million and $2.5 million, respectively. Interest income represents income earned on cash and investment balances. As a result of COVID-19 and the resulting economic

conditions, interest rates have decreased during the three months ended June 30, 2020 as compared to the three months ended June 30, 2019.

Other income (expense), net. Other income (expense), net for each of the three months ended June 30, 2020 and 2019 was income of $0.1 million and expense of $0.1 million, respectively. Other income (expense), net, primarily consists of gains and losses on foreign exchange transactions.

Comparison of Six Months Ended June 30, 2020 and June 30, 2019

Product revenue, net. We recorded net product revenue of $285.9 million and $173.1 million during the six months ended June 30, 2020 and 2019, respectively, an increase of $112.8 million, or 65%. This increase was driven primarily by volume of VASCEPA sales to our customers in the United States, as well as a modest increase in VASCEPA's net selling price in the United States. Orders by such customers were supported by an increase in estimated normalized total VASCEPA prescriptions in the United States, reflecting various factors including managed care improvements. Based on data provided by Symphony Health and IQVIA, estimated normalized total VASCEPA prescriptions in the United States increased by approximately 778,000 and 733,000, respectively, over the six months ended June 30, 2019, representing growth of 57% and 59%, respectively. The increase in net product revenue was also driven by VASCEPA sales to our commercial partners outside of the United States of approximately $8.5 million during the six months ended June 30, 2020 as compared to $0.3 million during the six months ended June 30, 2019, primarily as a result of an initial order to ensure availability of adequate product supply for the launch of VASCEPA in Canada, such revenue is based on contractually agreed pricing and other terms.

All of our product revenue, net in the United States, in the six months ended June 30, 2020 and 2019 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 U.S. 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 six months ended June 30, 2020 and 2019, our Product revenue, net in the United States included adjustment for co-pay mitigation support provided by us for commercially insured patients. Such rebates are intended to offset a portion of the out-of-pocket expense that patients are required to pay for VASCEPA based upon the benefit of their insurances. Our cost for these co-payment support payments during the six months ended June 30, 2020 and 2019 was up to $150 and $110, respectively, per 30-day prescription filled and, up to $450 and $330, respectively per 90-day prescription filled.

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

In March 2020, COVID-19, or SARS-CoV-2, became widespread in the United States and other geographies around the globe. In recognition of guidance from public health officials, we announced on March 15, 2020 a temporary suspension of in-person promotional activities. In June 2020, we resumed sales force, field-based, face-to-face interactions with healthcare providers in a phased approach that is consistent with guidelines from local, state and government health officials in the United States. For a newly FDA-approved drug like VASCEPA to be prescribed, historically physicians need to have met with their patients for an examination and have received blood test results prior to prescribing the drug to the patient. Public reports from IQVIA showed patient visits to medical offices for non-emergency medical care were down approximately 70% in April 2020 during the height of the COVID-19 related social distancing. Also reported was a significant drop in the number of routine lab tests likely due to patients not seeking medical care for non-urgent medical needs and resources of the medical community shifting focus to address the COVID-19 pandemic. As a result, while VASCEPA prescription levels in the three months ended June 30, 2020 grew over the three months ended June 30, 2019, we witnessed a slowing of new patients being prescribed VASCEPA resulting in year over year growth in June 30, 2020 which was considerably slower than the growth reported in the three months ended March 31, 2020 when we launched VASCEPA for its new cardiovascular indication. According to IQVIA data, in June 2020 the number of patient visits to health care providers and the number of lab tests increased meaningfully over the lows of April 2020 but remained below the volume levels reported prior to mid-March 2020 when the impact of COVID-19 began to significantly impact the United States. We cannot predict the duration of this pandemic and we cannot quantify the impact of COVID-19 on our business beyond June 30, 2020. We are confident that the patient need for VASCEPA remains high and that the slowing of VASCEPA growth in the three months ended June 30, 2020 was COVID-19 related. While we are optimistic that the worst of the COVID-19 impact is behind us regarding the levels of patients seeking ordinary course doctor visits and lab tests, we expect that COVID-19 will continue, at least in the near term, to impact the level of VASCEPA prescriptions and the degree and timing to which we can, if at all, reaccelerate VASCEPA growth, particularly if there are resurgences in the spread of the infection in various geographies and a reinforcement of social distancing and other protocols.

Licensing and royalty revenue. Licensing and royalty revenue during the six months ended June 30, 2020 and 2019 was $4.4 million and $1.0 million, respectively, an increase of $3.4 million, or 350%. Licensing revenue relates to the recognition of amounts received in connection with the following VASCEPA licensing agreements:

- Eddingpharm – a $15.0 million up-front payment received in February 2015 and a $1.0 million milestone payment achieved in March 2016,
- HLS – a $5.0 million up-front payment which was received upon closing of the agreement in September 2017, a $2.5 million milestone payment that was received following achievement of the REDUCE-IT trial primary endpoint in September 2018, a $2.5 million milestone payment that was received following FDA approval of a new indication and label expansion in December 2019 and a $3.8 million milestone payment that was received as a result of obtaining a regulatory exclusivity designation in January 2020.

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.

As part of our licensing agreements with certain territories outside of the United States, we are entitled to a percentage of revenue earned based on sales by our partners. The royalty payments are being recognized as earned based on revenue recognized by our current partners.

Cost of goods sold. Cost of goods sold during the six months ended June 30, 2020 and 2019 was $63.6 million and $39.9 million, respectively, an increase of $23.7 million, or 59%. 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 June 30, 2020 and 2019 was sourced from multiple 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 2020 to be similar to or modestly lower than 2019. The average cost may be variable from period to period depending upon the timing and quantity of API purchased from each supplier.

Our overall gross margin on product sales for each of the six months ended June 30, 2020 and 2019 was 78% and 77%, respectively. The increase in gross margin on product sales is driven by gross margin on U.S. product sales of 80%, partially offset by the gross margin on product sales to our partners outside the U.S. which was based on contractually agreed upon terms with our commercial partners in those territories which partners incur the costs of promoting and selling the product in their territories. During the six months ended June 30, 2019, the $0.3 million product sales to our partners outside the U.S. had a negligible impact on gross margin levels.

Selling, general and administrative expense. Selling, general and administrative expense for the six months ended June 30, 2020 and 2019 was $226.3 million and $145.0 million, respectively, an increase of $81.3 million, or 56%. Selling, general and administrative expenses for the six months ended June 30, 2020 and 2019 are summarized in the table below:

	Six months ended June 30,	
In thousands	**2020**	**2019**
Selling expense (1)	$ 167,060	$ 107,619
General and administrative expense (2)	39,894	24,972
Non-cash stock-based compensation expense (3)	19,378	12,448
Total selling, general and administrative expense	$ 226,332	$ 145,039

(1) Selling expense for the six months ended June 30, 2020 and 2019 was $167.1 million and $107.6 million, respectively, an increase of $59.4 million, or 55%. This increase is primarily due to increased personnel costs related to the sales force expansion from approximately 440 sales professionals, including approximately 400 sales representatives, in 2019 to approximately 900 sales professionals, including approximately 800 sales representatives, as well as an increase in promotional activities and direct to consumer promotion following the launch of VASCEPA in early 2020 for the new indication and expanded label approved by FDA in December 2019.

(2) General and administrative expense for the six months ended June 30, 2020 and 2019 were $39.9 and $25.0 million, respectively, an increase of $14.9 million, or 60%. This increase is primarily a result of increased legal fees related to the ongoing ANDA patent litigation in the United States, personnel and related costs and insurance premiums.

(3) Non-cash stock-based compensation expense for the six months ended June 30, 2020 and 2019 was $19.4 million and $12.4 million, respectively, an increase of $6.9 million, or 56%. Non-cash stock-based compensation expense represents the estimated costs associated with equity awards issued to personnel supporting our selling, general and administrative functions. The increase is due primarily to an increase in the number of employees receiving equity awards as a result of the growth of our sales force and an increase in the underlying fair value of the equity awards.

We continuously evaluate all of our spending commitments and priorities, including the impact of the pending ANDA patent litigation and COVID-19 and as we work to increase revenue from VASCEPA. We currently plan to spend approximately $80.0 million in education and promotion in 2020 to increase awareness of VASCEPA as the only U.S. FDA-approved drug for lowering the risk of heart attacks, strokes, and other major adverse cardiovascular events in high risk patients beyond statin therapy. We plan to adjust our level of education and promotional activities based on various factors, including whether any generic company takes the risk of launching a generic version of VASCEPA during the patent litigation appeal process and the amount of any product launched.

Research and Development Expense. Research and development expense for the six months ended June 30, 2020 and 2019 was $20.2 million and $14.4 million, respectively, an increase of $5.9 million, or 41%. Research and development expenses for the six months ended June 30, 2020 and 2019 are summarized in the table below:

	Six months ended June 30,	
In thousands	**2020**	**2019**
REDUCE-IT study (1)	$ 7,213	$ 3,707
Regulatory filing fees and expenses (2)	1,181	663
Internal staffing, overhead and other (3)	8,509	7,684
Research and development expense, excluding non-cash Expense	16,903	12,054
Non-cash stock-based compensation expense (4)	3,344	2,318
Total research and development expense	$ 20,247	$ 14,372

The increase in research and development expenses for the six months ended June 30, 2020, as compared to the prior year period, is primarily due to timing of REDUCE-IT and related costs.

(1) In September 2018, we announced landmark positive topline results of the REDUCE-IT cardiovascular outcomes trial. The increase in expenses is primarily driven by costs beyond the conduct of the study to further analyze samples collected from REDUCE-IT patients.

(2) The regulatory filing fees included annual FDA fees for maintaining manufacturing sites. Such fees primarily represent fees for qualification of new suppliers, including increasing capacity capabilities, and fees for sites used for the manufacture of product used in the REDUCE-IT clinical outcomes study.

(3) Internal staffing, overhead and other research and development expenses primarily relate to the costs of our personnel employed to manage research, development and regulatory affairs activities and related overhead costs including consulting and other professional fees that are not allocated to specific projects. Also included are costs related to qualifying suppliers. In January 2020, we achieved certain milestones under our strategic collaboration agreement with Mochida, resulting in payment of $1.0 million. Also included are costs associated with various other investigations, including other costs in collaboration with Mochida and pilot studies regarding VASCEPA and COVID-19.

(4) Non-cash stock-based compensation expense represents the estimated costs associated with equity awards issued to personnel supporting our research and development and regulatory functions.

We are in the process of evaluating all of our spending commitments and priorities on research and development activities. Our research and development expenses may be variable in the coming quarters as we advance analysis of samples collected from REDUCE-IT patients, consider potential investigator initiatives involving VASCEPA and cardiovascular risk mitigation in COVID-19 patients, support international regulatory review of VASCEPA, particularly in Europe, and adjust to the potential impact of the launch of generic versions of VASCEPA in the United States.

Interest income (expense), net. Net interest income (expense) for the six months ended June 30, 2020 and 2019 was income of $1.4 million and expense of $0.9 million, respectively, an increase of $2.3 million, or 250%. Net interest income (expense) for the six months ended June 30, 2020 and 2019 is summarized in the table below:

	Six months ended June 30,	
In thousands	**2020**	**2019**
Long-term debt from royalty-bearing instrument (1):		
Cash interest	$ (1,260)	$ (2,368)
Non-cash interest	(490)	(877)
Total debt from royalty-bearing instrument interest expense	(1,750)	(3,245)
Other interest expense	(231)	(329)
Total interest expense	(1,981)	(3,574)
Interest income (2)	3,340	2,666
Total interest income (expense), net	$ 1,359	$ (908)

(1) Cash and non-cash interest expense related to the December 2012 royalty-bearing instrument for the six months ended June 30, 2020 and 2019 was $1.8 million and $3.2 million, respectively. These amounts reflect the fact that our VASCEPA net revenue levels have not been, and during these periods were not assumed to be, high enough to support repayment in accordance with the contractual repayment schedule without the optional reduction which is allowed to be elected by us if the threshold revenue levels are not achieved. To date, our revenues have been below the contractual threshold amount each quarter such that each payment reflects the calculated optional reduction amount as opposed to the contractual threshold payments for each quarterly period.

(2) Interest income for the six months ended June 30, 2020 and 2019 was $3.3 million and $2.7 million, respectively. Interest income represents income earned on cash and investment balances. The increase is driven by the increased cash and investment balances as a result of the public offering we completed in July 2019, which resulted in net proceeds of $440.1 million.

Other income (expense), net. Other income (expense), net, for the six months ended June 30, 2020 and 2019 was nominal and expense of $0.1 million, respectively. Other income (expense), net, primarily consists of gains and losses on foreign exchange transactions.

Income tax benefit. Income tax benefit for the six months ended June 30, 2020 and 2019 was $2.4 million and nil, respectively. The income tax benefit recorded for the period ended June 30, 2020 relates to the carryback of U.S. net operating losses as permitted under the CARES Act enacted in March 2020. The provision for each period is the result of losses generated by our U.S. and non-U.S. operations for which no tax benefit other than the benefit related to the loss carryback has been recognized based on our position that deferred tax benefits are not more likely than not to be realized based on available evidence.

Liquidity and Capital Resources

Our sources of liquidity as of June 30, 2020 exceeds $600.0 million which includes cash and cash equivalents and restricted cash of $217.9 million, short-term investments of $336.3 million and long-term investments of $61.0 million. Our cash and cash equivalents primarily include checking accounts and money market funds with original maturities less than 90 days. Our short-term investments consist of held-to-maturity securities that will be due in one year or less. Our long-term investments consist of held-to-maturity securities that will be due in more than one year. We invest cash in excess of our immediate requirements, in accordance with our investment policy, which limits the amounts we may invest in any one type of investment and requires all investments held by us to maintain minimum ratings from Nationally Recognized Statistical Rating Organizations so as to primarily achieve our goals of liquidity and capital preservation.

Our cash flows from operating, investing and financing activities, as reflected in the condensed consolidated statements of cash flows, are summarized in the following table:

	Six months ended June 30,	
In millions	**2020**	**2019**
Cash provided by (used in):		
Operating activities	$ 5.7	$ (22.2)
Investing activities	(396.3)	(0.8)
Financing activities	(40.0)	(4.5)
Decrease in cash and cash equivalents and restricted cash	$ (430.6)	$ (27.5)

Net cash provided in operating activities during the six months ended June 30, 2020 compared net cash used in operating activities during the same period in 2019 increased primarily as a result of higher collections due to an increase in product sales, partially offset by costs associated with expanding our United States-based sales force, as well as increased costs of promotional activities following the successful REDUCE-IT study results.

Net cash used in investing activities during the six months ended June 30, 2020 compared to the same period in 2019 increased as a result of our purchasing approximately $527.5 million investment-grade interest bearing instruments during 2020, partially offset by $131.4 million in proceeds from the maturity and sale of securities.

Net cash used by financing activities during the six months ended June 30, 2020 increased as compared to the same period in the prior year, primarily due to a decrease in the number of stock options that were exercised during the period and an increase in the payment made on our royalty-bearing instrument.

In December 2012, we entered into a financing agreement with BioPharma. Under this agreement, we granted to BioPharma a security interest in future receivables and all related rights to VASCEPA, in exchange for $100.0 million received at the closing of the agreement which closing occurred in December 2012. In December 2017, BioPharma assigned all rights under this agreement to CPPIB. We have agreed to repay up to $150.0 million of future revenue and receivables. As of June 30, 2020, the net remaining amount to be repaid to CPPIB is $23.0 million, which will be repaid in quarterly installments calculated as 10% of quarterly VASCEPA net revenues. We can prepay the net remaining amount at any time.

As of June 30, 2020, we had net accounts receivable $125.0 million and inventory of $124.8 million. We have incurred annual operating losses since our inception and, as a result, we had an accumulated deficit of $1.4 billion as of June 30, 2020. We anticipate that quarterly net cash outflows in future periods will continue to be variable as a result of the timing of certain items, including our purchases of API, VASCEPA promotional activities from approval by the FDA for the new indication and expanded label and the impact from COVID-19 on our operations and those of our customers, any potential generic competition in the United States as a result of our ANDA litigation and commercialization of VASCEPA in Europe. For Europe, we anticipate the number of added employees to be hired in 2020 to be fewer than twenty professionals as the initial focus in Europe is on regulatory approval and reimbursement.

We believe that our cash and cash equivalents of $214.0 million as of June 30, 2020 together with our short-term investments of $336.3 million as of June 30, 2020, will be sufficient to fund our projected operations for at least twelve months and is adequate to achieve positive cash flow from VASCEPA based on our current plans. We have based this estimate on assumptions that may prove to be wrong, including as a result of the risks discussed below under Part II, Item IA, “Risk Factors”, and we could use our capital resources sooner than we expect or fail to achieve positive cash flow.

Contractual Obligations

Our contractual obligations consist mainly of payments related to purchase obligations with certain supply chain contracting parties, operating leases related to real estate used as office space and debt and related interest. There have been no material changes during the six months ended June 30, 2020 to our contractual obligations as presented in Part II, Item 7 of our Annual Report on Form 10-K for the year ended December 31, 2019.

Off-Balance Sheet Arrangements

We do not have any special purpose entities or other off-balance sheet arrangements.

Item 3. ***Quantitative and Qualitative Disclosures about Market Risk***

There have been no material changes with respect to the information appearing in PART II, Item 7A “Quantitative and Qualitative Disclosures about Market Risk” of our Annual Report on Form 10-K filed with the Securities and Exchange Commission on February 25, 2020.

Item 4. ***Controls and Procedures***

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Securities Exchange Act of 1934, as amended, or the Exchange Act, is (1) recorded, processed, summarized, and reported within the time periods specified in the SEC’s rules and forms and (2) accumulated and communicated to our management, including our Principal Executive Officer and Principal Financial Officer, to allow timely decisions regarding required disclosure.

As of June 30, 2020, or the Evaluation Date, our management, with the participation of our Principal Executive Officer and Principal Financial Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our Principal Executive Officer and Principal Financial Officer have concluded, based upon the evaluation described above that, as of June 30, 2020, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

During the quarter ended June 30, 2020, there have been no changes in our internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15(d)-15(f) promulgated under the Exchange Act, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II

Item 1. ***Legal Proceedings***

In the ordinary course of business, we are 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 our Annual Report on Form 10-K for the fiscal year ended December 31, 2019 includes a discussion of our current legal proceedings. There have been no material changes to the matters described in those disclosures during the three months ended June 30, 2020, other than as set forth below.

The trial for the ANDA patent litigation against defendants, Dr. Reddy’s Laboratories, Inc. and Dr. Reddy’s Laboratories, Ltd., or, collectively, DRL, and Hikma Pharmaceuticals USA Inc., or Hikma, and certain of their respective affiliates, or the Defendants, took place in the United States District Court for the District of Nevada, or the Nevada Court (case no.: 2:16-cv-02525-MMD-NJK (consolidated with 2:16-cv-02562-MMD-NJK). Following conclusion of the trial in late January 2020, the Nevada Court, on March 30, 2020, decided in favor of the Defendants, ruling that our relevant patents are invalid due to obviousness. We have appealed this decision to the United States Court of Appeals for the Federal Circuit (case no.: 20-1723). We intend to vigorously enforce our intellectual property rights relating to VASCEPA, but we cannot predict the outcome of the appeal.

A settlement agreement with Apotex Inc., or Apotex, was reached in June 2020, that resolves patent litigation that would have resulted from the previously disclosed ANDA filed by Apotex with U.S. Food and Drug Administration, or FDA, and amended in May 2020, seeking approval of a generic form of VASCEPA capsules based on the MARINE study. As part of the settlement agreement, Apotex may not sell a generic version of VASCEPA in the United States until August 9, 2029 (the same such date provided for under the 2018 settlement agreement with Teva Pharmaceuticals USA, Inc., or Teva) or earlier under certain customary circumstances. As currently relevant, such circumstances include if we are not successful in our pending appeal of the March 2020 Nevada Court decision after issuance of the Federal Circuit mandate following any Federal Circuit rehearing or *en banc* review.

Item 1A. **Risk Factors**

This Quarterly Report on Form 10-Q contains forward-looking information based on our current expectations. Because our actual results may differ materially from any forward-looking statements that we make or that are made on our behalf, this section includes a discussion of important factors that could affect our actual future results, including, but not limited to, our ability to successfully commercialize VASCEPA, our capital resources, the progress and timing of our clinical programs, the safety and efficacy of our product candidates, risks associated with regulatory filings, the potential clinical benefits and market potential of our product candidates, commercial market estimates, future development efforts, patent protection, effects of healthcare reform, reliance on third parties effects of tax reform, and other risks set forth below.

Except those denoted below with a “”, these risk factors have not been materially updated from our Annual Report on 10-K for the year ended December 31, 2019 filed with the SEC on February 25, 2020.*

Risks Related to the Commercialization and Development of VASCEPA

**** We are substantially dependent upon VASCEPA, its commercialization in the United States and its development and commercialization in major markets. In the United States, VASCEPA could experience generic competition in the near term in light of a federal district court ruling in favor of the generic drug companies in our patent trial.***

The success of our company depends on our ability to successfully commercialize our sole product, VASCEPA® (icosapent ethyl) capsules, in major markets. Our primary focus has been on the U.S. market as much of our near-term financial results and value as a company has depended on our ability to execute our development and commercial strategy for VASCEPA in the United States. As previously disclosed, on March 30, 2020, following a trial, a federal district court ruled in favor of the generic drug companies in our patent litigation against two filers of abbreviated new drug applications, or ANDAs, for our VASCEPA franchise in the United States. We disagree with the ruling that our patents are invalid and are vigorously pursuing appeal. As detailed further below, if generic companies determine to launch generic versions of icosapent ethyl in the United States, such competition could have a material and adverse impact on our revenues and our results of operations.

We have expanded our development efforts to support regulatory approvals and launch of VASCEPA in major markets outside the United States primarily for the reduction of cardiovascular risk in high risk patients. This is the second indication approval for VASCEPA in the United States and is an indication that is different than that which is subject, in the United States, to the adverse patent litigation in the United States. We currently have multiple partners for the development and commercialization of VASCEPA in select geographies and intend to consider potential additional partners to commercialize VASCEPA in other parts of the world. For example, we have strategic collaborations for the development and commercialization of VASCEPA in Canada, the Middle East and Greater China. We are also currently developing VASCEPA on our own in Europe and are exploring possible strategic collaborations

within Europe and in other major markets. If commercialization efforts for VASCEPA do not meet expectations in major markets such as the United States and Europe, our business and prospects could be materially and adversely affected.

The development and commercial time cycle for VASCEPA or other products that we may develop from our research and development efforts could result in delays in our ability to achieve commercial success. For example, only after years of preceding product development, in December 2019, we announced that the EMA validated our MAA seeking approval for icosapent ethyl (brand name VASCEPA in the United States) as a treatment to reduce the risk of cardiovascular events in select high-risk patients.

Likewise, if we seek to diversify our development programs or product offerings through licensing or acquisitions, such transactions are also time-consuming, may be dilutive to existing shareholdings, and can be disruptive to operations, and may not be available on favorable terms, or at all. These dynamics can restrict our ability to respond rapidly to adverse business conditions for VASCEPA. If development of, or demand for, VASCEPA does not meet expectations, we may not have the ability to effectively shift our resources to the development of alternative products, or do so in a timely manner, without suffering material adverse effects on our business. As a result, the lack of alternative markets and products we develop could constrain our ability to generate revenues and achieve profitability.

**** As a result of the decision in favor of the two generic drug companies in connection with our ANDA patent trial, we could face generic competition in the near term and our revenues and results of operations could be materially and adversely affected if the generic companies were to receive final approval of their ANDAs, obtain adequate supply and launch one or more generic versions of VASCEPA in the United States.***

We have received paragraph IV certification notices from certain companies contending to varying degrees that certain of our patents are invalid, unenforceable and/or will not be infringed by the manufacture, use, sale or offer for sale of a generic form of VASCEPA as described in those companies' ANDAs. Following receipt of the paragraph IV certifications, beginning in late 2017 we were involved in litigation against these companies, including Dr. Reddy's Laboratories, Inc., or DRL, and Hikma Pharmaceuticals USA Inc., or Hikma, (formerly known as West-Ward) and certain of their affiliates, or the Defendants, in the U.S. District Court for the District of Nevada, or the Nevada Court. In these lawsuits, we sought, among other remedies, an order enjoining each Defendant from marketing generic versions of VASCEPA before the last to expire of the asserted patents in 2030.

On March 30, 2020, following conclusion of the trial in late January 2020, the Nevada Court issued its ruling in favor of the Defendants. The statutory stay on the FDA's ability to give final approval to a generic VASCEPA associated with the filing of these lawsuits expired in January 2020. Hikma received FDA approval of its ANDA in May 2020. The FDA could approve DRL's ANDA at any time. After FDA approval, subject to adequate supply, either company could commercially launch a generic version of VASCEPA in the United States.

The ruling of the Nevada Court could also permit Teva Pharmaceuticals USA, Inc., or Teva, to launch a generic version of VASCEPA under certain circumstances pursuant to a settlement agreement with us. For example, our settlement agreement with Teva provides that if another generic company obtains FDA approval and launches at risk pending appeal of the March 2020 Nevada Court ruling, Teva can launch its generic version of VASCEPA if we do not obtain an injunction removing such product from the market within 60 days. In such case, Teva's commercialization would be at risk as Teva would be required to withdraw its product from the market if the other entities that launched at risk withdraw their products. Our settlement with Apotex Inc., or Apotex, does not have this provision. Further, the Teva and Apotex settlement agreements permit such companies to launch their generic version of VASCEPA if we lose our appeal of the March 2020 Nevada Court decision at the Federal Circuit level. Like Teva, any launch by Apotex would be subject to FDA approval of the Apotex ANDA and procurement of adequate supply.

Once a generic version of VASCEPA is available in the market, whether based on a generic product with a MARINE indication label or REDUCE-IT indication label, it can be used to fill a prescription for any use of the drug. The possibility of generic competition in the near term could have, and any commercial launch of a generic version of VASCEPA into the market could have, a material and adverse impact on our revenues and our results of operations.

Further, although we are appealing the ruling of the Nevada Court, and may pursue additional remedies, including seeking a preliminary injunction pending appeal, we may not be successful in any such efforts, which will be costly and time-consuming to pursue. Such efforts will also require considerable attention of management and could, even if ultimately successful, negatively impact our results of operations.

Additionally, while we believe that VASCEPA is difficult to manufacture and that building capacity to manufacture VASCEPA is time-consuming and expensive, all of which may limit the amount of VASCEPA supply available to generic companies in the event that they launch a generic version of VASCEPA, we could be wrong. We do not have direct visibility into the supply levels of any of the ANDA filers and we rely on our own experience together with information from third parties. The ANDA filers could potentially find or develop sources of qualified VASCEPA supply that are not known to us.

**** Factors outside of our control make it more difficult for VASCEPA to achieve a level of market acceptance by physicians, patients, healthcare payors and others in the medical community necessary to meet expectations for commercial success.***

In January 2013, we launched VASCEPA based on the U.S. Food and Drug Administration, or FDA, approval of our MARINE indication, for use as an adjunct to diet to reduce triglyceride levels in adult patients with severe (TG $\geq$ 500 mg/dL) hypertriglyceridemia. Guidelines for the management of very high triglyceride levels suggest that the primary goal of reducing triglyceride levels in this patient population is reduction in the risk of acute pancreatitis. A secondary goal for this patient population is to reduce cardiovascular risk. The effect of VASCEPA on the risk for pancreatitis in patients with severe hypertriglyceridemia has not been determined and our FDA-approved labeling and promotional efforts state these facts.

In September 2018, we announced topline results from the REDUCE-IT®, or Reduction of Cardiovascular Events with EPA—Intervention Trial cardiovascular outcomes study of VASCEPA. In November 2018, we announced the primary results of our REDUCE-IT cardiovascular outcomes study confirming 25% relative risk reduction for the topline primary endpoint result with multiple robust demonstrations of efficacy, including 20% reduction in cardiovascular death. REDUCE-IT was a multinational, prospective, randomized, double-blind, placebo-controlled study, enrollment for which started in November 2011. REDUCE-IT investigated the effects of VASCEPA on CV risk in statin-treated adults with well-controlled LDL-C 41-100 mg/dL (median baseline LDL-C: 75 mg/dL) and other CV risk factors, including persistent elevated TG 150-499 mg/dL (median baseline TG: 216 mg/dL). REDUCE-IT topline results showed the trial met its primary endpoint demonstrating an approximately 25% relative risk reduction, to a high degree of statistical significance ($p<0.001$), in MACE in the intent-to-treat patient population with use of VASCEPA 4 grams/day as compared to placebo. MACE events were defined as a composite of cardiovascular death, nonfatal myocardial infarction (MI), nonfatal stroke, coronary revascularization, or unstable angina requiring hospitalization. This result was supported by robust demonstrations of efficacy across multiple secondary endpoints. VASCEPA was well tolerated in REDUCE-IT with a safety profile generally consistent with clinical experience associated with omega-3 fatty acids and current FDA-approved labeling.

In December 2019, the FDA approved a new indication and label expansion for VASCEPA as an adjunct to statin therapy to reduce the risk of MACE events in adult patients with elevated TG levels (≥150 mg/dL) and established cardiovascular disease or diabetes mellitus and two or more additional risk factors for cardiovascular disease.

Despite FDA approval for this new indication and expanded label for VASCEPA, we may not meet expectations for market acceptance by physicians, patients, healthcare payors and others in the medical community for this new approved use, even if we are successful in our appeal of the March 2020 ruling in the Nevada Court. If VASCEPA does not achieve an adequate level of acceptance, we may not generate product revenues sufficient to become profitable on an ongoing basis. The degree of market acceptance of VASCEPA for its approved indications and uses or otherwise will depend on a number of factors, including:

- the impact of and outcome of our pending appeal of the March 2020 Nevada Court ruling;
- the commercialization and pricing of any generic version of VASCEPA;
- the perceived efficacy and safety of VASCEPA by prescribing healthcare professionals and patients, as compared to no treatment and as compared to alternative treatments in various at-risk patient populations;
- peer review of different elements of REDUCE-IT results over time;
- continued review and analysis of the results of REDUCE-IT by regulatory authorities internationally;
- our ability to offer VASCEPA for sale at competitive prices;
- convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the scope, effectiveness and strength of product education, marketing and distribution support, including our sales and marketing team;
- publicity concerning VASCEPA or competing products;
- our ability to continually promote VASCEPA in the United States consistent with and outside of FDA-approved labeling and the related perception thereof;
- sufficient third-party coverage or reimbursement for VASCEPA and its prescribe uses, on-label and off-label;
- natural disasters, including pandemics such as the recent outbreak of coronavirus, and political unrest that could inhibit our ability to promote VASCEPA regionally and can negatively affect product demand by creating obstacles for patients to seek treatment and fill prescriptions;

- new policies or laws affecting VASCEPA sales, such as state and federal efforts to affect drug pricing and provide or remove healthcare coverage that includes reimbursement for prescription drugs; and
- the actual and perceived efficacy of the product and the prevalence and severity of any side effects and warnings in VASCEPA's approved labeling internationally.

For example, two major factors that affect market use of prescription drugs are their perceived cost-effectiveness and the breadth of their use among different patient populations, both on label and off-label. In October 2019, the Institute for Clinical and Economic Review, or ICER, released its final evidence report regarding clinical effectiveness and economic impacts on VASCEPA. The conclusion from the report is that VASCEPA easily met even the most stringent "commonly cited thresholds for cost-effectiveness and therefore represent(s) a high long-term value for money," based on the organization's value assessment framework. As part of the public meeting held by ICER analyzing REDUCE-IT data, the ICER review committee discussed whether, based on REDUCE-IT, VASCEPA should be considered for use in patients as an add-on to statin therapy generally, and not just in patients with persistent elevated triglyceride levels after statin therapy, which ICER defined as triglyceride levels of at least 135 mg/dL. Use as an add-on to statin therapy generally represents a larger patient population than studied in REDUCE-IT and larger than covered by FDA-approved labeling. By contrast, FDA-approved labeling for VASCEPA reflects limitations such as use in patients with persistent elevated triglyceride levels defined as triglyceride levels of at least 150 mg/dL after statin therapy and specific criteria designed to ensure the patient populations approved for use had sufficiently high degrees of CV risk. While the clinical judgment of prescribing physicians is the most important factor that determines the breadth of a drug's use in the United States and often results in prescriptions in patient populations that go beyond FDA labeling, FDA-approved labeling that is more closely tied to the patient population studied in a clinical trial could limit use generally and by making reimbursement more difficult.

The scale and scope of the coronavirus, or COVID-19, pandemic is uncertain and poses a significant threat to public health and infrastructure throughout the world, which could have a negative impact on our business.

The global spread of the coronavirus has created significant volatility, uncertainty and disruption in healthcare, social and economic infrastructures. The extent to which the coronavirus pandemic impacts our business, operations and financial results will depend on numerous evolving factors that we may not be able to accurately predict or plan around, including:

- the duration and scope of the pandemic;
- governmental, business and individuals' actions that have been and continue to be taken in response to the pandemic;
- the impact of the pandemic on economic and political activity and actions taken in response;
- the effect on patients, healthcare providers and business partners, including patients' ability to access supplies of VASCEPA and the willingness of patients to visit doctors for non-urgent medical examination or to visit labs for blood tests to assess biomarkers such as lipid levels;
- our ability to commercialize VASCEPA, including as a result of travel restrictions, social distancing and other containment measures;
- the enrollment or monitoring of patients in clinical trials, particularly at clinical trial sites located in highly impacted jurisdictions;
- the ability to access, secure and otherwise obtain and deliver sufficient and timely commercial or clinical supplies of VASCEPA to meet demand if the production capabilities of suppliers is disrupted;
- disruptions in regulatory oversight and actions if regulators and industry professionals are expending significant and unexpected resources addressing COVID-19;
- the availability of coverage and reimbursement from government and health administration authorities, private health insurers and other third-party payors if the system becomes overly strained; and
- any closures of our and our partners' offices, operations and facilities impeding our ability to work together as a company and with our business and healthcare partners.

To comply with travel restrictions, social distancing, quarantines and other containment measures implemented in various geographies, in March 2020, we suspended field based face-to-face interactions. We resumed sales force, field-based, face-to-face interactions with healthcare providers on a pilot scale in June 2020. As the situation changes, we hope to be able to resume more of our business efforts but there can be no assurance that this will be successful or that healthcare providers who have started to allow direct interactions with our sales force will continue to allow such interactions. In an effort to mitigate this disruption, we have implemented remote protocols and procedures to be able to support patient care and access of VASCEPA by providing digital and internet-based educational materials and copay cards. Although we expect such measures to be temporary, we cannot predict how long such measures will need to be in place. These efforts may not be as successful as traditional, in-person interactions, and are vulnerable

to disruptions that may occur if the digital infrastructures are insufficient to accommodate the increased usage as social distancing is implemented on a global scale. For example, access to healthcare professionals through the internet is not as productive as interactions under prior conditions.

Although we have a geographically diversified supply chain for VASCEPA and believe we have sufficient inventory on hand at pharmacies throughout the United States and other markets where it is approved for sale, and at various stages of manufacturing with our suppliers, the global spread of the outbreak and containment measures has been unprecedented and could have a negative impact on the availability of VASCEPA at various points in our supply chain, which would have a material and adverse effect on our business.

The disruptions associated with the coronavirus pandemic could also delay the timing of a determination on our patent ruling appeal and our ability to seek other legal remedies as travel, operational resources and personnel are disrupted, with respect to our efforts and capabilities, as well as those of our advisors and the courts. The disruptions associated with the coronavirus pandemic could also delay our plans to hire additional employees for the potential commercialization of VASCEPA in Europe and could also delay the potential timing of completion of the EMA review and subsequent review of our application to get VASCEPA approved to be marketed in Europe. For instance, COVID-19 appears to have modestly slowed certain aspects of the review with the overall timeline for the review being completed by the EMA shifting from what was previously estimated as late 2020 into our current estimate of early 2021.

As with any cardiovascular outcomes trial, over time further data assessment related to REDUCE-IT by international regulatory authorities or otherwise could yield additional useful information to inform greater understanding of study outcome. If the additional data or related interpretations do not meet expectations, the perception of REDUCE-IT results and VASCEPA revenue potential may suffer and our stock price may decline.

In December 2019, the FDA approved a new indication and label expansion for VASCEPA as an adjunct to statin therapy to reduce the risk of MACE events in adult patients with elevated TG levels (≥150 mg/dL) and established cardiovascular disease or diabetes mellitus and two or more additional risk factors for cardiovascular disease. Even though FDA has approved VASCEPA for this expanded label and new indication based on the REDUCE-IT results, additional data assessment by international regulatory authorities or otherwise could yield additional useful information to inform greater understanding of study outcome. Generally, trial data assessment sufficient to convey a complete picture of trial outcome can take years to complete and publish. When new data are assessed and released or presented it could exceed, match or may not meet investor expectations.

In addition, the same set of data can sometimes be interpreted to reach different conclusions. This was the case when Health Canada approved an indication based on REDUCE-IT data that was different in certain respects than that approved by FDA in the United States. It is possible the scope of subsequent regulatory approvals, if any, could likewise differ based on the same data, such as with our pending European Union, or EU, application. Conflicting interpretations of data, or new data, could impact public and medical community perception of the totality of the efficacy and safety data from REDUCE-IT.

Regulatory authorities and medical guideline committees outside of the United States may consider the following additional factors, which could lead to evaluations of the totality of the efficacy and safety data from REDUCE-IT that differ from those of the FDA:

- the magnitude of the treatment benefit and related risks on the primary composite endpoint, its components, secondary endpoints and the primary and secondary risk prevention cohorts;
- consideration of which components of the composite or secondary endpoints have the most clinical significance;
- the consistency of the primary and secondary outcomes;
- the consistency of findings across cohorts and important subgroups;
- safety considerations and risk/benefit considerations (such as related to adverse events such as bleeding and atrial fibrillation generally and in different sub-populations);
- consideration of REDUCE-IT results in the context of other clinical studies;
- consideration of the cumulative effect of VASCEPA in studied patients; and
- study conduct and data quality, integrity and consistency, including aspects such as analyses regarding the placebo used in REDUCE-IT and other studies of VASCEPA and its impact, if any, on the reliability of clinical data.

If regulatory authorities and medical guideline committees outside of the United States draw conclusions that differ from those of the FDA, the FDA could reevaluate its conclusions as to the safety and efficacy of VASCEPA. Likewise, if additional data or analyses released from time to time do not meet expectations, the perception of REDUCE-IT results and the perceived and actual

value of VASCEPA may suffer. In these instances our revenue and business could suffer and our stock price could significantly decline.

**** Ongoing clinical trials involving VASCEPA and similar moderate-to-high doses of eicosapentaenoic acid or icosapent ethyl could influence public perception of VASCEPA's clinical profile and the commercial and regulatory prospects of VASCEPA.***

Ongoing trials of moderate-to-high doses of VASCEPA and icosapent ethyl or a similar, eicosapentaenoic acid, product could provide further information on the effects of VASCEPA and its commercial and regulatory prospects.

The Effect of VASCEPA on Improving Coronary Atherosclerosis in People with High Triglycerides Taking Statin Therapy (EVAPORATE; ClinicalTrials.gov number, NCT02926027), is examining changes in patients' coronary plaque over 9 to 18 months. The goal of this study is to evaluate whether treatment with VASCEPA (4 grams/day) results in a greater change from baseline in low attenuation plaque than placebo in subjects with elevated triglycerides (200-499 mg/dL). Entry criteria for EVAPORATE include: elevated triglycerides (fasting value between 200-499 mg/dL) at qualifying or baseline visit; LDL-C >40 mg/dL and LDL-C ≤115 mg/dL on appropriate statin therapy; stable diet and exercise, as defined as the same pattern for the previous four weeks; and stable treatment with a statin with or without ezetimibe for at least four weeks. In November 2019, interim data from the EVAPORATE study were presented showing a reduction in total plaque volume when compared with placebo, with no shown reduction of low attenuation plaque volume compared with placebo. This study is continuing as designed and final results are expected to be announced in the second half of 2020.

In addition, the Randomized Trial for Evaluation in Secondary Prevention Efficacy of Combination Therapy–Statin and EPA (RESPECT-EPA; UMIN Clinical Trials Registry number, UMIN000012069), is a study examining Japanese patients with chronic coronary artery disease receiving LDL-C lowering treatment by statin therapy. Patients will be randomized to either a control group (standard treatment) or EPA group (standard treatment plus 1.8 grams/day of eicosapentaenoic acid), to examine the effects of a different formulation of icosapent ethyl than VASCEPA on the incidence of cardiovascular events. The relationship between the ratio of EPA to arachidonic acid and incidence of events will also be examined. Results from this study are expected in the second half of 2021, but could be announced sooner, or due to delay related to COVID-19 or otherwise, later.

We are also completing our assessment of a clinical study of VASCEPA in China similar in design to our MARINE study. We expect to announced results of that study in the second half of 2020. There can be no assurance that the results of this trial will be similar to the results of the MARINE study. Even if such results are similar additional clinical development efforts may be necessary in this market to demonstrate the effectiveness of VASCEPA in reducing major adverse cardiovascular events in Chinese patients with persistent cardiovascular risk.

We have also funded investigational studies on the use of VASCEPA in the prevention and treatment of COVID-19 results of which are expected over the next year.

If the outcomes of one or more of these studies do not meet expectations, the perception of existing clinical results of VASCEPA, such as MARINE or REDUCE-IT, or the perceived clinical profile and commercial value of VASCEPA and its regulatory status may suffer. If this occurs our revenue and business could suffer and our stock price could significantly decline.

**** Our current and planned commercialization efforts may not be successful in increasing sales of VASCEPA in the United States and developing sales internationally.***

It is estimated that over 25 million adults in the United States have elevated triglyceride levels ≥200 mg/dL and that more than 50 million adults in the United States have elevated triglyceride levels ≥150 mg/dL. Approximately two to three million adults in the United States have very high (≥500 mg/dL) triglyceride levels, the MARINE patient population. There are approximately 5 to 15 million people in the United States who meet the specific REDUCE-IT inclusion criteria. Since 1976, mean triglyceride levels have increased in concert with the growing epidemic of obesity, insulin resistance, and type 2 diabetes mellitus. In contrast, mean LDL-C levels have decreased. Prior to the REDUCE-IT results topline announcement in September 2018, our direct sales force consisted of approximately 170 sales professionals, including sales representatives and their managers. Based on the positive REDUCE-IT results, in early 2019, we increased the size of our sales force to approximately 440 sales professionals, including approximately 400 sales representatives. As a result of the additional indication and label expansion approved by the FDA in December 2019, in cardiovascular risk reduction, we completed the further expansion of our direct sales force to approximately 900 sales professionals, including approximately 800 sales representatives. This sales team promotes VASCEPA to a limited group of physicians and other healthcare professionals in select geographies in the United States. Even after planned expansion, this sales team is not large enough to call upon all physicians. Thus, despite this significant expansion of our sales team, we may not have sufficient sales personnel and resources to maximize the sales potential of VASCEPA.

In addition to the sales force expansion in the United States, we plan to work internally and with partners to support regulatory efforts toward approvals and commercialization outside the United States based primarily on REDUCE-IT results. For example, assuming regulatory approval, we plan to launch VASCEPA on our own in at least certain geographies in Europe. As such efforts progress, we may encounter further challenges associated with rapidly hiring and training personnel and managing larger teams of people, directly or through our partners in jurisdictions in which management has less experience than in the United States.

Factors related to building and managing a sales and marketing organization in different territories world-wide that could inhibit our efforts to successfully commercialize VASCEPA, include:

- the impact the expiration of regulatory exclusivities and entry into the market of one or more generic versions of VASCEPA, as covered above or with respect to the impact such an event may have on the factors below;
- our inability to attract and retain adequate numbers of effective sales and marketing personnel;
- our inability to adequately train our sales and marketing personnel and our inability to adequately monitor compliance with these requirements;
- the inability of our new sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe VASCEPA;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines;
- an inability by us or our partners to obtain regulatory and marketing approval or establish marketing channels in foreign jurisdictions; and
- unforeseen costs and expenses associated with operating a new independent sales and marketing organization.

If we are not successful in maintaining a sales force that is rightsized for our efforts to market and sell VASCEPA, our anticipated revenues or our expenses could be materially and negatively affected, and we may not obtain profitability, may need to cut back on research and development activities or implement other cost-containment measures, or we may need to raise additional funding that could result in substantial dilution or impose considerable restrictions on our business.

In response to the COVID-19 pandemic, we announced in March 2020 that face-to-face field sales and medical education activities would be temporary halted as a safety measure, and as a result emphasis was placed on conducting these initiatives virtually. In June 2020, we subsequently announced that face-to-face field promotion and medical education activities would be resumed in a phased manner, consistent with guidance from local, state and government health officials. As of June 30, 2020, approximately 450 sales professionals have returned to the field in certain geographies and to varying degrees of access to meet with healthcare professionals and with the levels of such access changing regularly to sometimes be more or less restrictive. We intend to carefully monitor the evolution of the COVID-19 pandemic and may make further adjustments consistent with any changes in guidance from local, state and government health officials. It is anticipated that virtual interactions will be continued for the foreseeable future to complement face-to-face interactions. Additional promotional and educational initiatives are also inclusive of multi-channel consumer education campaigns. There can be no assurance that such virtual interactions or other promotional and educational initiatives will be as effective as the promotion which was being conducted prior to restrictions resulting from COVID-19. In addition, areas of the country in which we have promoted VASCEPA the longest and have historically had the highest levels of reported prescriptions for

VASCEPA include cities and other densely populated areas which may be slower to resume direct interactions with our sales representatives and where patients may be more reluctant to resume visiting their healthcare providers for non-urgent medical care.

In July 2020 we launched our first ever direct to consumer promotional campaign regarding VASCEPA demonstrating results in lowering cardiovascular risk in patients with persistent cardiovascular risk in high risk patients. There can be no assurance that such promotion will have the intended positive increase in patients asking their healthcare providers regarding VASCEPA or that prescription rates for VASCEPA will increase in the near future or at all from such promotion. Data on increased product usage from similar promotion of other products suggests that the impact of television-based promotion can be positive and sustained but is rarely immediate in its effect.

**** Our promotion of VASCEPA is subject to regulatory scrutiny and associated risk generally and in connection with an ongoing U.S. government investigation.***

The Federal Food, Drug, and Cosmetic Act, or FDCA, has been interpreted by the FDA and the U.S. government to make it illegal for pharmaceutical companies to promote their FDA-approved products for uses that have not been approved by the FDA. Companies that market drugs for off-label uses or indications have been subject to related costly litigation, criminal penalties and civil liability under the FDCA and the False Claims Act. However, case law over the last several years has called into question the extent to which government in the United States, including FDA, can, and is willing to seek to, prevent truthful and non-misleading speech related to off-label uses of FDA-approved products such as VASCEPA.

In May 2015, we and a group of independent physicians filed a lawsuit against the FDA seeking a federal court declaration that would permit us and our agents to promote to healthcare professionals the use of VASCEPA in the ANCHOR population and promote on the potential of VASCEPA to reduce the risk of cardiovascular disease so long as the promotion is truthful and non-misleading. This use of VASCEPA at issue reflected recognized medical practice at the time but was not approved by the FDA and was thus not covered by then FDA-approved labeling for the drug. Promotion of an off-label use has generally been considered by the FDA to be illegal under the FDCA. The lawsuit, captioned *Amarin Pharma, Inc., et al. v. Food & Drug Administration, et al.*, 119 F. Supp. 3d 196 (S.D.N.Y. 2015), was filed in the United States District Court for the Southern District of New York. In the lawsuit, we contended principally that FDA regulations limiting off-label promotion of truthful and non-misleading information are unconstitutional under the freedom of speech clause of the First Amendment to the U.S. Constitution as applied in the case of our proposed promotion of VASCEPA. The physicians in the suit regularly treated patients at risk of cardiovascular disease and, as the complaint contended, have First Amendment rights to receive truthful and non-misleading information from Amarin. The suit was based on the principle that better-informed physicians make better treatment decisions for their patients. The FDA opposed this lawsuit but did not dispute the veracity of the subject ANCHOR clinical trial data (the safety data from which was already and currently is in FDA-approved labeling of VASCEPA) or the peer-reviewed research related to VASCEPA and the potential for cardiovascular risk reduction.

In August 2015, we were granted preliminary relief in this lawsuit through the court's declaratory judgment that confirmed we may engage in truthful and non-misleading speech promoting the off-label use of VASCEPA to healthcare professionals, i.e., to treat patients with persistently high triglycerides, and that such speech may not form the basis of a misbranding action under the FDCA. 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. The FDA did not appeal the court's ruling. In March 2016, we settled this litigation under terms by which the FDA and the U.S. government agreed to be bound by the conclusions from the federal court order 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. As part of the settlement, given, as expressed in the court's opinion, that the dynamic nature of science and medicine is that knowledge is ever-advancing and that a statement that is fair and balanced one day may become incomplete or otherwise misleading in the future as new studies are done and new data is acquired, we agreed that we bear the responsibility to ensure that our communications regarding off-label use of VASCEPA remain truthful and non-misleading, consistent with the federal court ruling.

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. In addition to claims classically considered to be on-label based on our expanded label for VASCEPA based on the REDUCE-IT results, we proactively communicate information related to VASCEPA in a manner that we believe is truthful and non-misleading and thus protected under the freedom of speech clause of the First Amendment to the United States Constitution.

Promotional activities in the biotechnology and pharmaceutical industries generally are subject to considerable regulatory scrutiny and, even though we have the benefit of a final settlement in this litigation, our efforts may be subject to enhanced scrutiny to ensure that our promotion remains within the scope covered by the settlement. For example, under the settlement, we remain responsible for ensuring our speech is truthful and non-misleading, which is subject to a considerable amount of judgment. We, the FDA, the U.S. government, our competitors and other interested parties may not agree on the truthfulness and non-misleading nature of our promotional materials. Federal and state governments or agencies may also seek to find other means to prevent our promotion of unapproved truthful and non-misleading information about VASCEPA.

In June 2020, we received a civil investigative demand, or CID, from the U.S. Department of Justice, or the DOJ, informing us that the DOJ is investigating whether aspects of our promotional speaker programs and copayment waiver program during the period from January 1, 2015 to the present violated the U.S. Anti-Kickback Statute and the U.S. False Claims Act in relation to the sale and marketing of VASCEPA by us and our previous co-marketing partner, Kowa Pharmaceuticals America, Inc. The CID requires us to produce documents and answer written questions, or interrogatories, relevant to the specified time period. We plan to cooperate with the DOJ and respond to the interrogatories and document requests of the CID. We cannot predict when the investigation will be resolved, the outcome of the investigation or its potential impact on our business. Such investigations can be lengthy, costly and could materially affect and disrupt our business. If the government determines that we have violated the Anti-Kickback Statute and False Claims Act, we could be subject to significant civil and criminal fines and penalties.

If our promotional activities or other operations are found to be in violation of any law or governmental regulation through existing or new interpretations, we may be subject to prolonged litigation, penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations. Also, if governmental parties or our competitors view our claims as misleading or false, we could be subject to liability based on fair competition-based statutes, such as the Lanham Act. Any allegations that our promotional activities are not truthful or misleading, even allegations without merit, could cause reputational harm and adversely affect our ability to operate our business and our results of operations.

We may not be able to compete effectively against our competitors' pharmaceutical products.

The biotechnology and pharmaceutical industries are highly competitive. There are many pharmaceutical companies, biotechnology companies, public and private universities and research organizations actively engaged in the research and development of products that may be similar to our product. It is probable that the number of companies seeking to develop products and therapies similar to our product will increase. Many of these and other existing or potential competitors have substantially greater financial, technical and human resources than we do and may be better equipped to develop, manufacture and market products. Should generic versions of VASCEPA be launched by third parties or us, our ability to afford market education to grow the market and maintain our current promotional efforts and attract favorable commercial terms in several aspects of our business will likely be adversely affected. These companies may develop and introduce products and processes competitive with, more efficient than or superior to ours. In addition, other technologies or products may be developed that have an entirely different approach or means of accomplishing the intended purposes of our products, which might render our technology and products noncompetitive or obsolete.

Our competitors both in the United States and abroad include large, well-established pharmaceutical and generic companies, specialty and generic pharmaceutical sales and marketing companies, and specialized cardiovascular treatment companies. GlaxoSmithKline plc currently sells Lovaza®, a prescription-only omega-3 fatty acid indicated for patients with severe hypertriglyceridemia, which was approved by FDA in 2004 and has been on the market in the United States since 2005. Multiple generic versions of Lovaza are available in the United States. Other large companies with competitive products include AbbVie, Inc., which currently sells Tricor® and Trilipix® for the treatment of severe hypertriglyceridemia and Niaspan®, which is primarily used to raise high-density lipoprotein cholesterol, or HDL-C, but is also used to lower triglycerides. Multiple generic versions of Tricor, Trilipix and Niaspan are also available in the United States. We compete with these drugs, and in particular, multiple low-cost generic versions of these drugs, in our FDA-approved indicated uses, even though such products do not have FDA approval to reduce CV risk on top of statin therapy.

In addition, in May 2014, Epanova® (omega-3-carboxylic acids) capsules, a free fatty acid form of omega-3 (comprised of 55% EPA and 20% DHA), was approved by the FDA for patients with severe hypertriglyceridemia. Epanova was developed by Omthera Pharmaceuticals, Inc., and is now owned by AstraZeneca Pharmaceuticals LP, or AstraZeneca. Also, in April 2014, Omtryg, another omega-3-acid fatty acid composition developed by Trygg Pharma AS, received FDA approval for severe hypertriglyceridemia. Neither Epanova nor Omtryg have been commercially launched, but could launch at any time. AstraZeneca has greater resources than we do, including financial, product development, marketing, personnel and other resources.

AstraZeneca had been conducting a long-term outcomes study to assess Statin Residual Risk Reduction With EpaNova in HiGh Cardiovascular Risk PatienTs With Hypertriglyceridemia (STRENGTH). The study is a randomized, double-blind, placebo-controlled (corn oil), parallel group design that is believed to have enrolled approximately 13,000 patients with hypertriglyceridemia and low HDL and high risk for cardiovascular disease randomized 1:1 to either corn oil plus statin or Epanova plus statin, once daily. On January 13, 2020 following the recommendation of an independent Data Monitoring Committee, AstraZeneca decided to close the STRENGTH trial due to its low likelihood of demonstrating benefit to patients with mixed dyslipidemia who are at increased risk of cardiovascular disease. AstraZeneca also stated that full data from the STRENGTH trial will be presented at a future medical meeting. In addition, in March 2017, Kowa Research Institute (a subsidiary of the Japanese company Kowa Co., Ltd) initiated a Phase 3 cardiovascular outcomes trial titled PROMINENT examining the effect of pemafibrate (experimental name K-877) in reducing cardiovascular events in Type II diabetic patients with hypertriglyceridemia. Kowa Research Institute has publicly estimated study completion in May 2022, and if successful, U.S. regulatory approval is estimated in mid-2023.

During 2018, two outcomes studies were completed of omega-3 mixtures which both failed to achieve their primary endpoints of cardiovascular risk reduction and two meta-analyses were published showing that omega-3 mixtures are not effective in lowering

cardiovascular risk. Results of these failed outcomes studies and analysis, while not done with VASCEPA, may negatively affect sales of VASCEPA. For example, results of VITamin D and OmegA-3 TriaL (VITAL), as announced immediately before the presentation of REDUCE-IT results at the 2018 Scientific Sessions of the AHA on November 10, 2018, failed to achieve its primary endpoint of lowering cardiovascular events. VITAL was an NIH funded randomized double-blind, placebo-controlled, 2x2 factorial trial of 2000 IU per day of vitamin D3 and 1 gram per day of omega-3 fatty acid mixture supplementation (Lovaza) for the primary prevention of cancer and cardiovascular disease in a nationwide USA cohort of 25,874 adults not selected for elevated cardiovascular or cancer risk.

Likewise, in 2018, results from A Study of Cardiovascular Events iN Diabetes (ASCEND) trial were released and showed negligible results for omega-3 fatty acid mixtures 1 gram daily. ASCEND was a British Heart Foundation funded 2x2 factorial design, randomized study to assess whether aspirin 100 mg daily versus placebo and separately, omega-3 fatty acid mixtures 1 gram daily versus placebo, reduce the risk of cardiovascular events in a nationwide UK cohort of over 15,000 individuals with diabetes who do not have atherosclerotic cardiovascular disease.

In a meta-analysis, presented in 2018 by the Cochrane Foundation and separately as published in JAMA, additional omega-3 studies were evaluated. Similar to the VITAL and ASCEND studies, most of the studies in these omega-3 meta-analyses were of omega-3 mixtures, including DHA, and most were studies of relatively low doses of omega-3 as is associated with dietary supplementation and/or they studied relatively low risk patient populations. The exception was the JELIS study, conducted in Japan, of highly pure EPA which showed a positive outcome benefit but had significant limitations in its application to a wider population. The negative results from such omega-3 mixture studies could create misleading impressions about the use of omega-3s generally, including VASCEPA, despite REDUCE-IT positive results and the highly pure and stable EPA active ingredient in VASCEPA and its higher dose regimen.

We are also aware of other pharmaceutical companies that are developing products that, if successfully developed, approved and marketed, would compete with VASCEPA. It is not fully clear at this time what the impact of COVID-19 will be on each of these programs. Acasti Pharma, or Acasti, a subsidiary of Neptune Technologies & Bioresources Inc., announced in December 2015 that it intends to pursue a regulatory pathway under section 505(b)(2) of the FDCA for its omega-3 prescription drug candidate, CaPre® (omega-3 phospholipid), derived from krill oil, for the treatment of hypertriglyceridemia. In September 2016, Acasti announced positive results from its pivotal bioavailability bridging study comparing CaPre to Lovaza, establishing a scientific bridge between the two that is expected to support the feasibility of a 505(b)(2) regulatory pathway. In the first quarter of 2018, Acasti initiated a Phase 3 clinical program (TRILOGY 1 & 2) to assess the safety and efficacy of CaPre in patients with very high (≥500 mg/dL) triglycerides. In January 2020, Acasti announced topline results of the TRILOGY 1 trial of CaPre. The study did not reach statistical significance and further analysis in underway. In April 2020, Acasti announced that it filed a meeting request with the FDA to discuss the TRILOGY 1 data and align on the interpretation of the results. Acasti also will seek FDA input on revisions to the pre-specified TRILOGY 2 statistical analysis plan, or SAP, and on a plan for pooling the data from TRILOGY 1 and TRILOGY 2 in support of an NDA filing. Acasti stated that it received a written response from the FDA in June 2020 confirming that the FDA will require pivotal efficacy analyses for TRILOGY 2 to be performed on the full Intent to Treat population as per the original SAP and supporting Acasti's conduct of exploratory post-hoc analyses in TRILOGY 1, depending on the outcome of TRILOGY 2.

Accordingly, Acasti may be required to conduct an additional clinical trial before submitting an NDA. Acasti also stated that they expect to announce topline results of TRILOGY 2 at the end of August. NDA submission (if any) and resultant review/approval timelines will be announced following completion of TRILOGY 1 and 2 data analysis. We believe Micelle BioPharma Inc., or Micelle, is also developing potential treatments for hypertriglyceridemia based on omega-3 fatty acids. To our knowledge, Micelle, after acquiring SC401 from Sancilio & Company, or Sancilio, is pursuing a regulatory pathway under section 505(b)(2) of the FDCA for its product and submitted an Investigational New Drug Application, or IND, in July 2015. Micelle (Sancilio) completed two pharmacokinetic studies and Phase 2 bioavailability studies (FASTR I&II), with one comparing SC401 to Lovaza. We expect the company or a potential partner to initiate a pivotal clinical Phase 3 study as the next step in development.

Matinas BioPharma, Inc., or Matinas, is developing an omega-3-based therapeutic (MAT9001) for the treatment of severe hypertriglyceridemia and mixed dyslipidemia. In the fourth quarter of 2014 Matinas filed an IND with the FDA to conduct a human study in the treatment of severe hypertriglyceridemia and, in June 2015, the company announced topline results for its head-to-head comparative short duration pharmacokinetic and pharmacodynamic study of MAT9001 versus VASCEPA in patients under conditions inconsistent with the FDA-approved label for VASCEPA and presented results based on biomarker modification without outcomes data. In September 2017, Matinas announced that it will be seeking a partner company to develop and commercialize MAT9001. In March 2019, Matinas announced that net proceeds from a public offering of common stock would be used for development activities for MAT9001. In March 2020, Matinas announced that it completed the clinical dosing for a comparative clinical bridging bioavailability study and the in-life portion of a 90-day comparative toxicology study in the first quarter of 2020. Both studies were conducted to support a planned 505(b)(2) registration pathway. In March, Matinas also initiated an additional Phase 2 head-to-head pharmacokinetic and pharmacodynamic study (ENHANCE-IT) against VASCEPA in patients with elevated triglycerides (150-499 mg/dL), while the study was paused in the first quarter of 2020 due to the COVID-19 pandemic. Matinas expects to resume enrollment in June 2020, with topline data expected in the first quarter of 2021. Matinas anticipates holding an End-of-Phase 2

meeting with the FDA in the third quarter of 2020 to discuss these data as well as the protocol for a Phase 3 registration trial of MAT9001 in patients with severe hypertriglyceridemia.

In June 2018, Gemphire Therapeutics (renamed NeuroBo Pharmaceuticals, Inc. following completion of a merger on December 31, 2019) announced positive topline results from a Phase 2b trial (INDIGO-1) of its drug candidate, gemcabene, in patients with severe hypertriglyceridemia. Gemcabene is an oral, once-daily pill for a number of hypercholesterolemic populations and severe hypertriglyceridemia. In August 2018, the FDA requested that Gemphire conduct an additional long-term toxicity study before commencing any further clinical testing, thereby effectively placing gemcabene on clinical hold. In March 2020 NeuroBo announced the completion of the requested studies, and in May 2020 the company announced that it received written communication from the FDA that the clinical development program for Gemcabene remains on partial clinical hold. In June 2019, Gemphire announced top-line clinical results from a Phase 2 trial in Familial Partial Lipodystrophy (FPL)/NASH in which Gemcabene safely met the primary endpoint in a sub-set of patients. Phase 3 studies for homozygous familial hypercholesterolemia (HoFH), heterozygous familial hypercholesterolemia (HeFH) and non-familial hypercholesterolemia in ASCVD patients are planned. Afimmune Ltd. has an oral, small molecule drug candidate, epeleuton (DS-102), in development for a number of conditions of the liver, lung, and metabolic system, including hypertriglyceridemia and cardiovascular risk reduction, Phase 2 clinical trials are currently ongoing for non-alcoholic fatty liver disease, or NAFLD, chronic obstructive pulmonary disease, or COPD, and planned for hypertriglyceridemia and Type 2 diabetes (TRIAGE), in the United States. In November 2019, Afimmune Ltd. announced positive results from an exploratory Phase 2 study of epeleuton in patients with NAFLD in which the molecule decreased triglycerides, improved glycemic control, and decreased markers of inflammation.

Based on prior communications from the FDA, including communications in connection with its review of the ANCHOR indication for VASCEPA, it is our understanding that the FDA is not prepared to approve any therapy for treatment of cardiovascular risk based on biomarker modification without cardiovascular outcomes study data, with the exception of therapies which lower LDL-cholesterol, depending on the circumstances. In particular, it is our understanding that the FDA is not prepared to approve any therapy based primarily on data demonstrating lowering of triglyceride levels. In our view, this position from the FDA did not change based on the REDUCE-IT study particularly in light of significant independence of the positive benefit demonstrated in the REDUCE-IT study from triglyceride levels and benefit from the REDUCE-IT study supporting that the positive effects of VASCEPA are unique to VASCEPA and extend beyond triglyceride reduction. If the FDA were to change this position, it could potentially have a negative impact on Amarin by making it easier for other products to achieve a cardiovascular risk reduction indication without the need in advance to conduct a long and expensive cardiovascular outcomes study.

**** Generic company competitors are seeking FDA approval of generic versions of VASCEPA in the United States. We are pursuing an appeal of a March 2020 federal court decision that declared as invalid a group of patents that protect our exclusivity in the United States and could face additional patent litigation related to another group of patents related to FDA approval of a REDUCE-IT-based indication.***

The FDCA, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, as amended, or the Hatch-Waxman Amendments, permits the FDA to approve ANDAs for generic versions of brand name drugs like VASCEPA. We refer to the process of generic drug applications as the "ANDA process." The ANDA process permits competitor companies to obtain marketing approval for a drug product with the same active ingredient, dosage form, strength, route of administration, and labeling as the approved brand name drug, but without having to conduct and submit clinical studies to establish the safety and efficacy of the proposed generic product. In place of such clinical studies, an ANDA applicant needs to submit data demonstrating that its product is bioequivalent to the brand name product, usually based on pharmacokinetic studies.

As an alternate path to FDA approval for modifications of products previously approved by the FDA, an applicant may submit a new drug application, or NDA, under Section 505(b)(2) of the FDCA (enacted as part of the Hatch-Waxman Amendments). This statutory provision permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference from the owner of the data. The Hatch-Waxman Amendments permit the applicant to rely upon the FDA findings of safety and effectiveness of a drug that has obtained FDA approval based on preclinical or clinical studies conducted by others. In addition to relying on FDA prior findings of safety and effectiveness for a referenced drug product, the FDA may require companies to perform additional preclinical or clinical studies to support approval of the modification to the referenced product.

If an application for a generic version of a branded product or a Section 505(b)(2) application relies on a prior FDA finding of safety and effectiveness of a previously-approved product including an alternative strength thereof, the applicant is required to certify to the FDA concerning any patents listed for the referenced product in the FDA publication called "Approved Drug Products with Therapeutic Equivalence Evaluations," otherwise known as the "Orange Book." Specifically, the applicant must certify in the application that:

(I) there is no patent information listed for the reference drug;

(II) the listed patent has expired for the reference drug;

(III) the listed patent for the reference drug has not expired, but will expire on a particular date and approval is sought after patent expiration; or

(IV) the listed patent for the reference drug is invalid, unenforceable, or will not be infringed by the manufacture, use or sale of the product for which the ANDA or 505(b)(2) NDA is submitted.

The Hatch-Waxman Amendments require an applicant for a drug product that relies, in whole or in part, on the FDA's prior approval of VASCEPA, to notify us of its application, a "paragraph IV" notice, if the applicant is seeking to market its product prior to the expiration of the patents that both claim VASCEPA and are listed in the Orange Book. A bona fide paragraph IV notice may not be given under the Hatch-Waxman Amendments until after the generic company receives from the FDA an acknowledgement letter stating that its ANDA is sufficiently complete to permit a substantive review.

The paragraph IV notice is required to contain a detailed factual and legal statement explaining the basis for the applicant's opinion that the proposed product does not infringe our patents, that the relevant patents are invalid, or both. After receipt of a valid notice, the branded product manufacturer has the option of bringing a patent infringement suit in federal district court against any generic company seeking approval for its product within 45 days from the date of receipt of each notice. If such a suit is commenced within this 45-day period, the Hatch-Waxman Amendments provide for a 30-month stay on FDA's ability to give final approval to the proposed generic product, which period begins on the date the paragraph IV notice is received. Generally, during a period of time in which generic applications may be submitted for a branded product based on a product's regulatory exclusivity status, if no patents are listed in the Orange Book before the date on which a complete ANDA application for a product (excluding an amendment or supplement to the application) is submitted, an ANDA application could be approved by FDA without regard to a stay. For products entitled to five-year exclusivity status, the Hatch-Waxman Amendments provide that an ANDA application may be submitted after four years following FDA approval of the branded product if it contains a certification of patent invalidity or non-infringement to a patent listed in the Orange Book. In such a case, the 30-month stay runs from the end of the five-year exclusivity period. Statutory stays may be shortened or lengthened if either party fails to cooperate in the litigation and it may be terminated if the court decides the case in less than 30 months. If the litigation is resolved in favor of the ANDA applicant before the expiration of the 30-month period, the stay will be immediately lifted and the FDA's review of the application may be completed. Such litigation is often time-consuming and costly, and may result in generic competition if such patents are not upheld or if the generic competitor is found not to infringe such patents.

In September and October 2016, we received paragraph IV certification notices from four companies contending to varying degrees that certain of our patents are invalid, unenforceable and/or will not be infringed by the manufacture, use, sale or offer for sale of a generic form of the 1-gram dose strength of VASCEPA as described in those companies' ANDAs. These certifications were expected given the eligibility for submission of ANDAs under the NCE regulatory structure, after the expiration of four years from the July 2012 approval of VASCEPA.

We filed patent infringement lawsuits against three of these four ANDA applicants, which filings were based on the MARINE study. In October 2016, Amarin filed a lawsuit against Roxane Laboratories, Inc. and related parties, collectively, Roxane, in the U.S. District Court for the District of Nevada. The case against Roxane was captioned *Amarin Pharma, Inc. et al. v. Roxane Laboratories, Inc. et al.*, Civ. A. No. 2:16-cv-02525 (D. Nev.). According to a stipulation filed with the Nevada Court, in December 2016, Roxane transferred its ANDA to West-Ward Pharmaceuticals International Limited, which then designated West-Ward Pharmaceuticals Corp. (or together with West-Ward Pharmaceuticals International Limited, or West-Ward and now known as Hikma) as its agent for FDA communications. In view of the ANDA transfer, in February 2017, West-Ward replaced Roxane and related parties as Defendants in the above-referenced case. The case against West-Ward was captioned *Amarin Pharma, Inc. et al. v. West-Ward Pharmaceuticals Corp. et al.*, Civ. A. No. 2:16-cv-02525 (D. Nev.). In November 2016, Amarin filed a lawsuit against Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd., collectively, DRL, and, together with Hikma and their respective affiliates involved in the litigations, or the Defendants, in the Nevada Court. The case against DRL was captioned *Amarin Pharma, Inc. et al. v. Dr. Reddy's Laboratories, Inc. et al*., Civ. A. No. 2:16-cv-02562 (D. Nev.). In November 2016, Amarin filed a lawsuit against Teva Pharmaceuticals USA, Inc. and Teva Pharmaceuticals Industries Limited, or collectively, Teva, in the Nevada Court. The case against Teva was captioned *Amarin Pharma, Inc. et al. v. Teva Pharmaceuticals USA, Inc. et al*., Civ. A. No. 2:16-cv-02658. In all three lawsuits, we were seeking, among other remedies, an order enjoining each defendant from marketing generic versions of the 1-gram dose strength of VASCEPA before the last to expire of the asserted patents in 2030. The three lawsuits were consolidated for pretrial proceedings.

In October 2016, we introduced to the market a 0.5-gram dose strength of VASCEPA. In August 2017, as anticipated, we received a paragraph IV certification notice from Teva contending that certain of our patents are invalid, unenforceable and/or will not be infringed by the manufacture, use, sale or offer for sale of a generic form of the 0.5-gram dose strength of VASCEPA, as described in the Teva ANDA. This Teva ANDA was filed as an amendment to the 1-gram Teva ANDA and is related to patents already at issue in the 1-gram VASCEPA patent litigation. This certification followed the related listing in the Orange Book of patents associated with

the 0.5-gram product in June 2017. This June 2017 listing was within the five-year, post NDA-approval period during which the Hatch-Waxman Amendments require a paragraph IV certification of patent invalidity or non-infringement under the Hatch-Waxman, five-year, NCE regulatory scheme. Accordingly, in October 2017, we filed a patent infringement lawsuit against Teva in the Nevada Court. The case was captioned *Amarin Pharma, Inc.* et al. *v. Teva Pharmaceuticals USA, Inc.* et al., Civ. A. No. 2:17-cv-2641 (D. Nev.). In this lawsuit, we sought, among other remedies, an order enjoining Teva from marketing generic versions of the 0.5-gram dose strength of VASCEPA before the last to expire of the asserted patents in 2030.

In July 2018, we received a paragraph IV certification notice from DRL contending that certain of our patents are invalid, unenforceable and/or will not be infringed by the manufacture, use, sale or offer for sale of a generic form of the 0.5-gram dose strength of VASCEPA, as described in the DRL ANDA. This DRL ANDA was filed as an amendment to the 1-gram DRL ANDA and is related to patents already at issue in the 1-gram VASCEPA patent litigation. This certification followed the related listing in the Orange Book of patents associated with the 0.5-gram product in June 2017. This June 2017 listing was within the five-year, post NDA-approval period during which the Hatch-Waxman Amendments require a paragraph IV certification of patent invalidity or non-infringement under the Hatch-Waxman, five-year, NCE regulatory scheme. Accordingly, in August 2018, we filed a patent infringement lawsuit against DRL in the Nevada Court. The case was captioned *Amarin Pharma, Inc. et al. v. Dr. Reddy's Laboratories, Inc. et al*., Civ. A. No. 2:18-cv-01596 (D. Nev.). In this lawsuit, we sought, among other remedies, an order enjoining DRL from marketing generic versions of the 0.5-gram dose strength of VASCEPA before the last to expire of the asserted patents in 2030. In light of the overlap between the cases, DRL and Amarin have stipulated that the final judgment on the merits of the parties' contentions in the consolidated 1-gram action shall also be binding in the 0.5-gram case. Amarin and Hikma have agreed similarly with respect to Hikma's proposed 0.5-gram capsule product.

On May 24, 2018, we entered into a settlement agreement with Teva that resolves our ANDA patent litigation as it relates to Teva's as amended ANDA for both the 1-gram and 0.5-gram dose strengths of VASCEPA. As part of this settlement agreement, Teva may first begin selling its generic version of VASCEPA in the United States on August 9, 2029, or earlier under certain customary circumstances, including commercial launch by another generic manufacturer under certain circumstances.

On March 30, 2020, the Nevada Court issued its ruling in favor of the Defendants (DRL and Hikma). On May 22, 2020, Hikma received FDA approval to market its generic version of VASCEPA. To date, Hikma has not launched a generic version of VASCEPA. We are pursuing an appeal of the decision and may pursue additional remedies, including seeking a preliminary injunction against a generic product launch. We can make no guarantees as to the success, timing or efforts involved in connection with such appeal, or a preliminary injunction if we determine to pursue it, including that we would be able to successfully recover any damages for patent infringement even if we were to appear on appeal. In light of the FDA's approval of its ANDA, Hikma can launch a generic version of VASCEPA, subject to having qualified supply available and elects to launch at risk during the appeal process, DRL's ANDA could similarly be approved at any time. Generic competition from one or both such companies in the near term could have a material and adverse impact on our revenues and our stock price.

The ruling of the Nevada Court could also permit Teva to launch a generic version of VASCEPA under certain circumstances pursuant to a settlement agreement with us. For example and as discussed above, the settlement agreement provides that if another generic company obtains FDA approval and launches at risk pending appeal of the March 2020 Nevada Court ruling, Teva can commercialize a generic version of VASCEPA if we do not obtain an injunction removing such product from market within 60 days. Further, the settlement agreement permits Teva to commercialize a generic version of VASCEPA if we ultimately lose our appeal of the March 2020 Nevada Court decision at the Federal Circuit.

The fourth ANDA applicant referenced above is Apotex Inc., or Apotex, which sent us a paragraphs III and IV certification notice in September 2016. A settlement agreement with Apotex was reached in June 2020 that resolves patent litigation that would have resulted from the ANDA filed by Apotex with the FDA and amended in May 2020 seeking approval of a generic form of VASCEPA. As part of the settlement agreement, Apotex may not sell a generic version of VASCEPA in the United States until August 9, 2029 (the same such date provided for under the 2018 settlement agreement with Teva) or earlier under certain customary circumstances. As currently relevant, such circumstances include if Amarin is not successful in its pending appeal of the March 2020 Nevada Court decision after issuance of the Federal Circuit mandate following any Federal Circuit rehearing or *en banc* review.

We expect to face similar patent litigation related to the patents filed in the Orange Book related to the REDUCE-IT study. In addition, a three-year period of exclusivity under the Hatch-Waxman Amendments is generally granted for a drug product that contains an active moiety that has been previously approved, such as when the application contains reports of new clinical investigations (other than bioavailability studies) conducted by the sponsor that were essential to approval of the application. Accordingly, we received three-year exclusivity in connection with the approval of our sNDA for REDUCE-IT study results. Such three-year exclusivity protection precludes the FDA from approving a marketing application for an ANDA, a product candidate that the FDA views as having the same conditions of approval as VASCEPA (for example, the same indication and/or other conditions of use), or a 505(b)(2) NDA submitted to the FDA with VASCEPA as the reference product until December 13, 2022, three years from the date of FDA approval of the REDUCE-IT sNDA. While this three-year exclusivity would prevent such an approval based on our

REDUCE-IT indication during such time, it does not preclude tentative or final approval of an ANDA based on our MARINE indication. The FDA may accept and commence review of such REDUCE-IT-related applications during the three-year exclusivity period. Such three-year exclusivity grant does not prevent a company from challenging the validity of REDUCE-IT patents during such period. This three-year form of exclusivity may also not prevent the FDA from approving an NDA that relies only on its own data to support the change or innovation. Regulatory exclusivity is in addition to exclusivity afforded by issued patents related to VASCEPA.

We may also face challenges to the validity of our patents through a procedure known as *inter partes* review. *Inter partes* review is a trial proceeding conducted through the Patent Trial and Appeal Board, of the U.S. Patent and Trademark Office. Such a proceeding could be introduced against us within the statutory one-year window triggered by service of a complaint for infringement related to an ANDA filing or at any time by an entity not served with a complaint. Such proceedings may review the patentability of one or more claims in a patent on specified substantive grounds such as allegations that a claim is obvious on the basis of certain prior art.

We intend to vigorously enforce our intellectual property rights relating to VASCEPA, but we cannot predict the outcome of the pending lawsuits, any appeals, or any subsequently filed lawsuits or *inter partes* review.

Generally, if an ANDA filer meets the approval requirements for a generic version of VASCEPA to the satisfaction of the FDA under its ANDA, FDA may grant tentative approval to the ANDA during a Hatch-Waxman 30-month stay period and during the Hatch-Waxman 36-month regulatory exclusivity period. A tentative approval is issued to an ANDA applicant when its application is approvable prior to the expiration of any exclusivities applicable to the branded, reference listed drug product. A tentative approval does not allow the applicant to market the generic drug product and postpones the final ANDA approval until applicable exclusivity protections have expired.

The statutory NCE-related 30-month stay triggered by the 1-gram dose patent litigation following generic application submissions permitted on July 26, 2016 expired on January 26, 2020, seven-and-a-half years from our initial FDA approval of VASCEPA. Now that the Nevada Court has issued a decision in the MARINE-related patent litigation in favor of the Defendants and the FDA has approved the Hikma ANDA, we are at greater risk of a launch from the Defendants, which could then permit a similar launch by Teva under our settlement agreement earlier than the agreed-upon August 9, 2029 date noted above. Although we are pursuing an appeal of the Nevada Court's decision, the timing of such appeal proceedings and an outcome on the merits is difficult to predict. It is not uncommon for such an appeal to take from several months to approximately one year from the notice of appeal until judgment, which timing could be protracted in light of the disruptions caused by the coronavirus pandemic. Although we may file an expedited motion for an injunction to prevent any generic launch while our appeal is pending, such motion may require that we post a bond to secure generics' lost profits in the event that generics prevail on appeal, which bond and damages amount may be significant. There can be no guarantee we would be successful in any of such efforts.

Once a generic version of VASCEPA is available in the market, whether based on a generic product with a MARINE indication label or REDUCE-IT indication label, it can be used to fill a prescription for any intended use of the drug. If final approval of a generic ANDA (like Hikma's recently approved ANDA) is granted and an ANDA filer is able to supply the product in significant commercial quantities, unless we pursue and are successful with preliminary injunction efforts, generic companies could introduce generic versions of VASCEPA in the market, including in the near term. Although any such introduction of a generic version of VASCEPA would also be subject to current patent infringement claims that may then be subject to an appeal, pursuing such claims may be prohibitively costly or could put a substantial constraint on our resources.

Any significant degree of generic market entry would limit our U.S. sales, which would have a significant adverse impact on our business and results of operations. In addition, even if a competitor's effort to introduce a generic product is ultimately unsuccessful, the perception that such development is in progress and/or news related to such progress could materially affect the reputation of VASCEPA or the perceived value of our company and our stock price. For example, our stock price suffered a significant decline following our announcement of the Nevada Court's ruling in favor of the Defendants.

**** VASCEPA is a prescription-only omega-3 fatty acid product. Omega-3 fatty acids are also marketed by other companies as non-prescription dietary supplements. As a result, VASCEPA is subject to non-prescription competition and consumer substitution.***

Our only product, VASCEPA, is a prescription-only form of EPA, an omega-3 fatty acid in ethyl ester form. Mixtures of omega-3 fatty acids in triglyceride form are naturally occurring substances contained in various foods, including fatty fish. Omega-3 fatty acids are marketed by others in a number of chemical forms as non-prescription dietary supplements. We cannot be sure physicians will view the pharmaceutical grade purity and proven efficacy and safety of VASCEPA as having a superior therapeutic profile to unproven and loosely regulated omega-3 fatty acid dietary supplements. In addition, the FDA has not yet enforced to the full extent of its regulatory authority what we view as illegal claims made by certain omega-3 fatty acid product manufacturers to the extent we believe appropriate under applicable law and regulations, for example, claims that certain of such chemically altered products are dietary supplements and that certain of such products reduce triglyceride levels or could reduce cardiovascular risk.

Also, for over a decade, subject to certain limitations, the FDA has expressly permitted dietary supplement manufacturers that sell supplements containing the omega-3 fatty acids EPA and/or DHA to make the following qualified health claim directly to consumers: Supportive but not conclusive research shows that consumption of EPA and DHA omega-3 fatty acids may reduce the risk of coronary heart disease. Such companies are not, however, permitted, based on FDA enforcement activity, to make claims that suggest or imply treatment of cardiovascular disease.

These factors enable dietary supplements to compete with VASCEPA to a certain degree. Although we have taken steps to address these competitive issues, and plan to continue to do so vigorously, we may not be successful in such efforts.

For example, on October 29, 2018, Amarin filed two lawsuits in U.S. federal court, each against a different dietary supplement company for unlawfully using the results from the REDUCE-IT cardiovascular outcomes study to falsely and deceptively claim that their omega-3 dietary supplement products are effective in reducing cardiovascular risk. The defendants in the cases were Omax Health, Inc., or Omax, and The Coromega Company, Inc., or Coromega. In April 2019, based on the strength of our case and available legal remedies, Omax and Coromega settled these litigations under terms by which Omax and Coromega agreed to substantially all the demands in Amarin's complaints. Under the settlements, Coromega and Omax agreed to publicly correct their prior statements that wrongly suggested the REDUCE-IT cardiovascular outcomes trial supports the safety and efficacy of omega-3 dietary supplements. Each dietary supplement company also acknowledged that as a general matter under federal law dietary supplements may be lawfully marketed to supplement the diet, but they cannot be lawfully marketed to treat, mitigate, or prevent disease, such as cardiovascular disease.

Similarly, on August 30, 2017, Amarin filed a lawsuit with the United States International Trade Commission, or the ITC, against manufacturers, importers, and distributors of products containing synthetically produced omega-3 products in ethyl ester or re-esterified triglyceride form that contain more EPA than DHA or any other single component for use in or as dietary supplements. The lawsuit sought an investigation by the ITC regarding potentially unfair methods of competition and unfair acts involving the importation and sale of articles in the United States that injure or threaten injury to a domestic industry. In October 2017, the ITC determined to not institute our requested investigation. We appealed this determination to the U.S. Federal Circuit, but that court upheld ITC's determination. On July 30, 2019, we filed a petition with the U.S. Supreme Court seeking to appeal the Federal Circuit decision, which petition was denied on December 9, 2019. We have also engaged with FDA on the topic of synthetically produced omega-3 products through the citizen's petition process and otherwise.

In addition, to the extent the net price of VASCEPA after insurance and offered discounts is significantly higher than the prices of commercially available omega-3 fatty acids marketed by other companies as dietary supplements (through that lack of coverage by insurers or otherwise), physicians and pharmacists may recommend these commercial alternatives instead of writing or filling prescriptions for VASCEPA or patients may elect on their own to take commercially available omega-3 fatty acids. Also, insurance plans may increasingly impose policies that favor supplement use over VASCEPA. While VASCEPA is priced comparatively with, or in some cases lower than, many competing treatments, particularly when taking into account insurance coverage, such pricing might not be sufficient for healthcare providers or patients to elect VASCEPA over alternative treatments that may be perceived as less expense or more convenient to access. If healthcare providers or patients favor dietary supplements over prescribing VASCEPA, we may be constrained in how we price our product of VASCEPA's market acceptance may be less than expected, which would have a negative impact on our revenues and results of operations.

The commercial value to us of sales of VASCEPA outside the United States may be smaller than we anticipate.

There can be no assurance as to the adequacy for commercial success of VASCEPA outside the United States. For example, even if we obtain approval to commercialize VASCEPA in Europe or we and Eddingpharm obtain marketing approval in Mainland China, Hong Kong, Macau and Taiwan, or the China Territory, applicable regulatory agencies may impose restrictions on the

product's conditions for use, distribution or marketing and in some cases may impose ongoing requirements for post-market surveillance, post-approval studies or clinical trials.

Also, there is a degree of unpredictability with regard to the eventual pricing and reimbursement levels of medications in markets outside the United States. In some foreign countries, including Canada and major markets in Europe, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take six to 12 months or longer after the receipt of regulatory marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a pharmacoeconomic study that compares the cost-effectiveness of VASCEPA to other available therapies. Such pharmacoeconomic studies can be costly and the results uncertain. Our business could be harmed if reimbursement of our products is unavailable or limited in scope or amount or if pricing is set at unsatisfactory levels. If the pricing and reimbursement levels of VASCEPA are lower than we anticipate, then affordability of, and market access to, VASCEPA may be adversely affected and thus market potential in these territories would suffer.

We or our partners may even choose to not proceed with marketing VASCEPA in a market, even after a regulatory approval, due to negative commercial dynamics. Furthermore, with regard to any indications for which we may gain approval in territories outside the United States, the number of actual patients with the condition included in such approved indication may be smaller than we anticipate. Further, we could face competition from products similar or deemed equivalent to VASCEPA in various jurisdictions through regulatory pathways that are more lenient than in the United States or in jurisdictions in which we do not have exclusivity from regulations or intellectual property. If any of these market dynamics exist, the commercial potential in these territories for our product would suffer.

**** Our products and marketing efforts are subject to extensive post-approval government regulation.***

Once a product candidate receives FDA marketing approval, numerous post-approval requirements apply. Among other things, the holder of an approved NDA is subject to periodic and other monitoring and reporting obligations enforced by the FDA and other regulatory bodies, including obligations to monitor and report adverse events and instances of the failure of a product to meet the specifications in the approved application. Application holders must also submit advertising and other promotional material to regulatory authorities and report on ongoing clinical trials.

With respect to sales and marketing activities, advertising and promotional materials must comply with FDA rules in addition to other applicable federal and local laws in the United States and in other countries. The result of our First Amendment litigation and settlement may cause the government to scrutinize our promotional efforts or otherwise monitor our business more closely. Industry-sponsored scientific and educational activities also must comply with FDA and other requirements. In the United States, the distribution of product samples to physicians must comply with the requirements of the U.S. Prescription Drug Marketing Act. Manufacturing facilities remain subject to FDA inspection and must continue to adhere to the FDA's pharmaceutical current good manufacturing practice requirements, or cGMPs. Application holders must obtain FDA approval for product and manufacturing changes, depending on the nature of the change.

We also are subject to the federal transparency requirements under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the ACA, enacted in March 2010, which require manufacturers of certain drugs, devices, biologics, and medical supplies to report to the Centers for Medicare & Medicaid Services, or CMS, information related to payments and other transfers of value to physicians and teaching hospitals and physician ownership and investment interests. We may also be subject, directly or indirectly through our customers and partners, to various fraud and abuse laws, including, without limitation, the U.S. Anti-Kickback Statute, U.S. False Claims Act, and similar state laws, which impact, among other things, our proposed sales, marketing, and scientific/educational grant programs. We participate in the U.S. Medicaid Drug Rebate Program, the Federal Supply Schedule, or FSS, of the U.S. Department of Veterans Affairs, or the VA, and other government drug programs, and, accordingly, are subject to complex laws and regulations regarding reporting and payment obligations. We must also comply with requirements to collect and report adverse events and product complaints associated with our products. Our activities are also subject to U.S. federal and state consumer protection and unfair competition laws, non-compliance with which could subject us to significant liability. Similar requirements exist in many of these areas in other countries.

Depending on the circumstances, failure to meet post-approval requirements can result in criminal prosecution, fines or other penalties, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of pre-marketing product approvals, or refusal to allow us to enter into supply contracts, including government contracts. We may also be held responsible for the non-compliance of our partners, such as our former co-promotion partner Kowa Pharmaceuticals America, Inc. For example, in June 2020, we received a civil investigative demand, or CID, from the U.S. Department of Justice, or the DOJ, informing us that the DOJ is investigating whether aspects of our promotional speaker programs and copayment waiver programs during the period from January 1, 2015 to the present violated the U.S. Anti-Kickback Statute and the U.S. False Claims Act in relation to the sale of sale and marketing of VASCEPA by us and our previous co-marketing partner, Kowa Pharmaceuticals America, Inc. The CID requires us to produce documents and answer written questions, or interrogatories, relevant to the specified time period. We plan to cooperate with the DOJ and respond to the interrogatories and document requests of the CID. We cannot predict when the investigation will be resolved, the outcome of the investigations or its potential impact on our business. Such investigations can be lengthy, costly and could materially affect and disrupt our business. If the government determines that we have violated the Anti-Kickback Statute and False Claims Act, we could be subject to significant civil and criminal fines and penalties. In addition, even if we comply with FDA and other requirements, new information regarding the safety or effectiveness of a product could lead the FDA to modify or withdraw a product approval. Newly discovered or developed safety or effectiveness data may require changes to a drug's approved labeling and marketing, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures. Adverse regulatory action, whether pre- or post-approval, can potentially lead to product liability claims and increase our product liability exposure. We must also compete against other products in qualifying for coverage and reimbursement under applicable third-party payment and insurance programs. In addition, all of the above factors may also apply to any regulatory approval for VASCEPA obtained in territories outside the United States. Given our inexperience with marketing and commercializing products outside the United States, in certain territories we may need to rely on third parties, such as our partners in Canada, China and the Middle East, to assist us in dealing with any such issues.

Legislative or regulatory reform of the healthcare system in the United States and foreign jurisdictions may affect our ability to profitably sell VASCEPA.

Our ability to commercialize our future products successfully, alone or with collaborators, will depend in part on the extent to which coverage and reimbursement for the products will be available from government and health administration authorities, private health insurers and other third-party payors. The continuing efforts of the U.S. and foreign governments, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce healthcare costs may adversely affect our ability to set prices for our products which we believe are fair, and our ability to generate revenues and achieve and maintain profitability.

Specifically, in both the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes to the healthcare system in ways that could affect our ability to sell our products profitably. For example, on August 2, 2011, the Budget Control Act of 2011, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals for spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction, which triggered the legislation's automatic reductions. In concert with subsequent legislation, this has resulted in aggregate reductions to Medicare payments to providers of, on average, 2% per fiscal year through 2030 unless Congress takes additional action. These cuts reduce reimbursement payments related to our products, which could potentially negatively impact our revenue. However, these Medicare sequester reductions will be suspended from May 1, 2020 through December 31, 2020 due to the COVID-19 pandemic. Also for example, the ACA has substantially changed the way healthcare is financed by both governmental and private insurers and has significantly impacted the U.S. pharmaceutical industry. Among other cost-containment measures, the ACA establishes:

- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents;
- a new Medicare Part D coverage gap discount program, in which pharmaceutical manufacturers who wish to have their drugs covered under Part D must offer discounts to eligible beneficiaries during their coverage gap period; and
- a new formula that increases the rebates a manufacturer must pay under the Medicaid Drug Rebate Program and extends the Medicaid Drug Rebate Program to individuals enrolled in Medicaid managed care organizations.

There has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. The Trump administration is currently assessing additional proposals that are designed to affect drug pricing, such as tying U.S. drug prices to prices outside the United States. Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures have increasingly passed

legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. For example, the State of California enacted legislation that requires notice for exceeding specified limits on annual drug price increases and other legislation that seeks to limit the use of co-pay cards in certain situations.

In addition, it is time-consuming and expensive for us to go through the process of seeking coverage and reimbursement from Medicare and private payors. Our products may not be considered cost effective, and government and third-party private health insurance coverage and reimbursement may not be available to patients for any of our future products or sufficient to allow us to sell our products on a competitive and profitable basis. Our results of operations could be adversely affected by ACA and by other healthcare reforms that may be enacted or adopted in the future. In addition, increasing emphasis on managed care in the United States will continue to put pressure on the pricing of pharmaceutical products. For example, proposals are being considered to expand the use of dietary supplements in addition to or in place of drugs in government and private payor plans. In addition, cost control initiatives could decrease the price that we or any potential collaborators could receive for any of our future products and could adversely affect our profitability.

These and similar regulatory dynamics, including the entry of a generic version of VASCEPA into the market, can affect our ability to commercialize VASCEPA on commercially reasonable terms and limit the commercial value of VASCEPA.

If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate program or other governmental pricing programs, we could be subject to additional reimbursement requirements, penalties, sanctions and fines, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

We participate in the Medicaid Drug Rebate program, the 340B drug pricing program, and the VA's FSS pricing program. Under the Medicaid Drug Rebate program, we are required to pay a rebate to each state Medicaid program for our covered outpatient drugs that are dispensed to Medicaid beneficiaries and paid for by a state Medicaid program as a condition of having federal funds being made available to the states for our drugs under Medicaid and Medicare Part B. Those rebates are based on pricing data reported by us on a monthly and quarterly basis to CMS, the federal agency that administers the Medicaid Drug Rebate program. These data include the average manufacturer price and, in the case of innovator products, the best price for each drug which, in general, represents the lowest price available from the manufacturer to any entity in the U.S. in any pricing structure, calculated to include all sales and associated rebates, discounts and other price concessions. Our failure to comply with these price reporting and rebate payment obligations could negatively impact our financial results.

The ACA made significant changes to the Medicaid Drug Rebate program. CMS issued a final regulation, which became effective on April 1, 2016, to implement the changes to the Medicaid Drug Rebate program under the ACA. The issuance of the final regulation has increased and will continue to increase our costs and the complexity of compliance, has been and will continue to be time-consuming to implement, and could have a material adverse effect on our results of operations, particularly if CMS challenges the approach we take in our implementation of the final regulation.

Federal law requires that any company that participates in the Medicaid Drug Rebate program also participate in the Public Health Service's 340B drug pricing program in order for federal funds to be available for the manufacturer's drugs under Medicaid and Medicare Part B. The 340B program requires participating manufacturers to agree to charge statutorily defined covered entities no more than the 340B "ceiling price" for the manufacturer's covered outpatient drugs. These 340B covered entities include a variety of community health clinics and other entities that receive health services grants from the Public Health Service, as well as hospitals that serve a disproportionate share of low-income patients. The 340B ceiling price is calculated using a statutory formula based on the average manufacturer price and Medicaid rebate amount for the covered outpatient drug as calculated under the Medicaid Drug Rebate program, and in general, products subject to Medicaid price reporting and rebate liability are also subject to the 340B ceiling price calculation and discount requirement. Any additional future changes to the definition of average manufacturer price and the Medicaid rebate amount under the ACA, other legislation, or in regulation could affect our 340B ceiling price calculations and negatively impact our results of operations.

The Health Resources and Services Administration, or HRSA, which administers the 340B program, issued a final regulation regarding the calculation of the 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities, which became effective on January 1, 2019. It is currently unclear how HRSA will apply its enforcement authority under the new regulation. We also are required to report our 340B ceiling prices to HRSA on a quarterly basis. Implementation of the civil monetary penalties regulation and the issuance of any other final regulations and guidance could affect our obligations under the 340B program in ways we cannot anticipate. In addition, legislation may be introduced that, if passed, would further expand the 340B program to additional covered entities or would require participating manufacturers to agree to provide 340B discounted pricing on drugs used in the inpatient setting.

Pricing and rebate calculations vary across products and programs, are complex, and are often subject to interpretation by us, governmental or regulatory agencies and the courts. In the case of our Medicaid pricing data, if we become aware that our reporting for a prior quarter was incorrect, or has changed as a result of recalculation of the pricing data, we are obligated to resubmit the corrected data for up to three years after those data originally were due. Such restatements and recalculations increase our costs for complying with the laws and regulations governing the Medicaid Drug Rebate program and could result in an overage or underage in our rebate liability for past quarters. Price recalculations also may affect the ceiling price at which we are required to offer our products under the 340B program or could require us to issue refunds to 340B covered entities.

Significant civil monetary penalties can be applied if we are found to have knowingly submitted any false pricing information to CMS, or if we fail to submit the required price data on a timely basis. Such conduct also could be grounds for CMS to terminate our Medicaid drug rebate agreement, in which case federal payments may not be available under Medicaid or Medicare Part B for our covered outpatient drugs. Significant civil monetary penalties also can be applied if we are found to have knowingly and intentionally charged 340B covered entities more than the statutorily mandated ceiling price. We cannot assure you that our submissions will not be found by CMS or HRSA to be incomplete or incorrect.

In order to be eligible to have our products paid for with federal funds under the Medicaid and Medicare Part B programs and purchased by certain federal agencies and grantees, as noted above, we participate in the VA's FSS pricing program. As part of this program, we are obligated to make our products available for procurement on an FSS contract under which we must comply with standard government terms and conditions and charge a price that is no higher than the statutory Federal Ceiling Price, or FCP, to four federal agencies (the VA, U.S. Department of Defense, or DOD, Public Health Service, and the U.S. Coast Guard). The FCP is based on the Non-Federal Average Manufacturer Price, or Non-FAMP, which we calculate and report to the VA on a quarterly and annual basis. Pursuant to applicable law, knowing provision of false information in connection with a Non-FAMP filing can subject a manufacturer to significant penalties for each item of false information. These obligations also contain extensive disclosure and certification requirements.

We also participate in the Tricare Retail Pharmacy program, under which we pay quarterly rebates on utilization of innovator products that are dispensed through the Tricare Retail Pharmacy network to Tricare beneficiaries. The rebates are calculated as the difference between the annual Non-FAMP and FCP. We are required to list our covered products on a Tricare Agreement in order for these products to be eligible for DOD formulary inclusion. If we overcharge the government in connection with our FSS contract or Tricare Agreement, whether due to a misstated FCP or otherwise, we are required to refund the difference to the government. Failure to make necessary disclosures and/or to identify contract overcharges can result in allegations against us under the False Claims Act and other laws and regulations. Unexpected refunds to the government, and responding to a government investigation or enforcement action, would be expensive and time-consuming, and could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Changes in reimbursement procedures by government and other third-party payors may limit our ability to market and sell our approved drugs. These changes could have a material adverse effect on our business and financial condition.

In the U.S. and abroad, sales of pharmaceutical drugs are dependent, in part, on the availability of reimbursement to the consumer from third-party payors, such as government and private insurance plans. Third-party payors are increasingly challenging the prices charged for medical products and services. Some third-party payor benefit packages restrict reimbursement, charge copayments to patients, or do not provide coverage for specific drugs or drug classes.

In addition, certain healthcare providers are moving toward a managed care system in which such providers contract to provide comprehensive healthcare services, including prescription drugs, for a fixed cost per person. We are unable to predict the reimbursement policies employed by third-party healthcare payors.

We expect to experience pricing and reimbursement pressures in connection with the sale of our products due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative and executive proposals. In addition, we may confront limitations in insurance coverage for our products. If we fail to successfully secure and maintain reimbursement coverage for our approved drugs or are significantly delayed in doing so, we may have difficulty achieving market acceptance of our approved drugs and investigational drug candidates for which we obtain approval, and our business may be harmed. Congress has enacted healthcare reform and may enact further reform, which could adversely affect the pharmaceutical industry as a whole, and therefore could have a material adverse effect on our business.

Ongoing healthcare legislative and regulatory reform measures may have a material adverse effect on our business and results of operations.

Certain provisions of the ACA have been subject to judicial challenges, as well as efforts to repeal or replace them or to alter their interpretation or implementation. Since January 2017, the Trump administration has signed Executive Orders designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. One Executive Order directs federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. The second Executive Order terminated the cost-sharing subsidies under the ACA. Nineteen state Attorneys General filed suit to stop the administration from terminating the subsidies, but on July 18, 2018, the U.S. District Court for the Northern District of California dismissed the case without prejudice. Further, on June 14, 2018, U.S. Court of Appeals for the Federal Circuit ruled that, due to Congressional appropriations riders that prohibited the Department of Health and Human Services, or HHS, from paying out more in risk corridor payments than it collected, HHS was not required to pay more than $12 billion in ACA risk corridor payments owed to insurers under the risk corridor formula. On November 6, 2018, the Federal Circuit declined to rehear the case *en banc*. This decision was appealed to the U.S. Supreme Court, which on April 27, 2020, reversed the U.S. Court of Appeals for the Federal Circuit's decision and remanded the case to the U.S. Court of Federal Claims, concluding the government has an obligation to pay these risk corridor payments under the relevant formula. It is not clear what effect this result will have on our business, but we will continue to monitor any developments.

Moreover, the Tax Act included a provision that eliminated the tax-based shared responsibility payment for individuals who fail to maintain minimum essential coverage under section 5000A of the Internal Revenue Code of 1986, commonly referred to as the "individual mandate," effective January 1, 2019. The Bipartisan Budget Act of 2018, or the BBA, among other things, amends the ACA to create a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% (increase from 50% effective as of January 1, 2019) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D.

Under the Trump Administration, CMS has issued regulations that give states greater flexibility, starting in 2020, in the identification of the essential health benefits benchmarks for non-grandfathered individual and small group market health insurance coverage, including plans sold through the health insurance exchanges established under the ACA. On December 14, 2018, the U.S. District Court for the Northern District of Texas ruled (i) that the "individual mandate" was unconstitutional as a result of the associated tax penalty being repealed by Congress as part of the Tax Act; and (ii) the individual mandate is not severable from the rest of the ACA, as a result the entire ACA is invalid. On December 18, 2019, the U.S. Court of Appeals for the Fifth Circuit affirmed the district court's decision that the individual mandate is unconstitutional, but remanded the case to the district court to reconsider the severability question. It is unclear how the ultimate decision in this case, which is now pending before the U.S. Supreme Court, or other efforts to repeal, replace, or invalidate the ACA or its implementing regulations, or portions thereof, will impact our business. We will continue to evaluate the effect that the ACA and its possible repeal, replacement, or invalidation, in whole or in part, has on our business.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. In August 2011, the Budget Control Act of 2011, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals for spending reductions. The Joint Select Committee on Deficit Reduction did not reach required goals, thereby triggering the legislation's automatic reductions. This has resulted in aggregate reductions to Medicare payments to providers of, on average, 2% per fiscal year through 2030 unless Congress takes additional action. However, these Medicare sequester reductions will be suspended from May 1, 2020 through December 31, 2020 due to the COVID-19 pandemic.

We expect that the healthcare reform measures that have been adopted and may be adopted in the future, may result in more rigorous coverage criteria, and new payment methodologies, and in additional downward pressure on coverage and payment and the price that we receive for any approved product, and could seriously harm our future revenues. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private third-party payors.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. The enactment and implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our product. Such reforms could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop product candidates.

Failure to comply with health and data protection laws and regulations could lead to government enforcement actions (which could include civil or criminal penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business.

We and any potential collaborators may be subject to federal, state, and foreign data protection laws and regulations (i.e., laws and regulations that address privacy and data security). In the United States, numerous federal and state laws and regulations, including federal health information privacy laws, state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), that govern the collection, use, disclosure and protection of health-related and other personal information could apply to our operations or the operations of our collaborators. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA. Although we are not directly subject to HIPAA – other than with respect to providing certain employee benefits – we could potentially be subject to criminal penalties if we, our affiliates, or our agents knowingly obtain, use, or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA. In addition, state laws govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Compliance with U.S. and international data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. Failure to comply with these laws and regulations could result in government enforcement actions (which could include civil, criminal and administrative penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business. Moreover, clinical trial subjects, employees and other individuals about whom we or our potential collaborators obtain personal information, as well as the providers who share this information with us, may limit our ability to collect, use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

European data collection is governed by restrictive regulations governing the use, processing and cross-border transfer of personal information.

The REDUCE-IT cardiovascular outcomes trial was conducted in part through clinical sites in the EU. As a result, we are subject to additional privacy restrictions. The collection and use of personal health data in the EU is governed by the provisions of the General Data Protection Regulation, or GDPR. The GDPR imposes several requirements relating to the legal basis for processing personal data which may include the consent of the individuals to whom the personal data relates, the information provided to the individuals and the security and confidentiality of the personal data. The GDPR also imposes strict rules on the transfer of personal data out of the EU to the United States. Failure to comply with the requirements of the GDPR, and the related national data protection laws of the EU Member States may result in restrictions against regulatory approval in the EU or substantial fines for breaches of the data protection rules. The GDPR may impose additional responsibility and liability in relation to personal data that we process and we may be required to put in place additional mechanisms ensuring compliance with these and/or new data protection rules. This may be onerous and adversely affect our business, financial condition, prospects and results of operations.

**** The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products and promotional efforts such as speaker programs. If we or our partners are found to have improperly promoted uses, efficacy or safety of VASCEPA or otherwise are found to have violated the law or applicable regulations, we may become subject to significant fines and other liability. The government may seek to find means to prevent our promotion of truthful and non-misleading information beyond the current court ruling and litigation settlement or seek to find violations of other laws or regulations in connection with the promotional efforts we undertake on our own or through third parties.***

The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products. In particular, in general, the U.S. government's position has been that a product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling. The Federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. Even though we received FDA marketing approval for VASCEPA for the MARINE indication and for cardiovascular risk reduction based on the REDUCE-IT study, and we believe the First Amendment court ruling and litigation settlement affords us a degree of protection for other promotional efforts, physicians may still prescribe VASCEPA to their patients for use in the treatment of conditions that are not included as part of the indication statement in our FDA-approved VASCEPA label or our settlement. If we are found to have promoted VASCEPA outside the terms of the litigation settlement or in violation of what federal or state government may determine to be acceptable, we may become subject to significant government fines and other related liability, such as under the FDCA, the False Claims Act, or other theories of liability. Government may also seek to hold us responsible for the non-compliance of our former co-promotion partner, Kowa, or our commercialization partners outside the United States or other third-parties that we retain to help us implement our business plan.

In addition, incentives exist under applicable laws that encourage competitors, employees and physicians to report violations of rules governing promotional activities for pharmaceutical products. These incentives could lead to so-called "whistleblower lawsuits" as part of which such persons seek to collect a portion of moneys allegedly overbilled to government agencies due to, for example, promotion of pharmaceutical products beyond labeled claims. These incentives could also lead to suits that we have mischaracterized a competitor's product in the marketplace and we may, as a result, be sued for alleged damages to our competitors. Such lawsuits, whether with or without merit, are typically time-consuming and costly to defend. Such suits may also result in related shareholder lawsuits, which are also costly to defend.

In June 2020, we received a civil investigative demand, or CID, from the U.S. Department of Justice, or the DOJ, informing us that the DOJ is investigating whether aspects of our promotional speaker programs and copayment waiver program during the period from January 1, 2015 to the present violated the U.S. Anti-Kickback Statute and the U.S. False Claims Act in relation to the sale and marketing of VASCEPA by us and our previous co-marketing partner, Kowa Pharmaceuticals America, Inc. The CID requires us to produce documents and answer written questions, or interrogatories, relevant to the specified time period. We plan to cooperate with the DOJ and respond to the interrogatories and document requests of the CID. We cannot predict when the investigation will be resolved, the outcome of the investigation or its potential impact on our business. Such investigations can be lengthy, costly and could materially affect and disrupt our business. If the government determines that we have violated the Anti-Kickback Statute and False Claims Act, we could be subject to significant civil and criminal fines and penalties.

We may not be successful in developing and receiving regulatory approval for VASCEPA in other jurisdictions or marketing future products if we cannot meet the extensive regulatory requirements of regulatory agencies such as for quality, safety, efficacy and data privacy.

The success of our research and development efforts is dependent in part upon our ability, and the ability of our partners or potential partners, to meet regulatory requirements in the jurisdictions where we or our partners or potential partners ultimately intend to sell such products once approved. The development, manufacture and marketing of pharmaceutical products are subject to extensive regulation by governmental authorities in the United States and elsewhere. In the United States, the FDA generally requires preclinical testing and clinical trials of each drug to establish its safety and efficacy and extensive pharmaceutical development to ensure its quality before its introduction into the market. Regulatory authorities in other jurisdictions impose similar requirements. The process of obtaining regulatory approvals is lengthy and expensive and the issuance of such approvals is uncertain. The commencement and rate of completion of clinical trials and the timing of obtaining marketing approval from regulatory authorities may be delayed by many factors, including, among others:

- the lack of efficacy during clinical trials;
- the inability to manufacture sufficient quantities of qualified materials under cGMPs for use in clinical trials;
- slower than expected rates of patient recruitment;
- the inability to observe patients adequately after treatment;
- changes in regulatory requirements for clinical trials or preclinical studies;

- the emergence of unforeseen safety issues in clinical trials or preclinical studies;
- delay, suspension, or termination of a trial by the institutional review board responsible for overseeing the study at a particular study site;
- unanticipated changes to the requirements imposed by regulatory authorities on the extent, nature or timing of studies to be conducted on quality, safety and efficacy;
- compliance with laws and regulations related to patient data privacy;
- government or regulatory delays or "clinical holds" requiring suspension or termination of a trial; and
- political instability or other social or government protocols affecting our clinical trial sites.

Even if we obtain positive results from our efforts to seek regulatory approvals, from early stage preclinical studies or clinical trials, we may not achieve the same success in future efforts. Clinical trials that we or potential partners conduct may not provide sufficient safety and efficacy data to obtain the requisite regulatory approvals for product candidates. The failure of clinical trials to demonstrate safety and efficacy for our desired indications could harm the development of that product candidate as well as other product candidates, and our business and results of operations would suffer. For example, during the public advisory committee meeting held by FDA as part of its review of our ANCHOR data and sNDA in October 2013, a discussion regarding observed, nominally statistically significant changes from baseline in an adverse direction, while on background statin therapy, in certain lipid parameters, including LDL cholesterol and triglycerides, in the placebo group, raised questions about the possibility that the light liquid paraffin oil, or mineral oil, placebo used in the ANCHOR trial and then in use in the REDUCE-IT trial might not be biologically inert and might be viewed as artificially exaggerating the clinical effect of VASCEPA when measured against placebo. Ultimately, in 2012, no strong evidence for biological activity of mineral oil was identified by the FDA before its approval of VASCEPA after review of the MARINE and ANCHOR trials and consideration of other data regarding mineral oil. It was ultimately concluded that the between-group differences likely provided the most appropriate descriptions of the treatment effect of VASCEPA and that whatever factor(s) led to the within-group changes over time in the placebo group were likely randomly distributed to all treatment groups. Thus, the FDA approved VASCEPA for use in the MARINE indication in July 2012, FDA did not dispute the veracity of the ANCHOR trial data and, in connection with the March 2016 agreement we reached with the FDA allowing us to promote the results of the ANCHOR study, the FDA did not seek to require that we include any qualification related to this earlier question regarding the mineral oil placebo.

For example, in connection with FDA's review of REDUCE-IT data and sNDA in 2019, the agency determined that an interaction between mineral oil and statins leading to decreased absorption of statins cannot be excluded when the two are co-administered as could have been the case in some patients in REDUCE-IT and that, in the agency's view, indirect evidence suggested the presence of a potential inhibitory effect on statin absorption by mineral oil. However, FDA's exploratory analysis indicated that the effect of LDL cholesterol values on the time to the primary endpoint was numerically small and unlikely to change the overall conclusion of treatment benefit. FDA then relied on this assessment and all data available to it to approve a new indication statement and labeling based on REDUCE-IT results. This matter illustrates that concerns such as this may arise in the future that could affect our product development, regulatory reviews or the public perception of our products and our future prospects, including REDUCE-IT results.

Any approvals that are obtained may be limited in scope, may require additional post-approval studies or may require the addition of labeling statements, including boxed warnings, focusing on product safety that could affect the commercial potential for our product candidates. Any of these or similar circumstances could adversely affect our ability to gain approval for new indications and affect revenues from the sale of our products. Even in circumstances where products are approved by a regulatory body for commercialization, the regulatory or legal requirements may change over time, or new safety or efficacy information may be identified concerning a product, which may lead to the withdrawal of a product from the market or similar use restrictions. The discovery of previously unknown problems with a clinical trial or product, or in connection with the manufacturer of products, may result in regulatory issues that prevent proposed future approvals of a product and/or restrictions on that product or manufacturer, including withdrawal of an indication or the product from the market, which would have a negative impact on our potential revenue stream.

As we continue to evolve from a company primarily involved in research and development to a company also focused on establishing an infrastructure for commercializing VASCEPA, we may encounter difficulties in managing our growth and expanding our operations successfully.

The process of establishing a commercial infrastructure is difficult, expensive and time-consuming. Prior to the REDUCE-IT results topline announcement in September 2018, our direct sales force consisted of approximately 170 sales professionals, including sales representatives and their managers. Based on the positive REDUCE-IT results, in early 2019, we increased the size of our sales team to approximately 440 sales professionals, including approximately 400 sales representatives in the United States. As a result of

the additional indication and label expansion approved by the FDA in December 2019, in cardiovascular risk reduction, we completed the further expansion of our direct sales force to approximately 900 sales professionals, including approximately 800 sales representatives. This sales team promotes VASCEPA to a limited group of physicians and other healthcare professionals in select geographies in the United States. The impact of COVID-19, including the suspension of field based face-to-face interactions for an uncertain period of time may negatively affect promotional efforts. In addition, unless and until its appeal is successful, we intend to reduce the amount spent in the United States on VASCEPA related education and promotion with the intention of retaining the capability to ramp-up promptly if Amarin wins upon appeal. Even after planned expansion, this sales team is not large enough to call upon all physicians.

In addition to sales force expansion in the United States, Amarin continues to work on its own and with its international partners to support regulatory efforts outside the United States based on REDUCE-IT results. As our operations expand with the anticipated growth of our product sales, we expect that we will need to manage additional relationships with various collaborative partners, suppliers and other third parties. Future growth will impose significant added responsibilities on members of management, including the need to identify, recruit, maintain and integrate additional employees. Our future financial performance and our ability to commercialize VASCEPA and to compete effectively will depend, in part, on our ability to manage our future growth effectively, and such efforts may be disrupted by the COVID-19 protocols. To that end, we must be able to manage our development efforts effectively, and hire, train, integrate and retain additional management, administrative and sales and marketing personnel and have limited experience managing a commercial organization. We may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successfully growing our company.

Risks Related to Our Reliance on Third Parties

Our supply of product for the commercial market and clinical trials is dependent upon relationships with third-party manufacturers and suppliers.

We have no in-house manufacturing capacity and rely on contract manufacturers for our clinical and commercial product supply. We cannot ensure that we will successfully manufacture any product we may develop, either independently or under manufacturing arrangements, if any, with our third-party manufacturers. Moreover, if our manufacturers should cease doing business with us or experience delays, shortages of supply or excessive demands on their capacity, we may not be able to obtain adequate quantities of product in a timely manner, or at all. If we are not able to continue to operate our business relationships in a manner that is sufficiently profitable for us and our suppliers, certain members of our supply chain could complete with us through supply to competitors, such as generic drug companies, through breach of our agreements or otherwise.

Any manufacturing problem, natural or manmade disaster affecting manufacturing facilities, government action, or the loss of a contract manufacturer could be disruptive to our operations and result in lost sales. Any reliance on suppliers may involve several risks, including a potential inability to obtain critical materials and reduced control over production costs, delivery schedules, reliability and quality. Any unanticipated disruption to future contract manufacture caused by problems at suppliers could delay shipment of products, increase our cost of goods sold and/or result in lost sales. If our suppliers were unable to supply us with adequate volumes of active pharmaceutical ingredient (drug substance) or encapsulated bulk product (drug product), it would have a material adverse effect on our ability to continue to commercialize VASCEPA.

We have contractual freedom to source the API for VASCEPA and to procure other services supporting our supply chain. We have entered into supply agreements with multiple suppliers who also rely on other third-party suppliers to manufacture the API and other elements necessary for the sale of VASCEPA. Our strategy in sourcing API and other components in our supply chain from multiple suppliers has been to expand manufacturing capacity, maintain competitive advantages, and mitigate the risk of reliance on any single supplier.

Expanding manufacturing capacity and qualifying such capacity is complex and subject to numerous regulations and other operational challenges. The resources of our suppliers vary and are limited; costs associated with projected expansion and qualification can be significant. There can be no assurance that the expansion plans of any of our suppliers will be successful. Our aggregate capacity to produce API is dependent upon the continued qualification of our API suppliers and, depending on the ability of existing suppliers to meet our supply demands, potentially the qualifications of new suppliers. Each of our API suppliers has outlined plans for potential further capacity expansion. If no additional API supplier is approved by the FDA as part of an sNDA, our API supply will be limited to the API we purchase from previously approved suppliers. If our third-party manufacturing capacity is not expanded and/or compliant with applicable regulatory requirements, we may not be able to supply sufficient quantities of VASCEPA to meet anticipated demand. We cannot guarantee that we can contract with any future manufacturer on acceptable terms or that any such alternative supplier will not require capital investment from us in order for them to meet our requirements. Alternatively, our purchase of supply may exceed actual demand for VASCEPA.

There can be no guarantee that current suppliers and future suppliers with which we have contracted to encapsulate API will be continually qualified to manufacture the product to our specifications or that current and any future suppliers will have the manufacturing capacity to meet anticipated demand for VASCEPA.

We may purchase too much or not enough supply to satisfy actual demand, which could have a material adverse effect on our financial results and financial condition.

Certain of our agreements with our suppliers include minimum purchase obligations and limited exclusivity provisions. These purchases are generally made on the basis of rolling 12-month forecasts which in part are binding on us and the balance of which are subject to adjustment by us subject to certain limitations. Certain of our agreements also include contractual minimum purchase commitments regardless of the rolling 12-month forecasts. We may not purchase sufficient quantities of VASCEPA to meet actual demand or our purchase of supply may exceed actual demand. In either case, such event could have a material adverse effect on our financial results and financial condition.

Our dependence on third parties in the distribution channel from our manufacturers to patients subject us to risks that limit our profitability and could limit our ability to supply VASCEPA to large market segments.

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. These parties exercise a substantial amount of bargaining power over us given their control over large segments of the market for VASCEPA. This bargaining power has led us to bear increasingly higher discounts in the sale of VASCEPA. In addition, payors have broad latitude to change individual products' formulary position or to implement other barriers that inhibit patients from receiving therapies prescribed by their healthcare professionals. These payor barriers include requirements that patients try another drug before VASCEPA, known as step edits, and the requirement that prior authorization be obtained by a healthcare provider after a prescription is written before a patient will be reimbursed by their health plan for the cost of a VASCEPA prescription. Further, pharmacy benefit managers implement plans that act as disincentives for VASCEPA use, such as increasingly higher deductibles. One practical impact of higher deductibles is that they may cause patients to delay filling prescriptions for asymptomatic, chronic care medications such as hypertriglyceridemia earlier in the year, until patients meet their deductible and the cost of VASCEPA is then borne more by their insurance carrier. Collectively, these dynamics negatively affect our profitability for the sale of VASCEPA and could increase over time further impacting our operating results. Consolidation among these industry participants could increase the pressure from these market dynamics.

The manufacture, packaging and distribution of pharmaceutical products such as VASCEPA are subject to FDA regulations and those of similar foreign regulatory bodies. If we or our third-party manufacturers fail to satisfy these requirements, our product development and commercialization efforts may be materially harmed.

The manufacture, packaging and distribution of pharmaceutical products, such as VASCEPA, are regulated by the FDA and similar foreign regulatory bodies and must be conducted in accordance with the FDA's current good manufacturing practices, or cGMPs, and comparable requirements of foreign regulatory bodies. There are a limited number of manufacturers that operate under these cGMPs as well as the International Council for Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, or ICH, regulations and guidelines, that are both capable of manufacturing VASCEPA and willing to do so. Failure by us or our third-party manufacturers to comply with applicable regulations, requirements, or guidelines could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our products, delays, suspension or withdrawal of approvals, license revocation, seizures or voluntary recalls of product, operating restrictions and criminal prosecutions and penalties, any of which could significantly and adversely affect our business. If we are not able to manufacture VASCEPA to required specifications through our current and potential API suppliers, we may be delayed in successfully supplying the product to meet anticipated demand and our anticipated future revenues and financial results may be materially adversely affected.

Changes in the manufacturing process or procedure, including a change in the location where the product is manufactured or a change of a third-party manufacturer, may require prior FDA review and pre-approval of the manufacturing process and procedures in accordance with the FDA's cGMPs. Any new facility may be subject to a pre-approval inspection by the FDA and would again require us to demonstrate product comparability to the FDA. There are comparable foreign requirements under ICH guidelines. This review may be costly and time consuming and could delay or prevent the launch of a product.

Furthermore, the FDA and foreign regulatory agencies require that we be able to consistently produce the API and the finished product in commercial quantities and of specified quality on a repeated basis, including demonstrated product stability, and document our ability to do so. This requirement is referred to as process validation. This includes stability testing, measurement of impurities and testing of other product specifications by validated test methods. If the FDA does not consider the result of the process validation or required testing to be satisfactory, the commercial supply of VASCEPA may be delayed, or we may not be able to supply sufficient quantities of VASCEPA to meet anticipated demand.

The FDA and similar foreign regulatory bodies may also implement new requirements, or change their interpretation and enforcement of existing requirements, for manufacture, packaging or testing of products at any time. If we or our approved suppliers are unable to comply, we may be subject to regulatory, civil actions or penalties, or we may be prevented from manufacturing or selling VASCEPA, all of which could significantly and adversely affect our business.

**** Our commercialization of VASCEPA outside the United States is substantially dependent on third parties and other circumstances outside our control.***

We have expanded our VASCEPA commercialization activities outside of the United States through several contractual arrangements in territories including China, the Middle East, North Africa and Canada. We continue to assess other opportunities to develop VASCEPA commercialization outside of the United States through similar arrangements.

In February 2015, we entered into a Development, Commercialization and Supply Agreement, or the DCS Agreement, with Eddingpharm related to the development and commercialization of VASCEPA in the China Territory. Under the DCS Agreement, Eddingpharm is responsible for development and commercialization activities in the China Territory and associated expenses. Additionally, Eddingpharm is required to conduct clinical trials in the China Territory to secure regulatory approval in certain territories. For example, in December 2017, Eddingpharm commenced a pivotal clinical trial aimed to demonstrate that VASCEPA lowers triglyceride levels and otherwise has beneficial effects in Chinese patients with severe hypertriglyceridemia (TG $\geq$500 mg/dL), as we previously demonstrated with VASEPA in the more diverse population studied in the MARINE study. There can be no assurance that the results of this trial will be similar to the results of the MARINE study. Even if such results are similar additional clinical development efforts may be necessary in this market to demonstrate the effectiveness of VASCEPA in reducing major adverse cardiovascular events in Chinese patients with persistent cardiovascular risk. Any development and regulatory efforts in the China Territory may be negatively impacted by the spread of the coronavirus and the unexpected diversion of resources by regulators and industry professionals to address the coronavirus outbreak. Any development and regulatory efforts in the China Territory may be negatively impacted by heightened political tension between China and the United States pursuant to COVID-19 and to overall issues expressed between the countries regarding trade practices, tariffs and honoring intellectual property rights. If Eddingpharm is not able to effectively develop and commercialize VASCEPA in the China Territory, we may not be able to generate revenue from the DCS Agreement resulting from the sale of VASCEPA in the China Territory.

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. Biologix obtained approval of VASCEPA in Lebanon on March 2018, in United Arab Emirates on July 2018 and in Qatar in January 2020. VASCEPA was launched in Lebanon and the United Arab Emirates on June 2018 and February 2019, respectively. VASCEPA is under registration in additional countries in the MENA region. Commercialization across the Middle East and North Africa is subject to similar risks as in the China Territory, and has been negatively impacted by COVID-19 and the destabilized local economy in Saudi Arabia in the second quarter of 2020.

In September 2017, we entered into an agreement with HLS Therapeutics Inc., or HLS, to register, commercialize and distribute VASCEPA in Canada. Under the agreement, HLS is responsible for regulatory and commercialization activities and associated costs. Amarin 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. In December 2019, VASCEPA was approved for use in Canada to reduce the risk of cardiovascular events in statin-treated patients with elevated triglycerides, who are at high risk of cardiovascular events due to established cardiovascular disease, or diabetes, and at least one other cardiovascular risk factor. In January 2020, HLS obtained an extended regulatory exclusivity designation. In February 2020, HLS launched VASCEPA in Canada, with strong initial uptake before the impact of COVID-19 pandemic. However, if HLS Therapeutics is not able to effectively commercialize VASCEPA in Canada through effective pricing (initially and over time) or otherwise we may not be able to generate revenue from the sale of VASCEPA in Canada.

Our efforts to launch VASCEPA on our own in Europe, assuming a regulatory approval, is a complex undertaking for a company that has not launched a product in Europe and could be subject to significant risks of execution to our successful development of VASCEPA in Europe.

We have limited experience working with partners outside the United States to develop and market our products in non-U.S. jurisdictions. In order for our partners to market and sell VASCEPA in any country outside of the United States for any indication, it will be necessary to obtain regulatory approval from the appropriate regulatory authorities. The requirements and timing for regulatory approval, which may include conducting clinical trials, vary widely from country to country and may in some cases be different than or more rigorous than requirements in the United States. Any failure by us or our partners to obtain approval for VASCEPA in non-U.S. jurisdictions in a timely manner may limit the commercial success of VASCEPA and our ability to grow our revenues.

**** Our relationships with healthcare providers and physicians and third-party payors are subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose use to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.***

Healthcare providers, physicians and third-party payors in the United States and elsewhere play a primary role in the recommendation and prescription of pharmaceutical products. Arrangements with third-party payors and customers can expose pharmaceutical manufacturers to broadly applicable fraud and abuse and other healthcare laws and regulations, which may constrain the business or financial arrangements and relationships through which such companies sell, market and distribute pharmaceutical products. In particular, the promotion, sales and marketing of healthcare items and services, as well as a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business arrangements, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. The applicable federal and state healthcare laws and regulations laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. Liability may be established without a person or entity having actual knowledge of the federal anti-kickback statute or specific intent to violate it. In addition, the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain activities from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases, or recommendations may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Our practices may not in all cases meet all of the criteria for safe harbor protection from anti-kickback liability. Violations are subject to significant civil and criminal fines and penalties for each violation, plus up to three times the renumeration involved, imprisonment, and exclusion from government healthcare workers;
- the federal civil and criminal false claims laws, including the federal Civil False Claims Act (FCA), which prohibits, among other things, any person from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment of government funds, or knowingly making or using, or causing to be made or used, a false record or statement material to an obligation to pay money to the government or knowingly concealing, or knowingly and improperly avoiding, decreasing, or concealing an obligation to pay money to the federal government. The FCA also permits a private individual acting as a “whistleblower” to bring actions on behalf of the federal government alleging violations of the statute and to share in any monetary recovery. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to “case” the submission of false or fraudulent claims. Recently, several pharmaceutical and other healthcare companies have been investigated or faced enforcement actions under the FCA for a variety of alleged improper marketing activities, including allegations that they caused false claims to be submitted because of the company’s marketing of the product for unapproved, and thus allegedly non-reimbursable, uses. Federal enforcement agencies also have showed increased interest in pharmaceutical companies’ product and patient assistance programs, including reimbursement and co-pay support services, and a number of investigations into these programs have resulted in significant civil and criminal settlements. A claim that includes items or services resulting from a violations of the federal Anti-Kickback Statute constitutes a false or fraudulent claim under the FCA. When an entity is determined to have violated the FCA, the government may impose civil fines and penalties for each false claim, plus treble damages, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs. Pharmaceutical and other healthcare companies also are subject to other federal false claims laws, including, among others, federal criminal healthcare fraud and false statement statutes that extend to non-government health benefit programs;
- HIPAA, which, among other things, imposes criminal and civil liability for knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third-party payor and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services;

- HIPAA, and its implementing regulations, which impose, among other things, requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization. The Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions;
- the federal Physician Payment Sunshine Act, being implemented as the Open Payments Program, which requires manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to CMS information related to direct or indirect payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held in the company by physicians and their immediate family members. Beginning in 2022, applicable manufacturers also will be required to report information regarding payments and transfers of value provided to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, and certified nurse-midwives;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; and other state or local laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; restrict the ability of manufacturers to offer co-pay support to patients for certain prescription drugs; require drug manufacturers to report information related to clinical trials, or information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and/or require identification or licensing of sales representatives; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies continue to give regular and close scrutiny to interactions between healthcare companies and healthcare providers, and such scrutiny often leads to investigations, prosecutions, convictions and settlements in the healthcare industry. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource-consuming and can divert a company's attention from the business. For example, in June 2020, we received a civil investigative demand, or CID, from the U.S. Department of Justice, or the DOJ, informing us that the DOJ is investigating allegations that false claims were submitted to federal healthcare programs in violation of the U.S. False Claims Act in relation to VASCEPA as marketed by our previous co-marketing partner, Kowa Pharmaceuticals, Inc. and us in connection with speaker programs and copayment waivers. The investigation also covers information that would be relevant to determining whether violations of the U.S. Anti-Kickback Statute occurred. The CID requires the production of documents and information from January 1, 2015 to the present. We are in the process of responding to the DOJ with the required documents and information, including answers to written interrogatories. We plan to cooperate with the DOJ on this investigation, we cannot predict when the investigation will be resolved, the outcome of the investigation or its potential impact on our business. Such investigations can be lengthy, costly and could materially affect and disrupt our business. If the government determines that we have violated the Anti-Kickback Statute and Fake Claims Act, we could be subject to significant civil and criminal fines and penalties.

The failure to comply with any of these laws or regulatory requirements subjects entities to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in significant civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from participation in federal and state funded healthcare programs (such as Medicare and Medicaid), contractual damages and the curtailment or restructuring of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws. Any action for violation of these laws, even if successfully defended, could cause a pharmaceutical manufacturer to incur significant legal expenses and divert management's attention from the operation of the business. If any of the physicians or other healthcare providers or entities with whom we expect to do business is

found not to be in compliance with applicable laws, that person or entity may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Prohibitions or restrictions on sales or withdrawal of future marketed products could materially affect business in an adverse way.

Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent inappropriate conduct may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations.

In addition, the approval and commercialization of any of our products outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

We rely on third parties to conduct our clinical trials, and those third parties may not perform satisfactorily, including failing to meet established deadlines for the completion of such clinical trials.

Our reliance on third parties for clinical development activities reduces our control over these activities. However, if we sponsor clinical trials, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trials. Moreover, the FDA requires us to comply with requirements, commonly referred to as good clinical practices, for conducting, recording, and reporting the results of clinical trials to ensure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Our reliance on third parties does not relieve us of these responsibilities and requirements. Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may be delayed in obtaining regulatory approvals for our product candidates and may be delayed in our efforts to successfully commercialize our product candidates for targeted diseases.

Risks Related to Our Intellectual Property

**** We are dependent on patents, proprietary rights and confidentiality to protect the commercial potential of VASCEPA.***

Our success depends in part on our ability to obtain and maintain intellectual property protection for our drug candidates, technology and know-how, and to operate without infringing the proprietary rights of others. While certain key patents related to our product based on the MARINE clinical study were determined to be invalid as obvious by a district court in the United States, and we are pursuing an appeal of that judgment, it remains the case that our ability to successfully implement our business plan and to protect our products with our intellectual property will depend in large part on our ability to:

- obtain, defend and maintain patent protection and market exclusivity for our current and future products;
- preserve any trade secrets relating to our current and future products;
- acquire patented or patentable products and technologies; and
- operate without infringing the proprietary rights of third parties.

We have prosecuted, and are currently prosecuting, multiple patent applications to protect the intellectual property developed during the VASCEPA development program. As of the date of this report, we had 96 patent applications in the United States that have been either issued or allowed and more than 30 additional patent applications are pending in the United States. Such 96 allowed and issued applications include the following:

- two issued U.S. patents directed to a pharmaceutical composition of VASCEPA in a capsule that have terms that expire in 2020 and 2030, respectively;
- one issued U.S. patent covering a composition containing highly pure EPA that expires in 2021;
- 49 U.S. patents covering or related to the use of VASCEPA in either the MARINE or ANCHOR populations that have terms that expire in 2030 or later;
- 18 U.S. patents covering or related to the use of VASCEPA in the REDUCE-IT population with terms expiring in 2033 or later;
- one additional US patent directed to a pharmaceutical composition comprised of free fatty acids with a term that expires in 2030;
- four additional patents related to the use of a pharmaceutical composition comprised of free fatty acids to treat the ANCHOR patient population with a term that expires in 2030 or later;

- two additional patents related to the use of a pharmaceutical composition comprised of free fatty acids to treat the MARINE patient population with a term that expires in 2030;
- three additional patents related to the use of a pharmaceutical composition comprised of free fatty acids to treat the REDUCE-IT population expiring 2033;
- three additional patents related to a pharmaceutical composition comprised of free fatty acids and uses thereof to treat both the MARINE and ANCHOR patient populations with a term that expires in 2030;
- one additional patent related to the use of a pharmaceutical composition comprised of re-esterified EPA triglyceride to treat the REDUCE-IT population expiring 2033;
- three additional patents related to a formulation of EPA/DHA and uses thereof with a term that expires in 2030;
- two additional patents related to the use of VASCEPA to treat obesity with a term that expires in 2034;
- three additional patents covering a pharmaceutical composition comprised of EPA and a hydroxyl compound with a term that expires in 2034; and
- four additional patents covering a new combination therapy comprised of EPA and another drug.

A Notice of Allowance is issued after the USPTO makes a determination that a patent can be granted from an application. A Notice of Allowance does not afford patent protection until the underlying patent is issued by the USPTO. No assurance can be given that applications with issued notices of allowance will be issued as patents or that any of our pending patent applications will issue as patents. No assurance can be given that, if and when issued, our patents will prevent competitors from competing with VASCEPA. For example, we may choose to not assert all issued patents in patent litigation and patents or claims within patents may be determined to be invalid.

We are the owner of the above-listed patents. We are also the exclusive licensee of certain patents owned by others covering products and products in development. To secure our debt under our outstanding royalty-like instrument, we have granted the holders of such instrument a security interest in our VASCEPA-related patents.

We are also pursuing patent applications related to VASCEPA in multiple jurisdictions outside the United States. Geographies outside the United States in which VASCEPA is sold and under regulatory review are not subject to the U.S. patent litigation and judgment. No litigation involving potential generic versions of VASCEPA is pending outside the United States. VASCEPA is currently available by prescription in Canada, Lebanon and the United Arab Emirates. In Canada, VASCEPA has the benefit of eight years of data protection afforded through Health Canada (until the end of 2027), in addition to separate patent protection with expiration dates that could extend into 2039. Amarin is pursuing additional regulatory approvals for VASCEPA in Europe, China and the Middle East. In China and the Middle East, Amarin is pursuing such regulatory approvals and subsequent commercialization of VASCEPA with commercial partners. Ten to eleven years of market protection is anticipated due to regulatory exclusivity in the European Union subject to an approval recommendation by the European Medicines Agency, or EMA, anticipated near the end of 2020 and associated European Community, or EC, approval expected promptly thereafter. In addition patent protection in Europe includes the following:

- 1 allowed patent related to the use of a pharmaceutical composition comprised of 4g of 96% EPA ethyl ester to treat the REDUCE-IT population expiring 2033.

In addition, pending patent applications in Europe have the potential to extend exclusivity into 2039.

We may be dependent in some cases upon third-party licensors to pursue filing, prosecution and maintenance of patent rights or applications owned or controlled by those parties, including, for example, under our collaboration with Mochida. It is possible that third parties will obtain patents or other proprietary rights that might be necessary or useful to us. In cases where third parties are first to invent a particular product or technology, or first to file after various provisions of the America Invents Act of 2011 went into effect on March 16, 2013, it is possible that those parties will obtain patents that will be sufficiently broad so as to prevent us from utilizing such technology or commercializing our current and future products.

Although we intend to make reasonable efforts to protect our current and future intellectual property rights and to ensure that any proprietary technology we acquire or develop does not infringe the rights of other parties, we may not be able to ascertain the existence of all potentially conflicting claims. Therefore, there is a risk that third parties may make claims of infringement against our current or future products or technologies. In addition, third parties may be able to obtain patents that prevent the sale of our current or future products or require us to obtain a license and pay significant fees or royalties in order to continue selling such products.

We may in the future discover the existence of products that infringe patents that we own or that have been licensed to us. If we were to initiate legal proceedings against a third party to stop such an infringement, such proceedings could be costly and time consuming, regardless of the outcome. No assurances can be given that we would prevail, and it is possible that, during such a proceeding, our patent rights could be held to be invalid, unenforceable or both. Although we intend to protect our trade secrets and proprietary know-how through confidentiality agreements with our manufacturers, employees and consultants, we may not be able to prevent parties subject to such confidentiality agreements from breaching these agreements or third parties from independently developing or learning of our trade secrets.

We anticipate that competitors may from time to time oppose our efforts to obtain patent protection for new technologies or to submit patented technologies for regulatory approvals. Competitors may seek to oppose our patent applications to delay the approval process or to challenge our granted patents, for example, by requesting a reexamination of our patent at the USPTO, or by filing an opposition in a foreign patent office, even if the opposition or challenge has little or no merit. For example, one of our patents was revoked in an opposition proceeding in Europe due to a determination of improper claim amendments under a provision of law not applicable in the United States. Such proceedings are generally highly technical, expensive, and time consuming, and there can be no assurance that such a challenge would not result in the narrowing or complete revocation of any patent of ours that was so challenged.

Our issued patents may not prevent competitors from competing with VASCEPA, even if we seek to enforce our patent rights.

We plan to vigorously defend our rights under issued patents. For example, in March 2014, we filed a patent infringement suit against Omthera Pharmaceuticals, Inc., and its parent company, AstraZeneca Pharmaceuticals LP. The suit sought injunctive relief and monetary damages for infringement of our U.S. Patent No. 8,663,662. The complaint alleged infringement of the patent arising from the then expected launch of Epanova, a product that, in 2014, was expected to compete with VASCEPA in the United States. In November 2014, based on a representation from AstraZeneca Pharmaceuticals LP in the court proceedings that the commercial launch of Epanova was not imminent, the court dismissed our complaint, without prejudice (i.e., preserving our ability to later re-file the suit). The court required the defendant to notify us before any product launch. While we no longer expect a launch of Epanova due to the clinical failure of the STRENGTH cardiovascular outcomes trial announced in January 2020, we intend to pursue this litigation vigorously and aggressively protect our intellectual property rights should the product be launched. We likewise plan to engage in similar patent litigation should other competitors arise with products that infringe our intellectual property rights.

Patent litigation is a time-consuming and costly process. There can be no assurance that we will be successful in enforcing this patent or that it will not be successfully challenged and invalidated. Even if we are successful in enforcing this patent, the process could take years to reach conclusion.

Other drug companies may challenge the validity, enforceability, or both of our patents and seek to design its products around our issued patent claims and gain marketing approval for generic versions of VASCEPA or branded competitive products based on new clinical studies. The pharmaceutical industry is highly competitive and many of our competitors have greater experience and resources than we have. Any such competition could undermine sales, marketing and collaboration efforts for VASCEPA, and thus reduce, perhaps materially, the revenue potential for VASCEPA.

Even if we are successful in enforcing our issued patents, we may incur substantial costs and divert management's time and attention in pursuing these proceedings, which could have a material adverse effect on us. Patent litigation is costly and time consuming, and we may not have sufficient resources to bring these actions to a successful conclusion.

There can be no assurance that any of our pending patent applications relating to VASCEPA or its use will issue as patents.

We have filed and are prosecuting numerous families of patent applications in the United States and internationally with claims designed to protect the proprietary position of VASCEPA. For certain of these patent families, we have filed multiple patent applications. Collectively the patent applications include numerous independent claims and dependent claims. Several of our patent applications contain claims that are based upon what we believe are unexpected and favorable findings from the MARINE, ANCHOR and REDUCE-IT trials. If granted, many of the resulting granted patents would expire in 2030 or beyond. However, no assurance can be given that these additional patents or any of our pending patent applications intended to cover the indication based on results from the REDUCE-IT clinical trial will be granted or, if they grant, that they will prevent competitors from competing with VASCEPA.

Securing patent protection for a product is a complex process involving many legal and factual questions. The patent applications we have filed in the United States and internationally are at varying stages of examination, the timing of which is outside our control. The process to getting a patent granted can be lengthy and claims initially submitted are often modified in order to satisfy the requirements of the patent office. This process includes written and public communication with the patent office. The process can also include direct discussions with the patent examiner. There can be no assurance that the patent office will accept our arguments with respect to any patent application or with respect to any claim therein. The timing of the patent review process is independent of and has no effect on the timing of the FDA's review of our NDA or sNDA submissions. We cannot predict the timing or results of any

patent application. In addition, we may elect to submit, or the patent office may require, additional evidence to support certain of the claims we are pursuing. Furthermore, third parties may attempt to submit publications for consideration by the patent office during examination of our patent applications. Providing such additional evidence and publications could prolong the patent office's review of our applications and result in us incurring additional costs. We cannot be certain what commercial value any granted patent in our patent estate will provide to us.

Despite the use of confidentiality agreements and/or proprietary rights agreements, which themselves may be of limited effectiveness, it may be difficult for us to protect our trade secrets.

In addition to our patent portfolio and strategy, we will also rely upon trade secrets and know-how to help protect our competitive position. We rely on trade secrets to protect technology in cases when we believe patent protection is not appropriate or obtainable. However, trade secrets are difficult to protect. While we require certain of our academic collaborators, contractors and consultants to enter into confidentiality agreements, we may not be able to adequately protect our trade secrets or other proprietary information.

Risks Related to Our Business

If the estimates we make, or the assumptions on which we rely, in preparing our projected guidance prove inaccurate, our actual results may vary from those reflected in our projections and accruals.

In January 2020, we issued financial and business guidance, including expected fiscal year 2020 total net revenue and expectations regarding inventory build, and 2020 operating expenses. We have since updated certain aspects of that guidance. All such guidance and updates are based on estimates and the judgment of management. Because of the inherent nature of estimates, there could be significant differences between our estimates and the actual amount of product demand. If we fail to realize or if we change or update any element of our publicly disclosed financial guidance as we have done in the past or other expectations about our business change, our stock price could decline in value.

Potential technological changes in our field of business create considerable uncertainty.

The pharmaceutical industry in which we operate is characterized by extensive research efforts and rapid technological progress. New developments in research are expected to continue at a rapid pace in both industry and academia. We cannot assure you that research and discoveries by others will not render some or all of our programs or product candidates uncompetitive or obsolete. Our business strategy is based in part upon new and unproven technologies to the development of therapeutics to improve cardiovascular health. We cannot assure you that unforeseen problems will not develop with these technologies or applications or that any commercially feasible products will ultimately be developed by us.

Our internal computer systems, or those of our third-party clinical research organizations or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our research and development programs.

Despite the implementation of security measures, our internal computer systems and those of our third-party clinical research organizations and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war, and telecommunication and electrical failures. Any such incident could cause interruptions in our operations or a material disruption of our programs. To the extent that any disruption or security breach results in a loss of or damage to our data or applications or other data or applications relating to our technology or products candidates, or inappropriate disclosure of confidential or proprietary information, we could incur liabilities and our research and development program could be delayed.

We could be subject to risks caused by misappropriation, misuse, leakage, falsification or intentional or accidental release or loss of information maintained in the information systems and networks of our company and our vendors, including personal information of our employees and patients, and company and vendor confidential data. In addition, outside parties may attempt to penetrate our systems or those of our vendors or fraudulently induce our personnel or the personnel of our vendors to disclose sensitive information in order to gain access to our data and/or systems. We may experience threats to our data and systems, including malicious codes and viruses, phishing and other cyber-attacks. The number and complexity of these threats continue to increase over time. For example, in June 2019, a report published by security researchers claimed that a database belonging to one of our vendors containing information about individuals who use or have expressed interest in VASCEPA was accessible to unauthorized users. Although we were informed that such breach did not include social security numbers or credit card information, we cannot guarantee that a more material breach will not occur in the future. If a material breach of our information technology systems or those of our vendors occurs, the market perception of the effectiveness of our security measures could be harmed and our reputation and credibility could be damaged. We could be required to expend significant amounts of money and other resources to repair or replace information systems or networks and to repair reputational costs. In addition, we could be subject to regulatory actions and/or claims made by individuals and groups in private litigation involving privacy issues related to data collection and use practices and other data privacy laws and regulations, including claims for misuse or inappropriate disclosure of data, as well as unfair or deceptive practices. We may

incur significant costs or divert significant internal resources as a result of any regulatory actions or private litigation. Any of the foregoing consequences may adversely affect our business and financial condition.

Although we develop and maintain systems and controls designed to prevent these events from occurring, and we have a process to identify and mitigate threats, the development and maintenance of these systems, controls and processes is costly and requires ongoing monitoring and updating as technologies change and efforts to overcome security measures become increasingly sophisticated. Moreover, despite our efforts, the possibility of these events occurring cannot be eliminated entirely. As we outsource more of our information systems to vendors, engage in more electronic transactions with payors and patients, and rely more on cloud-based information systems, the related security risks will increase and we will need to expend additional resources to protect our technology and information systems. In addition, there can be no assurance that our internal information technology systems or those of our third-party contractors, or our consultants' efforts to implement adequate security and control measures, will be sufficient to protect us against breakdowns, service disruption, data deterioration or loss in the event of a system malfunction, or prevent data from being stolen or corrupted in the event of a cyberattack, security breach, industrial espionage attacks or insider threat attacks which could result in financial, legal, business or reputational harm.

We are subject to potential product liability.

We are subject to the potential risk of product liability claims relating to the manufacturing and marketing of VASCEPA. Any person who is injured as a result of using VASCEPA may have a product liability claim against us without having to prove that we were at fault.

In addition, we could be subject to product liability claims by persons who took part in clinical trials involving our current or former development stage products. A successful claim brought against us could have a material adverse effect on our business. We cannot guarantee that a product liability claim will not be asserted against us in the future.

A change in our tax residence could have a negative effect on our future profitability.

We expect that our tax jurisdiction will remain in Ireland. Under current UK legislation, a company incorporated in England and Wales, or which is centrally managed and controlled in the UK, is regarded as resident in the UK for taxation purposes. Under current Irish legislation, a company is regarded as resident for tax purposes in Ireland if it is centrally managed and controlled in Ireland, or, in certain circumstances, if it is incorporated in Ireland. Up to December 31, 2019, where a company was treated as tax resident under the domestic laws of both the UK and Ireland, then the provisions of article 4(3) of the Double Tax Agreement, or DTA, between the UK and Ireland provided that such enterprise would be treated as resident only in the jurisdiction in which its place of effective management is situated. We had at all times sought to conduct our affairs in such a way so as to be solely resident in Ireland for tax purposes by virtue of having our place of effective management situated in Ireland.

These rules regarding determination of tax residence changed effective January 1, 2020, when a modified Ireland-UK DTA came into effect pursuant to the OECD's Multilateral Instrument, or MLI. Under the modified Ireland-UK DTA, from January 1, 2020, we would be solely tax resident in Ireland and not tax resident in the UK if we continued to be centrally managed and controlled in Ireland and if it were mutually agreed between the Irish and UK tax authorities under the MLI "tie-breaker rule" that we are solely tax resident in Ireland. Having made the relevant submission under the amended provisions, we received confirmation effective January 1, 2020 of the mutual agreement of Irish and UK tax authorities that we are solely tax resident in Ireland for the purposes of the modified DTA.

However, we cannot assure you that we are or will continue to be solely resident in Ireland for tax purposes. It is possible that in the future, whether as a result of a change in law or the practice of any relevant tax authority or as a result of any change in the conduct of our affairs, we could become, or be regarded as having become resident in a jurisdiction other than Ireland. Should we cease to be an Irish tax resident, we may be subject to a charge to Irish capital gains tax on our assets and the basis on which our income is taxed may also change. Similarly, if the tax residency of our Irish or UK subsidiaries were to change from their current jurisdiction, they may be subject to a charge to local capital gains tax on their assets and the basis on which their income is taxed may also change.

Our and our subsidiaries' income tax returns are periodically examined by various tax authorities, including the Internal Revenue Service, or the IRS, and states. We recently completed the audits by the IRS for the years 2013 to 2014, with no material changes to the filed income tax returns. In addition, the IRS began an examination of our 2018 US income tax return in the first quarter of 2020. Although the outcome of tax audits is always uncertain and could result in significant cash tax payments, we do not believe the outcome of any future audits will have a material adverse effect on our consolidated financial position or results of operations.

The effect on us of comprehensive U.S. tax reform legislation whether adverse or favorable, is uncertain.

On December 22, 2017, President Trump signed into law H.R. 1, "An Act to provide for reconciliation pursuant to titles II and V of the concurrent resolution on the budget for fiscal year 2018", or informally, the Tax Cuts and Jobs Act. Among a number of significant changes to the U.S. federal income tax rules, the Tax Cuts and Jobs Act reduces the marginal U.S. corporate income tax rate from 35% to 21%, limits the deduction for net interest expense, shifts the United States toward a more territorial tax system, and imposes new taxes to combat erosion of the U.S. federal income tax base. The effect of the Tax Cuts and Jobs Act on our company and our affiliates, whether adverse or favorable, is uncertain, and may not become evident for some period of time. You are urged to consult your tax adviser regarding the implications of the Tax Cuts and Jobs Act for an investment in our ADSs.

The loss of key personnel could have an adverse effect on our business.

We are highly dependent upon the efforts of our senior management. The loss of the services of one or more members of senior management could have a material adverse effect on us. Given our rapidly expanding enterprise coupled with a streamlined management structure, the departure of any key person could have a significant impact and would be potentially disruptive to our business until such time as a suitable replacement is hired. Furthermore, because of the specialized nature of our business, as our business plan progresses we will be highly dependent upon our ability to attract and retain qualified scientific, technical and key management personnel. As we continue to evolve from a development stage company to a commercial stage company we may experience turnover among members of our senior management team. We may have difficulty identifying and integrating new executives to replace any such losses. There is intense competition for qualified personnel in the areas of our activities. In this environment, we may not be able to attract and retain the personnel necessary for the development of our business, particularly if we do not achieve profitability. The failure to recruit key scientific, technical and management personnel would be detrimental to our ability to implement our business plan.

We could be adversely affected by our exposure to customer concentration risk.

A significant portion of our sales are to wholesalers in the pharmaceutical industry. Three customers individually accounted for 10% or more of our gross product sales. Customers A, B, and C accounted for 25%, 37%, and 29%, respectively, of gross product sales for the six months ended June 30, 2020, and represented 32%, 38%, and 23%, respectively, of the gross accounts receivable balance as of June 30, 2020. Customers A, B, and C accounted for 24%, 37%, and 29%, respectively, of gross product sales for the six months ended June 30, 2019, and represented 38%, 32%, and 22%, respectively, of the gross accounts receivable balance as of June 30, 2019. There can be no guarantee that we will be able to sustain our accounts receivable or gross sales levels from our key customers. If, for any reason, we were to lose, or experience a decrease in the amount of business with our largest customers, whether directly or through our distributor relationships, our financial condition and results of operations could be negatively affected.

**** Legal, political and economic uncertainty surrounding the exit of the UK from the EU may be a source of instability in international markets, create significant currency fluctuations, adversely affect our operations in the UK and pose additional risks to our business, revenue, financial condition, and results of operations.***

On June 23, 2016, the UK held a referendum in which a majority of the eligible members of the electorate voted to leave the EU, commonly referred to as Brexit. Pursuant to Article 50 of the Lisbon Treaty, the UK ceased being a Member State of the EU on January 31, 2020. However, the terms of the withdrawal have yet to be fully negotiated and the UK is currently in an implementation period which began on January 31, 2020 and will continue until December 31, 2020. During this 11-month period, the UK remains subject to the majority of the EU's rules, including the EU's pharmaceutical law, and the UK's trading relationship will remain the same. A trade deal is currently being negotiated between the UK and the EU but it is unclear whether an agreement on the terms of future trade will be reached by December 31, 2020 and, even if a deal is reached, what such a deal will look like. In addition, the UK is negotiating deals in a number of other areas where cooperation with the EU is required, and there is uncertainty as to which EU regulations and directives will be replicated into UK domestic law, or replaced, going forward. This lack of clarity on future UK laws and regulations and their divergence from, or consistency with, the EU laws and regulations may negatively impact foreign direct investment in the UK, increase costs, depress economic activity and restrict access to capital.

The continued uncertainty concerning the UK's legal, political and economic relationship with the EU after Brexit may be a source of instability in the international markets, create significant currency fluctuations, and/or otherwise adversely affect trading agreements or similar cross-border co-operation arrangements (whether economic, tax, fiscal, legal, regulatory or otherwise) both during and (depending on the terms of any trade deal that is reached) after the implementation period.

These developments, or the perception that any of them could occur, may have a significant adverse effect on global economic conditions and the stability of global financial markets, and could significantly reduce global market liquidity and limit the ability of key market participants to operate in certain financial markets. In particular, it could also lead to a period of considerable uncertainty in relation to the UK financial and banking markets, as well as on the regulatory process in Europe. Asset valuations, currency exchange rates and credit ratings may also be subject to increased market volatility.

If the UK and the EU are unable to negotiate acceptable agreements or if other EU member states pursue withdrawal, barrier-free access between the UK and other EU member states or among the European Economic Area, or EEA, overall could be diminished or eliminated. The long-term effects of Brexit will depend on any agreements (or lack thereof) between the UK and the EU and, in particular, any arrangements for the UK to retain access to EU markets either during the transitional period or more permanently.

Such a withdrawal from the EU is unprecedented, and it is unclear how the UK's access to the European single market for goods, capital, services and labor within the EU, or single market, and the wider commercial, legal and regulatory environment, will impact our current and future operations (including business activities conducted by third parties and contract manufacturers on our behalf) and clinical activities in the UK. In addition to the foregoing, our UK operations support our current and future operations and clinical activities in other countries in the EU and EEA and these operations and clinical activities could be disrupted by the ongoing effects of Brexit, particularly in regards to the specific terms of any trade deal that is reached between the UK and the EU.

We may also face new regulatory costs and challenges that could have an adverse effect on our operations. Depending on the terms of any trade deal between the UK and EU, the UK could lose the benefits of global trade agreements negotiated by the EU on behalf of its members, which may result in increased trade barriers that could make our doing business in the EU and the EEA more difficult. Since the regulatory framework in the UK covering quality, safety and efficacy of pharmaceutical products, clinical trials, marketing authorization, commercial sales and distribution of pharmaceutical products is derived from EU directives and regulations, Brexit could materially impact the future regulatory regime with respect to the approval of our product candidates in the UK. For instance, in November 2017, EU member states voted to move the EMA, the EU's regulatory body for medicines, from London to Amsterdam. Operations in Amsterdam commenced in March 2019, and the move itself may cause significant disruption to the regulatory approval process in Europe. It remains to be seen how, if at all, Brexit will impact regulatory requirements for product candidates and products in the UK, particularly after the end of the implementation period. Any delay in obtaining, or an inability to obtain, any regulatory approvals, as a result of Brexit or otherwise, would prevent us from commercializing our product candidates in the UK and/or the EU and restrict our ability to generate revenue and achieve and sustain profitability. If any of these outcomes occur, we may be forced to restrict or delay efforts to seek regulatory approval in the UK and/or EU for our product candidates, which could significantly and materially harm our business. The uncertainty around the UK's future relationship with the EU continues to cause economic uncertainty which could adversely impact customer confidence resulting in customers reducing their spending budgets on our solutions, which could adversely affect our business, revenue, financial condition, results of operations and could adversely affect the market price of our ADSs.

Risks Related to Our Financial Position and Capital Requirements

We have a history of operating losses and anticipate that we will incur continued losses for an indefinite period of time.

We have not yet reached sustained profitability. For the fiscal years ended December 31, 2019, 2018, and 2017, we reported losses of approximately $22.6 million, $116.4 million and $67.9 million, respectively, and we had an accumulated deficit as of December 31, 2019 of $1.4 billion. For the six months ended June 30, 2020 and 2019, we reported losses of approximately $16.1 million and $26.3 million, respectively, and we had an accumulated deficit as of June 30, 2020 of $1.4 billion. Substantially all of our operating losses resulted from costs incurred in connection with our research and development programs, from general and administrative costs associated with our operations, and costs related to the commercialization of VASCEPA. Additionally, as a result of our significant expenses relating to research and development and to commercialization, we expect to continue to incur significant operating losses for an indefinite period. Because of the numerous risks and uncertainties associated with developing and commercializing pharmaceutical products, we are unable to predict the magnitude of these future losses. Our historic losses, combined with expected future losses, have had and will continue to have an adverse effect on our cash resources, shareholders' deficit and working capital.

Although we began generating revenue from VASCEPA in January 2013, we may never be profitable for a full year.

Our ability to become profitable on a sustained basis depends upon our ability to generate revenue. We have been generating product revenue from sales of VASCEPA since January 2013, but we may not be able to generate sufficient revenue to achieve a steady state of profitability. Our ability to generate profits on sales of VASCEPA is subject to the market acceptance and commercial success of VASCEPA and our ability to manufacture commercial quantities of VASCEPA through third parties at acceptable cost levels, and may also depend upon our ability to effectively market and sell VASCEPA through our strategic collaborations.

Even though VASCEPA has been approved by the FDA for marketing in the United States for two important indications, it may not gain enough market acceptance to support profitability. We anticipate continuing to incur significant costs associated with expanding the commercialization of VASCEPA. We may not achieve profitability on a sustained basis in the near term due to high costs associated with, for example, our expanded commercialization efforts. If we are unable to continue to generate robust product revenues, we will not become profitable on a sustained basis in the near term, if ever, and may be unable to continue operations without continued funding.

Our operating results are unpredictable and may fluctuate. If our operating results are below the expectations of securities analysts or investors, the trading price of our stock could decline.

Our operating results are difficult to predict and will likely fluctuate from quarter to quarter and year to year, and VASCEPA prescription figures will likely fluctuate from month to month. VASCEPA sales are difficult to predict from period to period and as a result, you should not rely on VASCEPA sales results in any period as being indicative of future performance, and sales of VASCEPA may be below the expectation of securities analysts or investors in the future. We believe that our quarterly and annual results of operations may be affected by a variety of factors, including those risks and uncertainties described in this Part II, Item 1A and the following:

- any launch of a generic version of VASCEPA;
- continued disruption to our business from the COVID-19 pandemic;
- the continuing evolution of the medical community’s and the public’s perception of the REDUCE-IT study results;
- the level of demand for VASCEPA, due to changes in prescriber sentiment, quarterly changes in Distributor purchases, and other factors;
- the extent to which coverage and reimbursement for VASCEPA is available from government and health administration authorities, private health insurers, managed care programs and other third-party payers and the timing and extent to which such coverage and reimbursement changes;
- the timing, cost and level of investment in our sales and marketing efforts to support VASCEPA sales and the resulting effectiveness of those efforts;
- disruptions or delays in our or our partners’ commercial or development activities, including as a result of political instability, civil unrest, terrorism, pandemics or other natural disasters, such as the recent outbreak of coronavirus;
- the timing and ability of efforts outside the United States, to develop, register and commercialize VASCEPA in Europe, China Territory, several Middle Eastern and North African countries, and Canada, for example, including obtaining necessary regulatory approvals, favorable pricing and establishing marketing channels;
- additional developments regarding our intellectual property portfolio and regulatory exclusivity protections, if any;
- outcomes of litigation and other legal proceedings; and
- our ongoing regulatory dialogue.

We may require substantial additional resources to fund our operations. If we cannot find additional capital resources, we will have difficulty in operating as a going concern and growing our business.

We currently operate with limited resources. We believe that our cash and cash equivalents balance of $214.0 million and short-term investment balance of $336.3 million as of June 30, 2020 will be sufficient to fund our projected operations for at least 12 months. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we expect or fail to achieve positive cash flow. Depending on the level of cash generated from operations, and depending in part on the rate of prescription growth for VASCEPA, additional capital may be required to support planned VASCEPA promotion and potential VASCEPA promotion beyond which we are currently executing and for commercialization of VASCEPA in Europe. 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 as a result of the timing of certain items, including our purchases of API, VASCEPA promotional activities from approval by the FDA for the new indication and expanded label and the impact from COVID-19 on our operations and those of our customers and any potential generic competition as a result of our ANDA litigation.

In order to fully realize the market potential of VASCEPA, we may need to enter into a new strategic collaboration or raise additional capital.

Our future capital requirements will depend on many factors, including:

- the timing, amount and consistency of revenue generated from the commercial sale of VASCEPA;
- the costs associated with commercializing VASCEPA in the United States, including expenditures such as potential direct-to-consumer advertising and increased sales force sizing, and for commercializing VASCEPA in Europe, including hiring experienced professionals, and for additional regulatory approvals internationally, if any, the cost and timing of securing commercial supply of VASCEPA and the timing of entering into any new strategic collaboration with others relating to the commercialization of VASCEPA, if at all, and the terms of any such collaboration;
- continued costs associated with litigation and other legal proceedings;
- the time and costs involved in obtaining additional regulatory approvals for VASCEPA based on REDUCE-IT results internationally;
- the extent to which we continue to develop internally, acquire or in-license new products, technologies or businesses; and
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

If we require additional funds and adequate funds are not available to us in amounts or on terms acceptable to us or on a timely basis, or at all, our commercialization efforts for VASCEPA may suffer materially.

The potential future benefit of our substantial net operating loss carryforwards could be lost and our prospects for profitability could be materially diminished if tax regulations or rates change or if we are deemed to not have active operations in Ireland.

Tax law and policies in the United States and Ireland are subject to change based on adjustments in political perspectives. In the United States and internationally, how to tax entities with international operations, like Amarin, has been subject to significant re-evaluation. We believe we developed VASCEPA in and from Ireland based on understanding of applicable requirements. In recent years, particularly since 2013 when commercial sale of VASCEPA commenced in the United States, the majority of our consolidated operations have been in the United States. Ownership of VASCEPA continues to reside with our wholly-owned Ireland-based subsidiary, Amarin Pharmaceuticals Ireland Ltd., and oversight and operations of that entity are structured to be maintained in Ireland. In order to effectively utilize our accumulated net operating loss carryforwards for tax purposes in Ireland, our operations, particularly for this subsidiary, need to be active in Ireland under applicable requirements. In addition, utilization of these accumulated net operating loss carryforwards assumes that tax treaties between Ireland and other countries, particularly the United States, do not change in a manner that limit our future ability to offset earnings with these operating loss carryforwards for tax purposes.

Similarly, a change in our Irish tax residence could materially affect our ability to obtain and maintain profitability, if otherwise achievable. Changes in tax law and tax rates, particularly in the United States and Ireland, could also impact our assessment of deferred taxes. Any change in our assessment of the realizability or the timing for realizing deferred taxes could have a negative impact our future profitability.

Negative economic conditions would likely have a negative effect on our ability to obtain financing on acceptable terms.

While we may seek additional funding through public or private financings, we may not be able to obtain financing on acceptable terms, or at all. There can be no assurance that we will be able to access equity or credit markets in order to finance our

current operations or expand development programs for VASCEPA, or that there will not be deterioration in financial markets and confidence in economies, particularly in light of the recent volatility attributed to COVID-19. We may also have to scale back or further restructure our operations. If we are unable to obtain additional funding on a timely basis, we may be required to curtail or terminate some or all of our research or development programs or our commercialization strategies.

Raising additional capital may cause dilution to our existing shareholders, restrict our operations or require us to relinquish rights.

To the extent we are permitted under our December 2012 Purchase and Sale Agreement with CPPIB Credit Europe S.à r.l., or CPPIB, as successor in interest to BioPharma Secured Debt Fund II Holdings Cayman LP, we may seek additional capital through a combination of private and public equity offerings, debt financings and collaboration, strategic and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a shareholder.

Debt financing, if available, may involve agreements that include burdensome covenants limiting or restricting our ability to take specific actions such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaboration, strategic alliance and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, VASCEPA or product candidates beyond the rights we have already relinquished, or grant licenses on terms that are not favorable to us.

Potential business combinations or other strategic transactions may disrupt our business or divert management's attention.

On a regular basis, we explore potential business combination transactions, including an acquisition of us by a third party, exclusive licenses of VASCEPA or other strategic transactions or collaborations with third parties. The consummation and performance of any such future transactions or collaborations will involve risks, such as:

- diversion of managerial resources from day-to-day operations;
- exposure to litigation from the counterparties to any such transaction, other third parties or our shareholders;
- misjudgment with respect to the value;
- higher than expected transaction costs; or
- an inability to successfully consummate any such transaction or collaboration.

As a result of these risks, we may not be able to achieve the expected benefits of any such transaction or collaboration or deliver the value thereof to our shareholders. If we are unsuccessful in consummating any such transaction or collaboration, we may be required to reevaluate our business only after we have incurred substantial expenses and devoted significant management time and resources.

Risks Related to Ownership of our ADSs and Common Shares

The price of our ADSs and common shares may be volatile.

The stock market has from time to time experienced significant price and volume fluctuations that may be unrelated to the operating performance of particular companies. In addition, the market prices of the securities of many pharmaceutical and medical technology companies have been especially volatile in the past, and this trend is expected to continue in the future.

As of July 31, 2020, we had 388,673,381 common shares outstanding including 388,472,048 shares held as ADSs and 201,333 held as ordinary shares (which are not held in the form of ADSs). There is a risk that there may not be sufficient liquidity in the market to accommodate significant increases in selling activity or the sale of a large block of our securities. Our ADSs have historically had limited trading volume, which may also result in volatility. If any of our large investors seek to sell substantial amounts of our ADSs, particularly if these sales are in a rapid or disorderly manner, or other investors perceive that these sales could occur, the market price of our ADSs could decrease significantly.

The market price of our ADSs and common shares may also be affected by factors such as:

- developments or disputes concerning ongoing patent prosecution efforts and any future patent or proprietary rights;
- litigation and regulatory developments in the United States affecting our VASCEPA promotional rights, and regulatory developments in other countries;
- actual or potential medical results relating to our products or our competitors' products;

- interim failures or setbacks in product development;
- innovation by us or our competitors;
- currency exchange rate fluctuations; and
- period-to-period variations in our results of operations.

Further, the United Kingdom ceased to be a member of the European Union on January 31, 2020, commonly referred to as Brexit, and is currently in an 11-month implementation period which will end on December 31, 2020. The effects of Brexit remain uncertain and may have a negative effect on global economic conditions, financial markets and our business, which could reduce the price of our ADSs and common shares. In particular, Brexit could lead to a period of considerable uncertainty in relation to the UK financial and banking markets, as well as on the regulatory process in Europe, which could cause the broader global financial markets to experience significant volatility. Asset valuations, currency exchange rates and credit ratings may also be subject to increased market volatility due to the ongoing uncertainty, particularly in regards to whether there will be a trade deal between the UK and the EU. Lack of clarity about future UK laws and regulations as the United Kingdom determines which EU rules and regulations to replace or replicate could decrease foreign direct investment in the UK, increase costs, disrupt our business, depress economic activity and restrict our access to capital, any of which could negatively impact the price of our ADSs and common shares.

**** The number of our ordinary shares, or ADSs representing such ordinary shares, outstanding may increase substantially as a result of our 2015 private placements and the later consolidation and redesignation of the Series A Preference Shares represented by Preference ADSs issued thereunder, and some of the investors may then beneficially own significant blocks of our ordinary shares; the ordinary shares and Series A Preference Shares resulting from the private placement are generally available for resale in the public market upon consolidation and redesignation.***

In March and July 2015, we completed a private placement of American Depositary Shares in two tranches representing 352,150,790 and 38,867,180 Series A Preference Shares, respectively, each ten (10) of which may be consolidated and redesignated into one (1) ordinary share in our capital. During 2015, 62,833,330 Series A Preference Shares were converted, resulting in the issuance of 6,283,333 ordinary shares and during 2018, the entire tranche completed in July 2015 of 38,867,180 Series A Preference Shares was converted, resulting in the issuance of 3,886,718 ordinary shares. In addition, in April and July 2020, 237,713,680 and 27,753,000 preferred shares, respectively, were converted, resulting in the issuance of 23,771,368 and 2,775,300 ordinary shares, respectively. The consolidation and redesignation of the Series A Preference Shares currently outstanding would result in an additional 2,385,078 ordinary shares outstanding, resulting in additional dilution to shareholders. Although the Series A Preference Shares do not have voting rights, in general, upon consolidation and redesignation into ordinary shares, including as a result of the April and July 2020 conversions described above, some of the investors in the private placement could then have significant influence over the outcome of any shareholder vote, including the election of directors and the approval of mergers or other business combination transactions.

Moreover, such securities are or will be generally available for immediate resale in the public market, which could cause the market price of our ordinary shares to fall as a result of an increase in the number of shares available for sale in the public market.

Failure to comply with our obligations under the March 2015 securities subscription agreements could result in our becoming liable for damages to certain investors under these agreements, including specified liquidated damages, which could be material in amount.

Under the terms of the March 2015 securities subscription agreements effecting the private placements described above, we are subject to various obligations, failure to comply with which could result in our becoming liable to certain investors under these agreement for damages, which could be material in amount.

For example, under each of these agreements we have agreed to file and maintain the effectiveness of certain resale registration statements for ADSs representing the ordinary shares underlying the Series A Preference Shares we issued and sold under these agreements. Specifically, we have agreed to pay liquidated damages to the investors in the respective private placements if (a) the applicable resale registration statements we are required to file are not declared effective within 120 days after the closing of the applicable private placement, or (b) after effectiveness and subject to certain specified exceptions, we suspend the use of the applicable registration statement or the registration statement ceases to remain continuously effective as to all the securities for which it is required to be effective. We refer to each of these events as a registration default. Subject to the specified exceptions, for each 30-day period or portion thereof during which a registration default remains uncured, we are obligated to pay liquidated damages to each investor in cash in an amount equal to 1% of the aggregate subscription price paid by each such investor in the private placement, up to a maximum of 8% of such aggregate subscription price. These amounts could be material, and any liquidated damages we are required to pay could have a material adverse effect on our financial condition.

In addition, under the March 2015 securities subscription agreement, we are required to not publicly disclose the identity of the investors party to that agreement, subject to certain exceptions for disclosures required in securities filings and under applicable law. If we fail to comply with these obligations we could become liable to these investors for damages, including specified liquidated damages. For example, following certain public statements made by us on a quarterly conference call concerning the 2015 private placement, we agreed to specified liquidated damages in the event we are found to have violated the confidentiality provisions of the subscription agreement in the future.

Actual or potential sales of our common shares by our employees, including members of our senior management team, pursuant to pre-arranged stock trading plans could cause our stock price to fall or prevent it from increasing for numerous reasons, and actual or potential sales by such persons could be viewed negatively by other investors.

In accordance with the guidelines specified under Rule 10b5-1 of the Securities Exchange Act of 1934 and our policies regarding stock transactions, a number of our directors and employees, including members of our senior management team, have adopted and may continue to adopt pre-arranged stock trading plans to sell a portion of our common stock. Generally, sales under such plans by members of our senior management team and directors require public filings. Actual or potential sales of our ADSs by such persons could cause the price of our ADSs to fall or prevent it from increasing for numerous reasons. For example, a substantial amount of our ADSs becoming available (or being perceived to become available) for sale in the public market could cause the market price of our ADSs to fall or prevent it from increasing. Also, actual or potential sales by such persons could be viewed negatively by other investors.

If we were to be characterized as a passive foreign investment company there could be adverse consequences to U.S. investors.

A non-U.S. corporation will be classified as a passive foreign investment company, or PFIC, for U.S. federal income tax purposes for any taxable year, if either (i) 75% or more of its gross income for such year consists of certain types of "passive" income or (ii) 50% or more of the value of its assets (determined on the basis of a quarterly average) during such year produce or are held for the production of passive income. Passive income generally includes dividends, interest, royalties, rents, annuities, net gains from the sale or exchange of property producing such income and net foreign currency gains. In addition, a non-U.S. corporation will be treated as owning its proportionate share of the assets and earning its proportionate share of the income of any other corporation in which it owns, directly or indirectly, no more than 25% (by value) of the stock.

Based on certain estimates of our gross income and gross assets, the latter determined by reference to the expected value of our ADSs and shares, we believe that we will not be classified as a PFIC for the taxable year ended December 31, 2019 and we do not expect to be treated as a PFIC in any future taxable year for the foreseeable future. However, because PFIC status is based on our income, assets and activities for the entire taxable year, which we expect may vary substantially over time, it is not possible to determine whether we will be characterized as a PFIC for any taxable year until after the close of the taxable year. Moreover, we must determine our PFIC status annually based on tests that are factual in nature, and our status in future years will depend on our income, assets and activities in each of those years. There can be no assurance that we will not be considered a PFIC for any taxable year.

Failure to meet our obligations under our December 2012 Purchase and Sale Agreement could adversely affect our financial results and liquidity.

Pursuant to our December 2012 Purchase and Sale Agreement with CPPIB, which was assigned to CPPIB by BioPharma Secured Debt Fund II Holdings Cayman LP in December 2017, we are obligated to make payments based on the amount of our net product sales of VASCEPA and any future products based on ethyl-EPA, or covered products, subject to certain quarterly caps.

Pursuant to this agreement, we may not, among other things: (i) incur indebtedness greater than a specified amount, which we refer to as the Indebtedness Covenant; (ii) pay a dividend or other cash distribution, unless we have cash and cash equivalents in excess of a specified amount after such payment; (iii) amend or restate our memorandum and articles of association unless such amendments or restatements do not affect CPPIB's interests under the transaction; (iv) encumber any of the collateral securing our performance under the agreement; and (v) abandon certain patent rights, in each case without the consent of CPPIB.

Upon a transaction resulting in a change of control of Amarin, as defined in the agreement, CPPIB will be automatically entitled to receive any amounts not previously paid, up to our maximum repayment obligation. As defined in the agreement, "change of control" includes, among other things, (i) a greater than 50 percent change in the ownership of Amarin, (ii) a sale or disposition of any collateral securing our debt with CPPIB and (iii), unless CPPIB has been paid a certain amount under the indebtedness, certain licensings of VASCEPA to a third party for sale in the United States. The acceleration of the payment obligation in the event of a change of control transaction may make us less attractive to potential acquirers, and the payment of such funds out of our available cash or acquisition proceeds would reduce acquisition proceeds for our shareholders.

To secure our obligations under the agreement, we granted CPPIB a security interest in our rights in 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, which we refer to as the collateral. If we (i) fail to deliver a payment when due and do not remedy that failure within specific notice period, (ii) fail to maintain a first-priority perfected security interest in the collateral in the United States and do not remedy that failure after receiving notice of such failure or (iii) become subject to an event of bankruptcy, then CPPIB may attempt to collect the maximum amount payable by us under this agreement (after deducting any payments we have already made).

There can be no assurance that we will not breach the covenants or other terms of, or that an event of default will not occur under, this agreement and, if a breach or event of default occurs, there can be no assurance that we will be able to cure the breach within the time permitted. Any failure to pay our obligations when due, any breach or default of our covenants or other obligations, or any other event that causes an acceleration of payment at a time when we do not have sufficient resources to meet these obligations, could have a material adverse effect on our business, results of operations, financial condition and future viability.

Our indebtedness could adversely affect our financial condition.

Our indebtedness and the related annual debt service requirements, if any, may adversely impact our business, operations and financial condition in the future. For example, they could:

- increase our vulnerability to general adverse economic and industry conditions;
- limit our ability to raise additional funds by borrowing or engaging in equity sales in order to fund future working capital, capital expenditures, research and development and other general corporate requirements;
- require us to dedicate a substantial portion of our cash to service payments on our debt or to restructure our debt; or
- limit our flexibility to react to changes in our business and the industry in which we operate or to pursue certain strategic opportunities that may present themselves.

We do not intend to pay cash dividends on the ordinary shares in the foreseeable future.

We have never paid dividends on ordinary shares and do not anticipate paying any cash dividends on the ordinary shares in the foreseeable future. Under English law, any payment of dividends would be subject to relevant legislation and our Articles of Association, which requires that all dividends must be approved by our Board of Directors and, in some cases, our shareholders, and may only be paid from our distributable profits available for the purpose, determined on an unconsolidated basis.

The rights of our shareholders may differ from the rights typically offered to shareholders of a U.S. corporation.

We are incorporated under English law. The rights of holders of ordinary shares and, therefore, certain of the rights of holders of ADSs, are governed by English law, including the provisions of the Companies Act 2006, and by our Articles of Association. These rights differ in certain respects from the rights of shareholders in typical U.S. corporations. The principal differences include the following:

- Under English law and our Articles of Association, each shareholder present at a meeting has only one vote unless demand is made for a vote on a poll, in which case each holder gets one vote per share owned. Under U.S. law, each shareholder typically is entitled to one vote per share at all meetings.
- Under English law, it is only on a poll that the number of shares determines the number of votes a holder may cast. You should be aware, however, that the voting rights of ADSs are also governed by the provisions of a deposit agreement with our depositary bank.
- Under English law, subject to certain exceptions and disapplications, each shareholder generally has preemptive rights to subscribe on a proportionate basis to any issuance of ordinary shares or rights to subscribe for, or to convert securities into, ordinary shares for cash. Under U.S. law, shareholders generally do not have preemptive rights unless specifically granted in the certificate of incorporation or otherwise.
- Under English law and our Articles of Association, certain matters require the approval of 75% of the shareholders who vote (in person or by proxy) on the relevant resolution (or on a poll of shareholders representing 75% of the ordinary shares voting (in person or by proxy)), including amendments to the Articles of Association. This may make it more difficult for us to complete corporate transactions deemed advisable by our board of directors. Under U.S. law, generally only majority shareholder approval is required to amend the certificate of incorporation or to approve other significant transactions.

- In the United Kingdom, takeovers may be structured as takeover offers or as schemes of arrangement. Under English law, a bidder seeking to acquire us by means of a takeover offer would need to make an offer for all of our outstanding ordinary shares/ADSs. If acceptances are not received for 90% or more of the ordinary shares/ADSs under the offer, under English law, the bidder cannot complete a "squeeze out" to obtain 100% control of us. Accordingly, acceptances of 90% of our outstanding ordinary shares/ADSs will likely be a condition in any takeover offer to acquire us, not 50% as is more common in tender offers for corporations organized under Delaware law. By contrast, a scheme of arrangement, the successful completion of which would result in a bidder obtaining 100% control of us, requires the approval of a majority of shareholders voting at the meeting and representing 75% of the ordinary shares voting for approval.
- Under English law and our Articles of Association, shareholders and other persons whom we know or have reasonable cause to believe are, or have been, interested in our shares may be required to disclose information regarding their interests in our shares upon our request, and the failure to provide the required information could result in the loss or restriction of rights attaching to the shares, including prohibitions on certain transfers of the shares, withholding of dividends and loss of voting rights. Comparable provisions generally do not exist under U.S. law.
- The quorum requirement for a shareholders' meeting is a minimum of two shareholders entitled to vote at the meeting and present in person or by proxy or, in the case of a shareholder which is a corporation, represented by a duly authorized officer (although the marketplace rules of the Nasdaq Stock Market require that shareholders holding at least one-third of our outstanding shares of voting stock are present at the meeting or by proxy). Under U.S. law, a majority of the shares eligible to vote must generally be present (in person or by proxy) at a shareholders' meeting in order to constitute a quorum. The minimum number of shares required for a quorum can be reduced pursuant to a provision in a company's certificate of incorporation or bylaws, but typically not below one-third of the shares entitled to vote at the meeting.

Shareholder protections found in provisions under the U.K. City Code on Takeovers and Mergers, or the Takeover Code, do not apply to us.

The Takeover Code provides a framework within which takeovers of certain companies organized in the United Kingdom are regulated and conducted. However, because our place of central management and control is currently outside of the United Kingdom, we are not subject to the Takeover Code. As a result, our shareholders are not entitled to the benefit of certain takeover offer protections provided under the Takeover Code. The following is a brief summary of some of the most important rules of the Takeover Code which, as noted, does not apply to us:

- In connection with a potential offer, if following an approach by or on behalf of a potential bidder, the company is "the subject of rumor or speculation" or there is an "untoward movement" in the company's share price, there is a requirement for the potential bidder to make a public announcement about a potential offer for the company, or for the company to make a public announcement about its review of a potential offer.
- When a person or group (a) acquires interests in shares carrying 30% or more of the voting rights of a company (which percentage is treated by the Takeover Code as the level at which effective control is obtained) or (b) increases the aggregate percentage interest they have when they are already interested in not less than 30% and not more than 50%, they must make a cash offer to all other shareholders at the highest price paid by them in the 12 months before the offer was announced.
- When interests in shares carrying 10% or more of the voting rights of a class have been acquired by an offeror (i.e., a bidder) in the offer period (i.e., before the shares subject to the offer have been acquired) and the previous 12 months, the offer must be in cash or be accompanied by a cash alternative for all shareholders of that class at the highest price paid by the offeror in that period. Further, if an offeror acquires any interest in shares during the offer period, the offer for the shares must be in cash or accompanied by a cash alternative at a price at least equal to the price paid for such shares during the offer period.
- If after an announcement is made, the offeror acquires an interest in shares in an offeree company (i.e., a target) at a price higher than the value of the offer, the offer must be increased accordingly.
- The offeree company must appoint a competent independent adviser whose advice on the financial terms of the offer must be made known to all the shareholders, together with the opinion of the board of directors of the offeree company.
- Favorable deals for selected shareholders are not permitted, except in certain circumstances where independent shareholder approval is given and the arrangements are regarded as fair and reasonable in the opinion of the financial adviser to the offeree.
- All shareholders must be given the same information.
- Those issuing takeover circulars must include statements taking responsibility for the contents thereof.

- Profit forecasts, quantified financial benefits statements and asset valuations must be made to specified standards and must be reported on by professional advisers.
- Misleading, inaccurate or unsubstantiated statements made in documents or to the media must be publicly corrected immediately.
- Actions during the course of an offer by the offeree company, which might frustrate the offer are generally prohibited unless shareholders approve these plans. Frustrating actions would include, for example, lengthening the notice period for directors under their service contract or agreeing to sell off material parts of the target group.
- Stringent requirements are laid down for the disclosure of dealings in relevant securities during an offer, including the prompt disclosure of positions and dealing in relevant securities by the parties to an offer and any person who is interested (directly or indirectly) in 1% or more of any class of relevant securities.
- Employees of both the offeror and the offeree company and the trustees of the offeree company's pension scheme must be informed about an offer. In addition, the offeree company's employee representatives and pension scheme trustees have the right to have a separate opinion on the effects of the offer on employment appended to the offeree board of directors' circular or published on a website.

U.S. shareholders may not be able to enforce civil liabilities against us.

We are incorporated under the laws of England and Wales, and our subsidiaries are incorporated in various jurisdictions, including foreign jurisdictions. A number of the officers and directors of each of our subsidiaries are non-residents of the United States, and all or a substantial portion of the assets of such persons are located outside the United States. As a result, it may not be possible for investors to affect service of process within the United States upon such persons or to enforce against them judgments obtained in U.S. courts predicated upon the civil liability provisions of the federal securities laws of the United States. We have been advised by our English solicitors that there is doubt as to the enforceability in England in original actions, or in actions for enforcement of judgments of U.S. courts, of civil liabilities to the extent predicated upon the federal securities laws of the United States.

U.S. holders of the ADSs or ordinary shares may be subject to U.S. federal income taxation at ordinary income tax rates on undistributed earnings and profits.

There is a risk that we will be classified as a controlled foreign corporation, or CFC, for U.S. federal income tax purposes. If we are classified as a CFC, any ADS holder or shareholder that is a U.S. person that owns directly, indirectly or by attribution, 10% or more of the voting power of our outstanding shares may be subject to U.S. income taxation at ordinary income tax rates on all or a portion of our undistributed earnings and profits attributable to "subpart F income." Such 10% holder may also be taxable at ordinary income tax rates on any gain realized on a sale of ordinary shares or ADS, to the extent of our current and accumulated earnings and profits attributable to such shares. The CFC rules are complex and U.S. holders of the ordinary shares or ADSs are urged to consult their own tax advisors regarding the possible application of the CFC rules to them in their particular circumstances.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

Issuer Purchases of Equity Securities

Shares purchased in the second quarter of 2020 are as follows:

Period	Total Number of Shares Purchased (1)	Average Price Paid per Share
April 1 – 30, 2020	19,328	$ 8.26
May 1 – 31, 2020	32,133	7.16
June 1 – 30, 2020	19,510	6.72
Total	70,971	$ 7.34

(1) Represents shares withheld to satisfy tax withholding amounts due from employees related to the receipt of stock which resulted from the exercise or vesting of equity awards.

Item 6. Exhibits

The following exhibits are incorporated by reference or filed as part of this report.

Exhibit Number	Description
31.1	Certification of President and Chief Executive Officer (Principal Executive Officer) pursuant to Section 302 of Sarbanes-Oxley Act of 2002
31.2	Certification of Senior Vice President and Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer) pursuant to Section 302 of Sarbanes-Oxley Act of 2002
32.1	Certification of President and Chief Executive Officer (Principal Executive Officer) and Senior Vice President and Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer) pursuant to Section 906 of Sarbanes-Oxley Act of 2002
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as inline XBRL with applicable taxonomy extension information contained in Exhibits 101.*)

SIGNATURE

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

AMARIN CORPORATION PLC

By: /s/ John F. Thero
John F. Thero

President and Chief Executive Officer
(Principal Executive Officer)
(On behalf of the Registrant)

Date: August 4, 2020

Exhibit 31.1

CERTIFICATION

I, John F. Thero, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Amarin Corporation plc;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 4, 2020

/s/ John F. Thero
John F. Thero
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION

I, Michael W. Kalb, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Amarin Corporation plc;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 4, 2020

/s/ Michael W. Kalb
Michael W. Kalb
Senior Vice President and Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

Exhibit 32.1

STATEMENT PURSUANT TO 18 U.S.C. § 1350

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), John F. Thero, President and Chief Executive Officer (Principal Executive Officer) of Amarin Corporation plc (the "Company"), and Michael W. Kalb, Senior Vice President and Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer) of the Company, each hereby certifies that, to the best of his knowledge:

(1) The Company's Quarterly Report on Form 10-Q for the period ended June 30, 2020, to which this Certification is attached as Exhibit 32.1 (the "Quarterly Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Quarterly Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ John F. Thero

Date: August 4, 2020

John F. Thero
President and Chief Executive Officer
(Principal Executive Officer)

/s/ Michael W. Kalb

Date: August 4, 2020

Michael W. Kalb
Senior Vice President and Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not incorporated by reference into any filing of Amarin Corporation plc under the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.