AMARIN CORP PLC\UK
Form 10-K
February 28, 2013
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

þ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2012

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. 0-21392

Amarin Corporation plc

(Exact name of registrant as specified in its charter)

England and Wales	**Not applicable**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

2 Pembroke House

Upper Pembroke Street 28-32, Dublin 2, Ireland

(Address of principal executive offices)

+353 (0) 1 6699 020

(Registrant s telephone number, including area code)

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

Title of Each Class	Name of Each Exchange on Which Registered
American Depositary Shares, each representing one Ordinary Share	
Ordinary Shares, 50 pence par value per share	The NASDAQ Stock Market LLC

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

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES þ NO ¨

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. YES ¨ NO þ

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 þ NO ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). YES þ NO ¨

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ¨

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

Large accelerated filer þ	Accelerated filer ¨
Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company ¨

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant as of June 30, 2012 was approximately $1.92 billion, based upon the closing price on the NASDAQ Capital Market reported for such date.

149,991,187 shares held as American Depository Shares (ADS), each representing one Ordinary Share, 50 pence par value per share, and 380,694 Ordinary Shares, were outstanding as of February 20, 2013.

DOCUMENTS INCORPORATED BY REFERENCE

Certain information required to be disclosed in Part III of this report is incorporated by reference from the registrant s definitive proxy statement to be filed not later than 120 days after the end of the fiscal year covered by this report.

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PART I

SPECIAL NOTE REGARDING

FORWARD-LOOKING STATEMENTS AND INDUSTRY DATA

This Annual Report on Form 10-K contains forward-looking statements. All statements other than statements of historical fact contained in this Annual Report on Form 10-K are forward-looking statements, including statements regarding the progress and timing of our clinical programs, regulatory filings and commercialization activities, and the potential clinical benefits, safety and market potential of our product candidates, as well as more general statements regarding our expectations for future financial and operational performance, regulatory environment, and market trends. In some cases, you can identify forward-looking statements by terminology such as may, would, should, could, expects, aim plans, anticipates, believes, estimates, predicts, projects, potential, or continue ; the negative of these terms; or other comparable ter These statements include but are not limited to statements regarding the commercial success of Vascepa in its first approved indication, the MARINE indication, the potential for, and timing of, approval of the Vascepa Supplemental New Drug Application, or sNDA, by the United States Food and Drug Administration, or FDA, in its potential second indication, the ANCHOR indication; the safety and efficacy of our product candidates; the scope of our intellectual property protection and the likelihood of securing additional patent protection and regulatory exclusivity; estimates of the potential markets for our product candidates; the likelihood of qualifying additional third party manufacturing suppliers and estimates of the capacity of manufacturing and other facilities to support our products; our operating and growth strategies; our industry; our projected cash needs, liquidity and capital resources; and our expected future revenues, operations and expenditures.

Forward-looking statements are only current predictions and are subject to known and unknown risks, uncertainties, and other factors that may cause our or our industry s actual results, levels of activity, performance, or achievements to be materially different from those anticipated by such statements. These factors include, among other things, those listed under Risk Factors in Item 1A of Part I of this Annual Report on Form 10-K and elsewhere in this Annual Report on Form 10-K. These and other factors could cause results to differ materially from those expressed in these forward-looking statements.

Although we believe that the expectations reflected in the forward-looking statements contained in this Annual Report on Form 10-K are reasonable, we cannot guarantee future results, performance, or achievements. Except as required by law, we are under no duty to update or revise any of such forward-looking statements, whether as a result of new information, future events or otherwise, after the date of this Annual Report on Form 10-K.

Unless otherwise indicated, information contained in this Annual Report on Form 10-K concerning our product candidates, the number of patients that may benefit from these product candidates and the potential commercial opportunity for our product candidates, is based on information from independent industry analysts and third-party sources (including industry publications, surveys, and forecasts), our internal research, and management estimates. Management estimates are derived from publicly available information released by independent industry analysts and third-party sources, as well as data from our internal research, and based on assumptions made by us based on such data and our knowledge of such industry, which we believe to be reasonable. None of the sources cited in this Annual Report on Form 10-K has consented to the inclusion of any data from its reports, nor have we sought their consent. Our internal research has not been verified by any independent source, and we have not independently verified any third-party information. While we believe that such information included in this Annual Report on Form 10-K is generally reliable, such information is inherently imprecise. In addition, projections, assumptions, and estimates of our future performance are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described in Risk Factors in Item 1A of Part I of this Annual Report on Form 10-K and elsewhere in this Annual Report on Form 10-K. These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties and by us.

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Item 1. ***Business***

References in this report to Amarin, the Company, we, our and us refer to Amarin Corporation plc and its subsidiaries, on a consolidated basis, unless otherwise indicated.

This Annual Report on Form 10-K includes the registered and unregistered trademarks and service marks of other parties.

Amarin Corporation plc (formerly Ethical Holdings plc) is a public limited company incorporated under the laws of England and Wales. Amarin Corporation plc was originally incorporated in England as a private limited company on March 1, 1989 under the Companies Act 1985, and re-registered in England as a public limited company on March 19, 1993.

Our registered office is located at One New Change, London EC4M 9AF, England. Our principal offices are located at 2 Pembroke House, Upper Pembroke Street 28-32, Dublin 2 Ireland. Our primary office in the United States is located at 1430 Route 206, Bedminster, NJ 07921, USA. Our telephone number at that location is (908) 719-1315.

For purposes of this Annual Report on Form 10-K, our ordinary shares may also be referred to as common shares or common stock.

Overview

We are a biopharmaceutical company focused on the commercialization and development of therapeutics to improve cardiovascular health. On July 26, 2012, we received approval from the U.S. Food and Drug Administration, or FDA, to market and sell our lead product Vascepa® (icosapent ethyl) capsules (formerly known as AMR101) as an adjunct to diet to reduce triglyceride, or TG, levels in adult patients with severe (TG ³500mg/dL) hypertriglyceridemia, which we sometimes refer to as the MARINE indication. Vascepa became commercially available in the United States by prescription in January 2013, when we commenced sales and shipments to our network of U.S.-based wholesalers. On January 28, 2013, we commenced our full commercial launch of Vascepa in the United States for the MARINE indication.

We are also developing Vascepa for the treatment of patients with high (TG ³ 200 mg/dL and <500 mg/dL) triglyceride levels who are also on statin therapy for elevated low-density lipoprotein cholesterol, or LDL-C, levels which we refer to as mixed dyslipidemia. We refer to this second proposed indication for Vascepa as the ANCHOR indication. In late February 2013, we submitted a Supplemental New Drug Application, or sNDA, for the ANCHOR indication with the FDA. If our sNDA is accepted by the FDA, assuming a ten-month FDA review period, we expect the FDA to assign a Prescription Drug User Fee Act, or PDUFA, action date which is not later than the end of 2013.

In December 2011, we announced commencement of patient dosing in our cardiovascular outcomes study of Vascepa, titled REDUCE-IT (Reduction of Cardiovascular Events with EPA Intervention Trial), that is designed to evaluate the efficacy of Vascepa in reducing major cardiovascular events in a high risk patient population on statin therapy. Based on communications with the FDA, we believe that we are required to be substantially underway with a cardiovascular outcomes study at the time of the submission of our sNDA seeking approval of the ANCHOR indication. We believe that we achieved this requirement prior to submitting the sNDA. However, there can be no assurance that the FDA will agree with our assessment or that they will accept our sNDA for the ANCHOR indication. We do not believe the final results of the REDUCE-IT study will be required for FDA approval of Vascepa for the ANCHOR indication.

Hypertriglyceridemia refers to a condition in which patients have high levels of triglycerides in the bloodstream. Triglycerides are fats in the blood. It is estimated that over 40 million adults in the United States

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have elevated triglyceride levels greater than 200mg/dL and approximately 4.0 million people in the United States have severely high (TG ³500mg/dL) triglyceride levels, commonly known as very high triglyceride levels. According to *The American Heart Association Scientific Statement on Triglycerides and Cardiovascular Disease* (2011), triglycerides also provide important information as a marker associated with the risk for heart disease and stroke, especially when an individual also has low high-density lipoprotein, or HDL-C (often referred to as good cholesterol), and elevated levels of LDL-C (often referred to as bad cholesterol). Guidelines for the management of very high triglyceride levels suggest that reducing triglyceride levels is the primary goal in patients to reduce the risk of acute pancreatitis. The effect of Vascepa on cardiovascular mortality and morbidity in patients with hypertriglyceridemia has not been determined. The effect of Vascepa on the risk for pancreatitis in patients with hypertriglyceridemia has not been determined.

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

Commercialization of Vascepa

Vascepa became commercially available in the United States by prescription in January 2013, when we commenced sales and shipments to our network of U.S.-based wholesalers. On January 28, 2013, we commenced our full commercial launch of Vascepa in the United States for use in the MARINE indication. In preparation for our commercial launch, we recently hired and trained a direct sales force of approximately 275 sales representatives. We also employ various marketing and medical affairs personnel to support our commercialization of Vascepa. Our clinical and commercial supply is provided to us under agreements with various third-party suppliers. As of the date of this Annual Report, we have announced that 18 patent applications in the United States have been either issued or allowed and more than 30 additional patent applications are pending in the United States. We are also pursuing patent applications related to Vascepa in multiple jurisdictions outside the United States. These patent applications are part of our strategy to protect the commercial potential of Vascepa, which generally includes obtaining and maintaining intellectual property rights, maintaining trade secrets, seeking regulatory exclusivity and taking advantage of manufacturing barriers to entry.

We believe that our sales and marketing teams are well positioned to support the commercialization of Vascepa for the MARINE indication. We also believe that a larger sales effort will be required to best support the commercialization of Vascepa for the ANCHOR indication, assuming FDA approval of the ANCHOR indication. To support the continued commercialization of Vascepa, we intend to consider strategic opportunities with larger pharmaceutical companies. From time to time we have held discussions with larger pharmaceutical companies on potential collaborations and other strategic opportunities, and we intend to continue having discussions regarding such opportunities in the future. These strategic opportunities may include licensing or similar transactions, joint ventures, partnerships, strategic alliances, business associations, or a sale of the company. However, we cannot estimate the timing of any such potential strategic transaction, and no assurance can be given that we will enter into any such strategic transaction. Until such time when we enter into such a strategic transaction, if ever, we plan to continue to execute on our plans to market and sell Vascepa on our own.

The U.S. market is currently our primary focus for Vascepa. Opportunities to seek regulatory approval and to market and sell Vascepa outside of the United States are also under evaluation.

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Financial Position

We believe that our cash balance of $260.2 million at December 31, 2012 is sufficient to fund our projected operations for at least the next twelve months, including commercialization of Vascepa in the United States for the MARINE indication, preparations for commercialization of Vascepa in the United States for the ANCHOR indication and the advancement of the REDUCE-IT cardiovascular outcomes study. In order to fund our commercialization plans, in particular to fully support the launch, marketing and sale of Vascepa in the ANCHOR indication, we will likely need enter into a strategic collaboration or raise additional capital.

Lipid Disorders and Cardiovascular Disease

Heart attacks, strokes and other cardiovascular events represent the leading cause of death and disability among men and women in western societies. According to the *2012 At-A-Glance Report* from the U.S. Center for Disease Control, more than 1 out of every 3 adults in the U.S. (approximately 83 million) currently lives with one or more types of cardiovascular disease; an estimated 935,000 heart attacks and 795,000 strokes occur each year; an estimated 71 million adults have high cholesterol (i.e. high levels of low-density lipoprotein cholesterol, or LDL-C); and only 1 out of 3 adults with high LDL cholesterol has the condition under control.

Hypertriglyceridemia refers to a condition in which patients have high levels of triglycerides in the bloodstream and has been recognized as an independent risk factor for cardiovascular disease. Triglyceride levels provide important information as a marker associated with the risk for heart disease and stroke, especially when an individual also has low HDL-C and elevated levels of LDL-C. The effect of Vascepa on cardiovascular mortality and morbidity in patients with hypertriglyceridemia has not been determined.

Guidelines for the management of very high triglyceride levels (≥500 mg/dL) suggest that reducing triglyceride levels is the primary goal in patients to reduce the risk of acute pancreatitis. Under these guidelines, targeting LDL-C goal for all patients remains important. Other important parameters to consider in patients with very high TGs include levels of apo B, non HDL-C, VLDL-C, TC, and HDL-C. The effect of Vascepa on the risk for pancreatitis in patients with hypertriglyceridemia has not been determined.

It is estimated that over 40 million adults in the United States have elevated triglyceride levels >200mg/dL and approximately 4.0 million people in the United States have very high triglyceride levels (≥500 mg/dL). 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.

Mixed dyslipidemia refers to a condition in which patients have a combination of two or more lipid abnormalities including elevated triglycerides, low HDL-C, and/or elevated LDL-C. Both hypertriglyceridemia and mixed dyslipidemia are components of a range of lipid disorders collectively referred to as dyslipidemia. Dyslipidemia has been linked to atherosclerosis, commonly referred to as hardening of the arteries.

Limitations of Current Therapies

It is estimated that fewer than 4% of U.S. adults with triglyceride levels ³ 200 mg/dL are currently receiving prescription medication for lowering triglycerides. Many of these patients are taking statin therapy directed primarily at lowering their LDL-C levels.

The leading treatments to lower triglyceride levels are fibrates (fenofibrate and gemfibrozil), statins and a prescription only omega-3 fatty acid, known as Lovaza® in the United States, and as Omacor® in Europe. The use of fenofibrates can lead to abnormal liver function tests (an increase in ALT (alanine transaminase) or AST (aspartate transaminase), which are liver enzymes, and are commonly measured clinically as a part of a diagnostic liver function test to determine liver health), especially when used with statins. The use of gemfibrozil can lead to rhabdomyolysis (severe breakdown of muscles), especially when used with a statin. Lovaza is comprised of omega-3 ethyl esters, which the FDA has described as a complex mixture of eicosapentanoic acid,

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or EPA, docosahexaenoic acid, or DHA, and other fatty acids. We believe that DHA may increase LDL-C levels and thereby partially offset one of the typically desired benefits of lipid-lowering therapies, which is lowering LDL-C. Also, in 2012, the FDA required an update to Lovaza product labeling to reflect the risk that Lovaza may increase the frequency of a heart rhythm problem known as atrial fibrillation, or heart flutter.

Potential Benefits and Market Opportunity for Vascepa

Vascepa is comprised of not less than 96% pure icosapent ethyl, or ethyl-EPA, and contains no DHA. We believe that the removal of DHA mitigates against the LDL-C raising effect observed in omega-3 formulations that include DHA, as well removing the fishy taste and smell that is sometimes associated with DHA. Based on the results of the MARINE trial, Vascepa was the first omega-3 based product to demonstrate statistically significant triglyceride reduction without a statistically significant increase in LDL-C in this very high triglyceride population.

We believe that the results of the MARINE trial and Vascepa s EPA only/DHA-free composition suggest that Vascepa has the potential to become a best-in-class triglyceride-lowering agent in the United States and the European Union. In addition, currently no omega-3 based product is approved in the United States for lowering high triglycerides in patients with mixed dyslipidemia. We believe that Vascepa has the potential to become first-in-class in the prescription-only omega-3 market for lowering triglycerides in patients with mixed dyslipidemia.

We believe the potential market for Vascepa is large and growing. We estimate that drug treatment for hypercholesterolemia patients exceeds $53 billion per year in the United States, with sales dominated by statin therapies. U.S. sales of fibrates as a class of products were approximately $3.1 billion in 2012 with Tricor and Trilipix leading the class. U.S. gross sales of Lovaza in 2012 were over $1.3 billion.

Commercialization of Vascepa

Vascepa became commercially available in the United States by prescription in January 2013, when we commenced sales and shipments to our network of U.S.-based wholesalers. On January 28, 2013, we commenced our full commercial launch of Vascepa in the United States for use in the MARINE indication. In preparation for our commercial launch, we recently hired and trained a direct sales force of approximately 275 sales representatives. We also employ various marketing and medical affairs personnel to support our commercialization of Vascepa. We continue to conduct the REDUCE-IT trial and will consider additional trials to further expand the potential indications of use for Vascepa. We do not believe the final results of our REDUCE-IT cardiovascular outcomes study will be required for FDA approval of Vascepa for use in the ANCHOR indication.

We believe that our sales and marketing teams are well positioned to support the commercialization of Vascepa for the MARINE indication. We also believe that a larger sales force will be required to best support the commercialization of Vascepa for the ANCHOR indication, assuming FDA approval for the ANCHOR indication. To support the continued commercialization of Vascepa, we intend to consider strategic opportunities with larger pharmaceutical companies. From time to time we have held discussions with larger pharmaceutical companies on potential collaborations and other strategic opportunities, and we intend to continue having discussions regarding such opportunities in the future. These strategic opportunities may include licensing or similar transactions, joint ventures, partnerships, strategic alliances, business associations, or a sale of the company. However, we cannot estimate the timing of any such potential strategic transaction and no assurance can be given that we will enter into any such strategic transaction. Until such time when we enter into such a strategic transaction, if ever, we plan to continue to execute on our plans to market and sell Vascepa on our own.

The U.S. market is currently our primary focus for Vascepa. Opportunities to seek regulatory approval of, and market and sell, Vascepa outside of the United States are also under evaluation.

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Clinical Trials

The MARINE Trial

The MARINE trial, the largest study ever conducted with the omega-3 fatty acid ethyl EPA in treating patients with very high triglycerides (³500 mg/dL), was a Phase 3, multi-center, placebo-controlled, randomized, double-blind, 12-week study. Patients were randomized into three treatment arms for treatment with Vascepa 4 gram/day, 2 gram/day or placebo. Patient enrollment in this trial began in December 2009, and enrollment and randomization was completed in August 2010 at 229 patients. The primary endpoint in the trial was the percentage change in triglyceride level from baseline compared to placebo after 12 weeks of treatment. The MARINE study was required to meet a stringent level of statistical significance of 1% ($p < 0.01$) in our Special Protocol Assessment, or SPA, agreement with the FDA.

On November 29, 2010, we reported top-line data for the MARINE trial. In the trial, Vascepa met its primary endpoint at doses of 4 grams and 2 grams per day with median placebo-adjusted reductions in triglyceride levels of 33% ($p < 0.0001$) compared to placebo for 4 grams and 20% ($p = 0.0051$) compared to placebo for 2 grams. The median baseline triglyceride levels were 703 mg/dL, 680 mg/dL and 657 mg/dL for the patient groups treated with placebo, 4 grams of Vascepa and 2 grams of Vascepa, respectively.

In a pre-specified secondary analysis in the subgroup of patients with baseline triglyceride > 750 mg/dL, representing 39% of all patients, the effect of Vascepa in reducing triglyceride levels compared to placebo was 45% for 4 grams and 33% for 2 grams, both statistically significant ($p = 0.0001$ for 4 grams and $p= 0.0016$ for 2 grams, respectively). The median baseline triglyceride levels in this subgroup were 1052 mg/dL, 902 mg/dL and 948 mg/dL for placebo, 4-gram and 2-gram groups, respectively. Twenty-five percent of patients in this trial were also on background statin therapy. These patients had greater median reduction in triglyceride levels, which was also statistically significant.

Importantly, the significant reduction in triglycerides was not associated with a statistically significant increase in median LDL-C compared to placebo at either dose (-2.3% for the 4-gram group and +5.2% for the 2-gram group [both p=NS]). In addition, there was a statistically significant decrease in median non-HDL-C (total cholesterol less so-called good cholesterol) compared to placebo with both of the Vascepa treated groups (-18% for the 4-gram group [$p < 0.001$] and -8% for the 2-gram group [$p < 0.05$]).

The MARINE trial results also included statistically significant reductions compared to placebo in several important lipid and inflammatory biomarkers, including apo B (apolipoprotein B) (8.5%), Lp-PLA2 (lipoprotein-phospholipase A2) (13.6%), VLDL-C (very low-density lipoprotein cholesterol) (28.6%), Total Cholesterol (16.3%), and hsCRP (high-sensitivity C-reactive protein) (36.0%) at the 4-gram dose. For these achieved endpoints, p-values were <0.01 for most and <0.05 for all. Apo B (apolipoprotein B) is believed to be a sensitive biomarker of cardiovascular risk and may be a better predictor of cardiovascular risk than LDL-C. Lp-PLA2 is an enzyme found in blood and atherosclerotic plaque; high levels have been implicated in the development and progression of atherosclerosis.

In the MARINE trial, patients treated with 4 grams per day of Vascepa experienced a significant reduction in median placebo-adjusted lipoprotein particle concentrations of total LDL and small LDL. When looking at lipoprotein particle concentrations and sizes as measured with nuclear magnetic resonance spectroscopy, Vascepa 4 grams per day, compared with placebo, significantly reduced median total LDL particle count by 16.3% ($p=0.0006$), which is an important factor in atherogenesis. LDL particle count and apo B are important risk markers for the prediction of cardiovascular events. Small LDL particle count, which is a common risk factor for cardiovascular events in patients with diabetes, was reduced by 25.6% ($p<0.0001$) compared with placebo. Vascepa 2 grams per day, compared with placebo, significantly reduced median small LDL particle count by 12.8% ($p <0.05$) and reduced median total LDL particle count by 1.1% (NS). LDL particle size did not change significantly for the 2 or 4 grams doses.

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Vascepa was well tolerated in the MARINE trial, with a safety profile comparable to placebo and there were no treatment-related serious adverse events observed. No significant changes in fasting blood glucose, hemoglobin A1C, vital signs, electrocardiograms, or liver or kidney function were observed with either Vascepa dose.

Patients enrolled in the MARINE trial were given the option to be treated with Vascepa for a period of up to 40 weeks after their last dose in the double-blind portion of the trial. Once participants completed the randomized, double blind, placebo-controlled 12-week MARINE registration trial, patients in all three randomized groups (4 grams, 2 grams and placebo) were offered the opportunity to participate in the open label extension, or OLE, phase. Patients in the OLE phase received 4 grams per day of Vascepa for a period of up to an additional 40 weeks. As is typical of such extension phases, the OLE phase was not a controlled trial, as differentiated from the randomized, double blind, placebo-controlled 12-week MARINE registration trial. In the OLE phase, participants were not randomized at entry, Vascepa administration was open-label (and thus not blinded), and no placebo group was maintained. Also, once patients entered in the OLE phase, investigators were free to add or modify other lipid-altering nutritional, lifestyle and drug treatment regimens. Given the lack of randomization, the open-label design, the addition of various other lipid-altering drugs and changes to doses of existing lipid-altering drugs, as well as the lack of placebo control, neither we nor our independent advisors were able to draw efficacy conclusions from the data. However, we have concluded that the MARINE OLE phase revealed no new safety signals after an additional 40 weeks of exposure to Vascepa, whether used alone or in combination with other lipid-altering regimens.

The ANCHOR Trial

The ANCHOR trial was a multi-center, placebo-controlled, randomized, double-blind, 12-week pivotal study in patients with high triglycerides (³ 200 and <500 mg/dL) who were also receiving optimized statin therapy. Patients were randomized into three arms for treatment with Vascepa 4 gram/day, 2 gram/day or placebo. Patient enrollment in this trial began in January 2010, and enrollment and randomization was completed in February 2011 at 702 patients. The primary endpoint in the trial was the percentage change in triglyceride level from baseline compared to placebo after 12 weeks of treatment.

In April 2011, we reported top-line results from the ANCHOR trial. The ANCHOR trial met its primary endpoint at doses of 4 grams and 2 grams per day with median placebo-adjusted reductions in triglyceride levels of 21.5% (p<0.0001 value) for 4 grams and 10.1% (p=0.0005) for 2 grams. The median baseline triglyceride levels were 259 mg/dL, 265 mg/dL and 254 mg/dL for the patient groups treated with placebo, 4 grams and 2 grams of Vascepa per day, respectively. The analysis of subgroups by baseline triglyceride tertiles showed that higher baseline triglycerides resulted in greater triglyceride reductions.

One of the trial s secondary endpoints was to demonstrate a lack of elevation in LDL-C, the primary target of cholesterol lowering therapy. The trial s non-inferiority criterion for LDL-C was met at both Vascepa doses. The upper confidence boundaries for both doses were below the pre-specified +6% LDL-C threshold limit. At the 4-gram dose the upper confidence boundary was below zero (-1.7%) and at the 2-gram dose the upper confidence boundary was close to zero (0.5%). For the 4 grams per day group, LDL-C decreased significantly by 6.2% from baseline versus placebo, demonstrating superiority over placebo (p=0.0067). For the 2-gram group, LDL-C decreased by 3.6% from baseline versus placebo (p=0.0867), which is not a statistically significant decrease.

Other secondary efficacy endpoints included the median placebo-adjusted percent change in non-high-density lipoprotein cholesterol (non-HDL-C), apolipoprotein B (apo B), and lipoprotein-associated phospholipase A2 (Lp-PLA2). The 4-gram dose was associated with statistically significant reductions in non-HDL-C (13.6%, p<0.0001), apo B (9.3%, p<0.0001), Lp-PLA2 (19%, p<0.0001) and high-sensitivity C-reactive protein (hsCRP) (22%, p<0.001), at week 12 compared to placebo. In addition to the previously reported favorable lipid effects of Vascepa on hypertriglyceridemic patients in the MARINE and ANCHOR studies, a recently published analysis of these studies showed that the Vascepa 4-gram daily dose also significantly decreased levels of the inflammatory marker oxidized low-density lipoprotein relative to placebo.

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Vascepa was well tolerated in the ANCHOR trial with a safety profile comparable to placebo and there were no treatment-related serious adverse events observed. No significant changes in fasting blood glucose, hemoglobin A1C, vital signs, electrocardiograms, or liver or kidney function were observed with either Vascepa dose.

Observed Efficacy of Ethyl-EPA

In Japan, ethyl-EPA is marketed under the product name of Epadel by Mochida Pharmaceutical Co. and is indicated for hyperlipidemia and peripheral vascular disease. Clinical data from Japan suggests that Epadel is effective in reducing triglycerides. In addition, in an outcomes study called the Japan EPA Lipid Intervention Study, or JELIS study, which consisted of more than 18,000 patients followed over multiple years, Epadel, when used in conjunction with statins, was shown to reduce cardiovascular events by 19% compared to the use of statins alone. In this study, cardiovascular events decreased by approximately 53% compared to statins alone in the subset of patients with triglyceride levels of ³ 150 mg/dL (average 269 mg/dL at entry) and HDL-C <40 mg/dL.

Observed Clinical Safety of Vascepa

Prior to commencing the MARINE and ANCHOR trials, we conducted a pre-clinical program for Vascepa, including toxicology and pharmacology studies. In addition, we previously investigated Vascepa in central nervous system disorders in several double-blind, placebo-controlled studies, including Phase 3 trials in Huntington s disease. Over 1,000 patients have been dosed with Vascepa in these studies, with over 100 receiving continuous treatment for a year or more. In all studies performed to date, Vascepa has shown a favorable safety and tolerability profile. In both the MARINE and ANCHOR trials, patients dosed with Vascepa demonstrated a safety profile similar to placebo. There were no treatment-related serious adverse events in the MARINE study or in the ANCHOR study. In the MARINE and ANCHOR trials, the most commonly reported adverse reaction (incidence >2% and greater than placebo) in Vascepa treated patients was arthralgia (joint pain) (2.3% for Vascepa vs. 1.0% for placebo).

In addition to the MARINE and ANCHOR trials, we completed a 28-day pharmacokinetic study in healthy volunteers, a 26-week study to evaluate the toxicity of Vascepa in transgenic mice and multiple pharmacokinetic drug-drug interaction studies in healthy subjects in which we evaluated the effect of Vascepa on certain common prescription drugs. All findings from these studies were consistent with our expectations and confirmed the overall safety profile of Vascepa.

The REDUCE-IT Study

In August 2011, we reached agreement with the FDA on an SPA for the design of the REDUCE-IT (Reduction of Cardiovascular Events with EPA Intervention Trial) cardiovascular outcomes study. An SPA is an evaluation by the FDA of a protocol with the goal of reaching an agreement that the Phase 3 trial protocol design, clinical endpoints, and statistical analyses are acceptable to support regulatory approval. The FDA agreed that, based on the information we submitted to the agency, the design and planned analysis of the REDUCE-IT study adequately addressed the objectives necessary to support a regulatory submission. An SPA is generally binding upon the FDA unless a substantial scientific issue essential to determining safety or efficacy is identified after the testing begins. Moreover, any change to a study protocol can invalidate an SPA. There can be no assurance that the FDA will ultimately consider our SPA to be binding. If the FDA does not consider the SPA to be binding or makes a determination that we did not follow the SPA appropriately, the agency could assert that additional studies or data are required to support a regulatory submission.

In September 2011, we engaged a clinical research organization, or CRO, and began initial trial and clinical site preparation for REDUCE-IT. In December 2011, we announced that the first patient was dosed in the study.

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The study duration is dependent on the rate of clinical events in the study which rate may be affected by the number of patients enrolled in the study and the epidemiology of the patients enrolled in the study. Based on preliminary assumptions for patient enrollment rates and the clinical profile of these patients, it is assumed that fewer than 10,000 patients will be required to complete the study with an optimized target in which the study is completed in approximately six years of 8,000 patients.

The REDUCE-IT study is designed to evaluate the efficacy of Vascepa in reducing major cardiovascular events in an at-risk patient population also receiving statin therapy. REDUCE-IT is a multi-center, prospective, randomized, double-blind, placebo-controlled, parallel-group study to evaluate the effectiveness of Vascepa, as an add-on to statin therapy, in reducing first major cardiovascular events in an at-risk patient population compared to statin therapy alone. The control arm of the study is comprised of patients on optimized statin therapy. The active arm of the study is comprised of patients on optimized statin therapy plus Vascepa. All subjects enrolled in the study will have elevated triglyceride levels and either coronary heart disease or risk factors for coronary heart disease. This study will be conducted internationally. Based on the results of REDUCE-IT, we may seek additional indications for Vascepa beyond the indication studied in the ANCHOR and MARINE trials such as a potential indication for prevention of cardiovascular events, although there can be no assurance as to whether the results of the study will support any such indication.

New Lipid Compounds and other Preclinical Programs

We are also considering development of other next generation compounds based on our internal lipid science expertise, including potential combination and derivative therapies.

In December 2012, we completed dosing and pharmacokinetic sampling in a study to test a fixed-dose combination of Vascepa capsules and a leading statin. The clinical name for this combination product candidate is AMR102. The purpose of the AMR102 study is to determine the bioavailability of the Vascepa and statin components when taken as a fixed-dose combination product, relative to the individual reference agents taken concomitantly. We anticipate reviewing the results of this study in the first half of 2013.

We believe that Vascepa and other lipid-based compositions may have an impact on a number of biological factors in the body such as anti-inflammatory mechanisms, cell membrane composition and plasticity, triglyceride levels and regulation of glucose metabolism. Currently all other clinic developments are in formulative or pre-clinical stages.

Manufacturing and Supply for Vascepa

We currently use third party manufacturers and suppliers to manufacture clinical and commercial quantities of ethyl-EPA, which constitutes the only active pharmaceutical ingredient, or API, within Vascepa, to encapsulate, bottle and package Vascepa and to maintain inventory of Vascepa. The approval of Vascepa in July 2012 included the approval of one active pharmaceutical ingredient, or API, manufacturer, Nisshin Pharma, Inc., and one API encapsulator, Patheon, Inc. (formerly Banner Pharmacaps Europe BV). Nisshin and Patheon are the API manufacturer and API encapsulator, respectively, with which we have had the longest working relationships. Their facilities were inspected by regulatory authorities as part of the process that led to the FDA s July 2012 approval of Vascepa, and we believe that the facilities are qualified to support our commercial launch of Vascepa. In October 2012, a second API encapsulator, Catalent Pharma Solutions LLC, was qualified to encapsulate API for Vascepa.

The API material that constitutes ethyl-EPA is a naturally occurring substance which is sourced from qualified producers of fish oil. A limited number of other manufacturers have the ability, know-how and suitable facilities to produce ethyl-EPA to a similar level of purity. Among the conditions for FDA approval of a pharmaceutical product is the requirement that the manufacturer s quality control and manufacturing procedures conform to current Good Manufacturing Practice, or cGMP, which must be followed at all times. The FDA typically inspects manufacturing facilities before regulatory approval of a product candidate, such as Vascepa,

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and on an ongoing basis. In complying with cGMP regulations, pharmaceutical manufacturers must expend resources and time to ensure compliance with product specifications as well as production, record keeping, quality control, reporting, and other requirements.

Our goal is to expand our supply chain to provide greater capacity to meet anticipated demand, enable supply diversification and flexibility and introduce cost competition. We have defined with the FDA our plan and specifications for qualifying the additional API suppliers. We intend to submit sNDAs for the use of additional API suppliers after the suppliers successfully complete the specified process and facility qualifications. However, Nisshin is currently our only supplier of Vascepa API. In 2011, after conducting an extensive global search for manufacturers capable of producing Vascepa API to our technical specifications, we entered into limited exclusivity, long-term agreements with two additional API suppliers, Chemport, Inc. and BASF (formerly Equateq Limited). In December 2012, we announced an agreement with an exclusive consortium of companies led by Slanmhor Pharmaceutical, Inc. Slanmhor was spun-out from Ocean Nutrition Canada (ONC) prior to the May 2012 acquisition of ONC by Royal DSM N.V., a global leader in life sciences and materials sciences.

In December 2012, we announced our submissions of two sNDAs to the FDA seeking approval for Chemport and BASF as additional Vascepa API suppliers. We intend to submit an additional sNDA for Slanmhor after it successfully completes the qualification process. Subject to appropriate regulatory approvals, the addition of Slanmhor would give us a total of four qualified worldwide suppliers of API for Vascepa to utilize in supporting the global commercialization of Vascepa.

Our agreements with our API suppliers include annual purchase levels to enable Amarin to maintain exclusivity with each respective supplier and to prevent potential termination of the agreements. Certain of these agreements also contain provisions under which the cost of supply to us decreases as we purchase increased product volume. The agreements with each of our API suppliers that have not yet been approved by the FDA also contemplate phased capacity expansion aimed at creating sufficient capacity to meet anticipated demand for API material for Vascepa. Accordingly, these suppliers are currently working to expand their production capabilities to manufacture the API for Vascepa. These API suppliers are self-funding these expansion and qualification plans with contributions from Amarin. There can be no assurance that additional suppliers will fully-fund the capital costs of our engagement or that these additional suppliers will successfully qualify with the FDA.

We intend to purchase increasing amounts of API to support the commercial launch of Vascepa. Our supply agreement with Nisshin contains minimum purchase commitments for metric tons of API, and we may purchase more than the minimum requirement. We received the majority of this API during 2012, in advance of our planned commercial launch of Vascepa. During 2013, we intend to further increase our purchases of API and finished capsules of Vascepa. These purchases are generally made on the basis of rolling twelve-month forecasts which in part are binding on us and the balance of which are subject to adjustment by us subject to certain limitations. We may elect to make certain of these purchases prior to sNDA approval of our added suppliers after we are satisfied that the material they produce and their facilities are qualified. However, in the event that we make such purchases, we will not be able to use such material for commercial sale until the sNDA for the applicable supplier is approved by the FDA. Similarly, if we are not compliant with other regulations with regard to this intended purchase of supply, the supply of product may be delayed.

Our strategy is to expand capacity and to mitigate risk by having multiple API suppliers. Our aggregate capacity to produce API is dependent upon the qualification of our API suppliers. Each of our API suppliers has outlined plans for potential further capacity expansion. We anticipate purchasing qualified API from multiple suppliers for our first year of commercial sales of Vascepa, including purchases from BASF, Chemport and/or Slanmhor prior to FDA approval of the respective sNDAs for these suppliers. If an sNDA for any of these three API suppliers is not approved, we will not be able to use the supply from such supplier for commercial product. Also, if no additional API supplier is approved by the FDA, our API supply will be limited to the API we purchase from Nisshin. We believe that our overall API manufacturing plan provides a pathway to the production of API in sufficient quantities to meet anticipated demand, subject to API supplier capacity expansion,

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qualification and regulatory approval. There can be no assurance that these expansion plans will be successful. If our third party manufacturing capacity is not expanded and compliant with application regulatory requirements, we may not be able to supply sufficient quantities of Vascepa to meet anticipated demand. Our purchase of supply may be insufficient to meet, or exceed, actual demand for Vascepa.

Our Marketing Plans

We are currently expanding our marketing, sales and distribution capabilities. In early 2013 we hired and trained approximately 275 sales representatives in the United States. Vascepa became commercially available in the United States by prescription in January 2013, when we commenced sales and shipments to our network of U.S.-based wholesalers. On January 28, 2013, we commenced our full commercial launch of Vascepa for use in the MARINE indication. We are initially targeting clinicians who are top prescribers of lipid regulating therapies.

Historical Product Development Programs

Prior to October 2009, the majority of Amarin s product development activities were focused on central nervous system and other non-cardiovascular disorders. In October 2009, we completed a private placement resulting in gross proceeds of $70.0 million. These proceeds were used primarily to fund the MARINE and ANCHOR studies for Vascepa. In connection with this private placement, our board of directors and executive management underwent significant change, and our research and development activities, as well as certain executive functions, were consolidated from multiple offices to our research and development headquarters in the United States. In connection with these changes, we re-focused our efforts on developing improved treatments for cardiovascular disease and ceased development of all product candidates outside of our cardiovascular disease focus. In particular, this decision resulted in our ceasing all direct development of product candidates on central nervous system disorders, which included product candidates for the treatment of Huntington s disease, Myasthenia gravis and Parkinson s disease.

Competition

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 products. It is probable that the number of companies seeking to develop products and therapies similar to our products 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. These companies may develop and introduce products and processes competitive with 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 potential competitors both in the United States and Europe include large, well-established pharmaceutical companies, specialty pharmaceutical sales and marketing companies and specialized cardiovascular treatment companies. These companies include GlaxoSmithKline plc, which currently markets Lovaza, a prescription-only omega-3 fatty acid indicated for patients with very high triglycerides, and Abbott Laboratories, which currently markets Tricor, Trilipix and Niaspan for the treatment of very high triglycerides and mixed dyslipidemia and Niaspan, which is primarily used to increase HDL-C, but which is also used to lower triglycerides. In March 2011, Pronova BioPharma Norge AS, which owns the patents for Lovaza, entered into an agreement with Apotex Corp. and Apotex Inc. to settle their patent litigation in the United States related to Lovaza. Pursuant to the terms of the settlement agreement, Pronova granted Apotex a license to enter the U.S. market with a generic version of Lovaza in the first quarter of 2015, or earlier, depending on circumstances. We expect Apotex to compete against us as well. Other companies are also seeking to introduce generic versions of Lovaza.

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In addition, we are aware of other pharmaceutical companies that are developing products that, if approved, would compete with Vascepa. These include a free fatty acid form of omega-3 (comprised of 55% EPA and 20% DHA) which is being developed by Omthera Pharmaceuticals which in April 2012 announced its top-line Phase 3 clinical trial results and indicated that it plans to submit an NDA during 2013 for the treatment of hypertriglyceridemia. In addition, Acasti Pharma, a subsidiary of Neptune Technologies & Bioresources Inc., announced in December 2012 that it intends to conduct a Phase 3 clinical program to assess the safety and efficacy of its omega-3 prescription drug candidate derived from krill oil for the treatment of hypertriglyceridemia. We believe Resolvyx Pharmaceuticals and Catabasis Pharmaceuticals are also developing potential treatments for hypertriglyceridemia based on omega-3 fatty acids, but we believe that neither has initiated a Phase 2 clinical trial of its product. In addition, we are aware that Essentialis, Inc is developing a controlled release diazoxide product for the treatment of hypertriglyceridemia. Essentialis, Inc. has reported that they have completed Phase 2 clinical studies with this product.

Vascepa will also face competition from dietary supplement companies marketing naturally occurring omega-3 fatty acids as nutritional supplements. We cannot be sure physicians and pharmacists will view the FDA-approved prescription-only status, EPA-only purity of Vascepa and stringent regulatory oversight as significant advantages versus naturally occurring omega-3 fatty acid dietary supplements.

In addition, other drug companies, known as generic drug companies, may challenge the validity, enforceability or both of our patents and seek to design products around our issued patent claims and, after a period of FDA-granted regulatory exclusivity gain marketing approval for generic versions of Vascepa or gain marketing approval for branded competitive products based on new clinical studies.

Regulatory Matters

Government Regulation and Regulatory Matters

Any product development activities related to Vascepa or products that we may develop or acquire in the future will be subject to extensive regulation by various government authorities, including the FDA and comparable regulatory authorities in other countries, which regulate the design, research, clinical and non-clinical development, testing, manufacturing, storage, distribution, import, export, labeling, advertising and marketing of pharmaceutical products and devices. Generally, before a new drug can be sold, considerable data demonstrating its quality, safety and efficacy must be obtained, organized into a format specific to each regulatory authority, submitted for review and approved by the regulatory authority. The data is generated in two distinct development stages: pre-clinical and clinical. Our drugs must be approved by the FDA through the NDA process before they may be legally marketed in the United States. For new chemical entities, the pre-clinical development stage generally involves synthesizing the active component, developing the formulation and determining the manufacturing process, as well as carrying out non-human toxicology, pharmacology and drug metabolism studies which support subsequent clinical testing.

The clinical stage of development can generally be divided into Phase 1, Phase 2 and Phase 3 clinical trials. In Phase 1, generally, a small number of healthy volunteers are initially exposed to a single dose and then multiple doses of the product candidate. The primary purpose of these studies is to assess the metabolism, pharmacologic action, side effect tolerability and safety of the drug. Phase 2 trials typically involve studies in disease-affected patients to determine the dose required to produce the desired benefits. At the same time, safety and further pharmacokinetic and pharmacodynamic information is collected. Phase 3 trials generally involve large numbers of patients at multiple sites, in multiple countries and are designed to provide the pivotal data necessary to demonstrate the effectiveness of the product for its intended use, its safety in use, and may include comparisons with placebo and/or other comparator treatments. The duration of treatment is often extended to mimic the actual use of a product during marketing.

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United States Drug Development

In the United States, the process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local, and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable United States requirements at any time during the product development process, approval process or after approval, may subject an applicant to administrative or judicial sanctions. These sanctions could include the FDA s refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning letters, product recalls, product seizures, total or partial suspension of production or distribution injunctions, fines, refusals of government contracts, restitution, disgorgement, or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

Prior to the start of human clinical studies for a new drug in the United States, preclinical laboratory and animal tests are often performed under the FDA s Good Laboratory Practices regulations, or GLP, and an investigational new drug application, or IND, is filed with the FDA. Similar filings are required in other countries; however, data requirements and other information needed for a complete submission may differ in other countries. The amount of data that must be supplied in the IND depends on the phase of the study. Phase 1 studies typically require less data than larger Phase 3 studies. A clinical plan must be submitted to the FDA prior to commencement of a clinical trial. If the FDA has concerns about the clinical plan or the safety of the proposed studies, they may suspend or terminate the study at any time. Studies must be conducted in accordance with good clinical practice and regular reporting of study progress and any adverse experiences is required. Studies are also subject to review by independent institutional review boards, or IRBs, responsible for overseeing studies at particular sites and protecting human research study subjects. An independent IRB may also suspend or terminate a study once initiated.

NDA and FDA Review Process

Following trial completion, trial data is analyzed to determine safety and efficacy. Data is then filed with the FDA in an NDA along with proposed labeling for the product and information about the manufacturing and testing processes and facilities that will be used to ensure product quality. The NDA must contain proof of safety, purity, potency and efficacy, which entails extensive pre-clinical and clinical testing. FDA approval of an NDA must be obtained before marketing a drug in the United States. In addition, in order to seek approval for a potentially expanded indication based on the ANCHOR study, we are required to have been substantially enrolled subjects in our REDUCE-IT cardiovascular outcomes study at the time of our NDA submission for the ANCHOR indication. Based upon feedback from the FDA and in accordance with the SPA for the ANCHOR study, we do not believe that the results of the REDUCE-IT outcomes study are required for approval of the indication studied in the ANCHOR trial.

The FDA will likely re-analyze the clinical trial data, which could result in extensive discussions between the FDA and us during the review process. The review and evaluation of applications by the FDA is extensive and time consuming and may take longer than originally planned to complete. The FDA may conduct a pre-approval inspection of the manufacturing facilities for the new product to determine whether they comply with current good manufacturing practice requirements and may also audit data from clinical and pre-clinical trials.

There is no assurance that the FDA will ultimately approve a drug product for marketing in the United States. Even if future indications for Vascepa are approved, the FDA s review will be lengthy and we may encounter significant difficulties or costs during the review process. After approving any drug product, the FDA may require post-marketing testing and surveillance to monitor the effects of approved products or it may place conditions on approvals including potential requirements or risk management plans that could restrict the commercial promotion, distribution, prescription or dispensing of products. Product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following initial marketing.

European Union Drug Development

In the European Union, or E.U., our future products may also be subject to extensive regulatory requirements. As in the United States, the marketing of medicinal products has been subject to the granting of

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marketing authorizations by regulatory agencies. Particular emphasis is also being placed on more sophisticated and faster procedures for reporting of adverse events to the competent authorities.

Similar to the United States, the various phases of pre-clinical and clinical research in the E.U. are subject to significant regulatory controls. Although the regulatory controls on clinical research are currently undergoing a harmonization process following the adoption of the Clinical Trials Directive 2001/20/EC, there are currently significant variations in the member state regimes. However, all member states currently require independent institutional review board approval of interventional clinical trials. With the exception of U.K. Phase 1 studies in healthy volunteers, all clinical trials require either prior governmental notification or approval. Most regulators also require the submission of adverse event reports during a study and a copy of the final study report.

European Union Drug Review and Approval

In the E.U., approval of new medicinal products can be obtained through one of three processes: the mutual recognition procedure, the centralized procedure and the decentralized procedure.

Mutual Recognition Procedure

An applicant submits an application in one E.U. member state, known as the reference member state. Once the reference member state has granted the marketing authorization, the applicant may choose to submit applications in other concerned member states, requesting them to mutually recognize the marketing authorizations already granted. Under this mutual recognition process, authorities in other concerned member states have 55 days to raise objections, which must then be resolved by discussions among the concerned member states, the reference member state and the applicant within 90 days of the commencement of the mutual recognition procedure. If any disagreement remains, all considerations by authorities in the concerned member states are suspended and the disagreement is resolved through an arbitration process. The mutual recognition procedure results in separate national marketing authorizations in the reference member state and each concerned member state.

Centralized Procedure

This procedure is currently mandatory for products developed by means of a biotechnological process and optional for new active substances and other innovative medicinal products with novel characteristics. Under this procedure, an application is submitted to the European Agency for the Evaluation of Medical Products. Two European Union member states are appointed to conduct an initial evaluation of each application. These countries each prepare an assessment report that is then used as the basis of a scientific opinion of the Committee on Proprietary Medical Products. If this opinion is favorable, it is sent to the European Commission, which drafts a decision. After consulting with the member states, the European Commission adopts a decision and grants a marketing authorization, which is valid throughout the European Union and confers the same rights and obligations in each of the member states as a marketing authorization granted by that member state.

Decentralized Procedure

The most recently introduced of the three processes for obtaining approval of new medicinal processes in the E.U., the decentralized procedure is similar to the mutual recognition procedure described above, but with differences in the timing that key documents are provided to concerned member states by the reference member state, the overall timing of the procedure and the possibility of clock stops during the procedure, among others.

Post-Marketing Requirements

Following approval of a new product, a pharmaceutical company generally must engage in numerous specific monitoring and recordkeeping activities and continue to submit periodic and other reports to the

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applicable regulatory agencies, including any cases of adverse events and appropriate quality control records. Modifications or enhancements to the products or labeling or changes of site of manufacture are often subject to the approval of the FDA and other regulators, which may or may not be received or may result in a lengthy review process.

Prescription drug advertising is subject to federal, state and foreign regulations. In the United States, the FDA regulates prescription drug promotion, including direct-to-consumer advertising. Prescription drug promotional materials must be submitted to the FDA in conjunction with their first use. Any distribution of prescription drug products and pharmaceutical samples must comply with the U.S. Prescription Drug Marketing Act, or the PDMA, a part of the U.S. Federal Food, Drug, and Cosmetic Act.

In the United States, once a product is approved, its manufacture is subject to comprehensive and continuing regulation by the FDA. The FDA regulations require that products be manufactured in specific approved facilities and in accordance with current good manufacturing practices, or cGMPs, and NDA holders must list their products and register their manufacturing establishments with the FDA. These regulations also impose certain organizational, procedural and documentation requirements with respect to manufacturing and quality assurance activities. NDA holders using contract manufacturers, laboratories or packagers are responsible for the selection and monitoring of qualified firms, and, in certain circumstances, qualified suppliers to these firms. These firms and, where applicable, their suppliers are subject to inspections by the FDA at any time, and the discovery of violative conditions, including failure to conform to cGMPs, could result in enforcement actions that interrupt the operation of any such facilities or the ability to distribute products manufactured, processed or tested by them.

Federal and State Fraud and Abuse Laws

In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal laws restrict certain marketing practices in the biopharmaceutical industry. These laws include anti-kickback statutes and false claims statutes.

The federal anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting, or receiving remuneration to induce or in return for a referral or the purchasing, leasing, ordering, or arranging for or recommending the purchase, lease, or order of any healthcare facility, item or service reimbursable under Medicare, Medicaid, or other federal healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, and formulary managers on the other. 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.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making or using, or causing to be made or used, a false statement to get a false claim paid. Recently, several pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the company s marketing of the product for unapproved, and thus non-reimbursable, uses. The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payer. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer s products from reimbursement under government programs, criminal fines, and imprisonment.

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Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of such laws. Such a challenge could have a material adverse effect on our business, financial condition and results of operations. As a company marketing an FDA-approved product in the United States, our operations may be directly, or indirectly through our customers, subject to various federal and state fraud and abuse laws, including, without limitation, the federal anti-kickback statute. These laws may impact, among other things, our proposed sales, marketing and education programs. In addition, we may be subject to patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include:

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information; and

- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payer, including commercial insurers, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

In the United States and foreign jurisdictions, there have been a number of legislative and regulatory changes to the healthcare system that could affect our future results of operations. In particular, there have been and continue to be a number of initiatives at the United States federal and state levels that seek to reduce healthcare costs. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or the MMA, imposed new requirements for the distribution and pricing of prescription drugs for Medicare beneficiaries. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities which will provide coverage of outpatient prescription drugs. Part D plans include both stand-alone prescription drug benefit plans and prescription drug coverage as a supplement to Medicare Advantage plans. Unlike Medicare Part A and B, Part D coverage is not standardized. Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. However, Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs in each category or class. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee. Government payment for some of the costs of prescription drugs may increase demand for our products for which we receive marketing approval. However, any negotiated prices for our products covered by a Part D prescription drug plan will likely be lower than the prices we might otherwise obtain. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private payers often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results from the MMA may result in a similar reduction in payments from non-governmental payers.

The American Recovery and Reinvestment Act of 2009 provides funding for the federal government to compare the effectiveness of different treatments for the same illness. A plan for the research will be developed by the Department of Health and Human Services, the Agency for Healthcare Research and Quality and the National Institutes for Health, and periodic reports on the status of the research and related expenditures will be made to Congress. Although the results of the comparative effectiveness studies are not intended to mandate

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coverage policies for public or private payers, it is not clear what effect, if any, the research will have on the sales of any product, if any such product or the condition that it is intended to treat is the subject of a study. It is also possible that comparative effectiveness research demonstrating benefits in a competitor s product could adversely affect the sales of our product candidates. If third-party payers do not consider our products to be cost-effective compared to other available therapies, they may not cover our products as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our products on a profitable basis.

Most recently, in March 2010 the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the PPACA, was enacted, which includes measures to significantly change the way healthcare is financed by both governmental and private insurers. Among the provisions of the PPACA of greatest importance to the pharmaceutical and biotechnology industry are the following:

- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic products, apportioned among these entities according to their market share in certain government healthcare programs, that began in 2011;
- new requirements to report certain financial arrangements with physicians and others, including reporting any transfer of value made or distributed to prescribers and other healthcare providers and reporting any investment interests held by physicians and their immediate family members;
- a licensure framework for follow-on biologic products;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- creation of the Independent Payment Advisory Board which, beginning in 2014, will have authority to recommend certain changes to the Medicare program that could result in reduced payments for prescription drugs and those recommendations could have the effect of law even if Congress does not act on the recommendations; and
- establishment of a Center for Medicare and Medicaid Innovation at the Centers for Medicare & Medicaid Services to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending that began on January 1, 2011.

Many of the details regarding the implementation of the PPACA are yet to be determined, and at this time, it remains unclear the full effect that the PPACA would have on our business.

Other Regulatory Matters

Manufacturing, sales, promotion, and other activities following product approval are also subject to regulation by numerous regulatory authorities in addition to the FDA, including, in the United States, the Centers for Medicare & Medicaid Services, other divisions of the Department of Health and Human Services, the Drug Enforcement Administration, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency, and state and local governments. Sales, marketing and scientific/educational programs must also comply with the U.S. Medicare-Medicaid Anti-Fraud and Abuse Act and similar state laws. Pricing and rebate programs must comply with the Medicaid rebate requirements of the U.S. Omnibus Budget Reconciliation Act of 1990. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. The handling of any controlled substances must comply with the U.S. Controlled Substances Act and Controlled Substances Import and Export Act. Products must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act. Manufacturing, sales, promotion and other activities are also potentially subject to federal and state consumer protection and unfair competition laws.

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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 failure to comply with regulatory requirements subjects firms to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory 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 product approvals, or refusal to allow a firm to enter into supply contracts, including government contracts. In addition, even if a firm complies 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. Prohibitions or restrictions on sales or withdrawal of future products marketed by us could materially affect our business in an adverse way.

Changes in regulations or statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products; or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

Marketing Exclusivity

Market-exclusivity provisions under the Food, Drug and Cosmetic Act, or FDCA, also can delay the submission or the approval of certain applications. The FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to gain approval of an NDA for a new chemical entity, or NCE. A drug is an NCE if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application, or ANDA, or a 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement. The FDCA also provides three years of marketing exclusivity for an NDA, 505(b)(2) NDA or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application (for example, for new indications, dosages, or strengths of an existing drug). This three-year exclusivity covers only the conditions associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the original active agent. Five-year and three-year exclusivity will not delay the submission or tentative approval of a full NDA; however, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

With respect to Vascepa, we are seeking five-year NCE marketing exclusivity under the FDCA. We believe that the active pharmaceutical ingredient in Vascepa, at least 96% ethyl-EPA, may be considered a new chemical entity, and could therefore be eligible for five-year market exclusivity under the FDCA. The only other omega-3 based product approved by the FDA is Lovaza. We believe the active moiety in Lovaza and the active moiety in Vascepa are different. Lovaza was approved as a lipid-regulating agent by the FDA in 2004 and has been described in its FDA-approved product label as a combination of ethyl esters of omega-3 fatty acids, principally ethyl-EPA and ethyl-DHA. Our belief that Vascepa should be granted NCE exclusivity is based in part on precedent at the FDA for granting NCE status to a previously uncharacterized active moiety, in this case, potentially ethyl-EPA that was part of a previously approved product. It is currently unclear whether the FDA will view the ethyl-EPA in Vascepa as a characterized and previously approved active moiety in Lovaza and deny our request that Vascepa be granted NCE status and the associated period of regulatory exclusivity. The FDA typically makes a determination on NCE exclusivity in connection with, or soon after, an NDA

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approval of a drug for a new indication. The FDA has not yet made its determination regarding NCE exclusivity of Vascepa for the MARINE indication. Separately, we expect to be granted three-year exclusivity of Vascepa for the ANCHOR indication. We cannot assure you that we will be granted our requested periods of exclusivity for the MARINE indication or the ANCHOR indication. If we are not granted NCE exclusivity for the MARINE indication, we expect that we will be granted three-year exclusivity. We also plan to seek regulatory exclusivity for Vascepa in Europe. There can be no assurance that we will be successful in securing marketing approval or regulatory exclusivity in the United States or in Europe.

Pediatric exclusivity is another type of exclusivity in the United States. Pediatric exclusivity, if granted, provides an additional six months to an existing exclusivity or a statutory delay in approval resulting from a patent certification. This six-month exclusivity, which runs from the end of other exclusivity protections or patent delay, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued Written Request for such a study. If market exclusivity, as described above, is successful, we will consider pursuing pediatric exclusivity, although there can be no assurance that we will be successful.

Patents, Proprietary Technology, Trade Secrets

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. We seek to protect our chemical compounds and technologies by, among other methods, filing U.S. and foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development of our business. We also rely on trade secrets, know-how, continuing technological innovation and in-licensing opportunities to develop and maintain our proprietary position. We, or our licensors, file patent applications directed to our key drug candidates in an effort to establish intellectual property positions for our product candidates as well as uses of our product candidates in the treatment of diseases. Our patenting strategy encompasses pursuing patents for compositions, formulations, indications/ uses and combinations with other drugs. Amarin is prosecuting multiple patent applications in an effort to protect the intellectual property developed during the Vascepa cardiovascular program.

We believe that patent protection of our technologies, processes and products is important to our future operations. The success of our products may depend, in part, upon our ability to obtain strong patent protection. There can, however, be no assurance that:

- any patents will be granted from our pending patent applications directed to Vascepa or any of our future products in any or all appropriate jurisdictions;
- any patents that we or our licensees currently hold or may obtain will not be successfully challenged in the future;
- our technologies, processes or products will not infringe upon the patents of third parties; or
- the scope of any patents will be sufficient to prevent third parties from developing similar products.

Our strategy is to file patent applications where we think it is appropriate to protect and preserve the proprietary technology and inventions considered significant to our business. As of the date of this Annual Report, we have announced that 18 patent applications in the United States have been either issued or allowed and more than 30 additional patent applications are pending in the United States. Of such 18 allowed and issued applications, we currently have 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 highly pure EPA which expires in 2021, eight additional U.S. patents covering the use of Vascepa and potentially competitive products in either the MARINE or anticipated ANCHOR indication that have terms that expire in 2030, and have announced Notices of Allowance from the United States Patent and Trademark Office, or USPTO, for seven additional patent applications that have terms that expire in 2030 and are related to the use of Vascepa and potentially competitive products in either the MARINE or anticipated ANCHOR indication. A Notice of Allowance is issued after the USPTO makes a determination that a patent can be granted from an

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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 our issued patents and our pending patents, if and when issued, will prevent competitors from competing with Vascepa.

We have filed and are prosecuting numerous additional patent applications in the United States and internationally that seek 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 based upon what we believe are unexpected findings from the MARINE and ANCHOR trials. If granted, we believe that many of these resulting patents would expire in 2030 or beyond. However, no assurance can be given that any of our patent applications will be granted or, if they are granted, 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 submissions for regulatory approvals. We cannot predict the timing or results of patent applications. In addition, we may elect to submit, or the patent office may require, additional evidence to support certain of the claims we are pursuing. Providing such additional evidence could result in us incurring additional costs. We cannot be certain what commercial value any granted patent in our patent portfolio will provide to us.

We will also rely upon trade secrets and know-how to retain our competitive position.

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. 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 in the United States, it is possible that those parties will obtain patents that will be sufficiently broad so as to prevent us from utilizing such technology. In addition, we may use unpatented proprietary technology, in which case there would be no assurance that others would not develop similar technology. See Item 1A Risk Factors Risks Related to our Intellectual Property and Regulatory Exclusivity We are dependent on patents, proprietary rights and confidentiality, and Risk Factors Risks Related to our Business Potential technological changes in our field of business create considerable uncertainty .

Employees

At December 31, 2012, we had 111 full-time employees employed in marketing, general and administrative and research and development functions. We believe our relations with our employees are good.

Organizational Structure

At December 31, 2012, we had the following subsidiaries:

Subsidiary Name	Country of Incorporation or Registration	Proportion of Ownership Interest and Voting Power Held
Amarin Pharmaceuticals Ireland Limited	Ireland	100%
Amarin Pharma Inc.	United States	100%
Amarin Neuroscience Limited	Scotland	100%
Corsicanto Ltd	Ireland	100%
Ester Neurosciences Limited	Israel	100%

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Our registered office is located at One New Change, London EC4M 9AF, England. Our principal offices are located at 2 Pembroke House, Upper Pembroke Street 28-32, Dublin 2 Ireland. Our primary offices in the United States are located at 1430 Route 206, Bedminster, NJ 07921, USA. Our telephone number at that location is (908) 719-1315. Our website address is *www.amarincorp.com* . No information contained on, or accessible through, our website is incorporated by reference into this Annual Report on Form 10-K.

As of the date of this Annual Report on Form 10-K, our principal operating activities were being conducted by Amarin Corporation plc, together with Amarin Pharmaceuticals Ireland Limited and Amarin Pharma Inc., with little to no operating activity being conducted by Amarin Neuroscience Limited, Corsicanto Ltd, or Ester Neurosciences Limited.

On January 9, 2012, Amarin, through its wholly-owned subsidiary Corsicanto Limited, a private limited company incorporated under the laws of Ireland, completed a private placement of $150.0 million in aggregate principal amount of its 3.50% exchangeable senior notes due 2032. The notes are the senior unsecured obligations of Corsicanto and are guaranteed by Amarin Corporation plc. Corsicanto was formed in November 2011 and was subsequently acquired by Amarin in January 2012 for the sole purpose of facilitating this financing transaction.

Financial Information

The financial information required under this Item 1 is incorporated herein by reference to Item 8 of this Annual Report on Form 10-K.

Where You Can Find More Information

You are advised to read this Annual Report on Form 10-K in conjunction with other reports and documents that we file from time to time with the Securities and Exchange Commission, or SEC. You may obtain copies of these reports after the date of this annual report directly from us or from the SEC at the SEC s Public Reference Room at 100 F Street, N.E. Washington, D.C. 20549. In addition, the SEC maintains information for electronic filers (including Amarin) at its website at www.sec.gov. The public may obtain information regarding the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. We make our periodic and current reports, as well as any amendments to such reports, available on our internet website, free of charge, as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC.

Item 1A. ***Risk Factors***

This Annual Report on Form 10-K 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 capital resources, our ability to successfully commercially launch Vascepa, 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, and other risks set forth below.

Risks Related to the Commercialization and Development of Vascepa

We are dependent upon the success of Vascepa, which only recently obtained FDA approval and launched commercially in the MARINE indication.

As a result of our reliance on a single product and our primary focus on the U.S. market in the near-term, much of our near-term results and value as a company depends on our ability to execute our commercial strategy for Vascepa in the United States. If commercialization efforts for Vascepa in the MARINE indication or, if

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approved, the ANCHOR indication, are not successful, our business will be materially and adversely affected. Even if we are able to develop additional products from our research and development efforts, the development time cycle for products typically takes several years. This restricts our ability to respond to adverse business conditions for Vascepa. If we are not successful in developing any future product or products, or if there is not adequate demand for Vascepa or the market for such product develops less rapidly than we anticipate, 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 products we develop could constrain our ability to generate revenues and achieve profitability.

We recently launched Vascepa in the MARINE indication in the United States with our own, newly established sales and marketing teams and distribution channels and we may not be successful.

In late January 2013, we began selling and marketing Vascepa in the United States through our own, newly established sales and marketing teams and through a newly established third-party commercial distribution infrastructure. We hired key personnel in these areas over the last several years and hired and trained a professional sales force in early January 2013. The commercial launch of a new pharmaceutical product is a complex undertaking for a company to manage, and we have no prior experience as a company operating in this area. Factors related to building and managing our own sales and marketing organization that can inhibit our efforts to successfully commercialize Vascepa on our own include:

- our inability to attract and retain adequate numbers of effective sales and marketing personnel;
- our inability to adequately train our sales and marketing personnel, in particular as it relates to various healthcare regulatory requirements applicable to the marketing and sale of pharmaceutical products, and our inability to adequately monitor compliance with these requirements;
- the inability of our new sales personnel, working for us as a new market entrant, 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; and
- unforeseen costs and expenses associated with operating a new independent sales and marketing organization.

We also have to compete with other pharmaceutical and life sciences companies to recruit, hire, train and retain sales and marketing personnel, and turnover in our sales force and marketing personnel could negatively affect sales of Vascepa. If we are not successful in our efforts to market and sell Vascepa on our own, market acceptance of Vascepa may be harmed, our anticipated revenues will be materially and negatively impacted, and we may need additional funding or seek a strategic licensing or co-promotion transaction in certain territories as a means of raising additional funds.

Vascepa may fail to achieve the degree of market acceptance by physicians, patients, healthcare payors and others in the medical community necessary for commercial success.

We only recently began marketing and selling Vascepa for use in the MARINE indication in January 2013. Vascepa may fail to gain sufficient market acceptance by physicians, patients, healthcare payors and others in the medical community. If Vascepa does not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of Vascepa for the MARINE indication and any future approved indications will depend on a number of factors, including:

- the perceived efficacy and potential advantages of Vascepa, as compared to alternative treatments;

our ability to offer Vascepa for sale at competitive prices;

convenience and ease of administration compared to alternative treatments;

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the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;

the scope, effectiveness and strength of marketing and distribution support, including our sales and marketing team;

sufficient third-party coverage or reimbursement; and

the prevalence and severity of any side effects.

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

The pharmaceutical industry is highly competitive. In attempting to achieve the widespread commercialization of Vascepa, we will face competition to the extent other pharmaceutical companies have on the market, or are able to develop, products for the treatment of similar indications. Potential competitors in this market include companies with greater experience in commercializing pharmaceutical products, and greater resources and name recognition than we have. Furthermore, to the extent we are able to acquire or develop additional marketable products in the future, such products will compete with a variety of other products within the United States or elsewhere, possibly including established drugs and major brand names and also generic versions of these products. Competitive factors, including generic competition, could force us to lower prices or could result in reduced sales. In addition, new products developed by others could emerge as competitors to our future products. Products based on new technologies or new drugs could render our products obsolete or uneconomical.

The success of Vascepa and any of our future products will also depend in large part on the willingness of physicians to prescribe these products to their patients. Vascepa will, and our future products may, compete against products that have achieved broad recognition and acceptance among medical professionals. In order to achieve an acceptable level of prescriptions for Vascepa or any future product, we must be able to meet the needs of both the medical community and end users with respect to cost, efficacy and other factors.

Our potential competitors both in the United States and Europe include large, well-established pharmaceutical companies, specialty pharmaceutical sales and marketing companies, and specialized cardiovascular treatment companies. These companies include GlaxoSmithKline plc, which currently markets Lovaza, a prescription-only omega-3 fatty acid indicated for patients with severe hypertriglyceridemia, and Abbott Laboratories, which currently markets Tricor and Trilipix for the treatment of severe hypertriglyceridemia and mixed dyslipidemia and Niaspan, which is primarily used to raise HDL-C, but is also used to lower triglycerides. In March 2011, Pronova BioPharma Norge AS, now owned by BASF, which owns the patents for Lovaza, entered into an agreement with Apotex Corp. and Apotex Inc. to settle their patent litigation in the United States related to Lovaza. Pursuant to the terms of the settlement agreement, Pronova granted Apotex a license to enter the United States market with a generic version of Lovaza in the first quarter of 2015, or earlier depending on circumstances. We expect Apotex to compete against us as well. Other companies are also seeking to introduce generic versions of Lovaza. These competitors have greater resources than we do, including financial, product development, marketing, personnel and other resources.

In addition, we are aware of other pharmaceutical companies that are developing products that, if approved, would compete with Vascepa. These include a free fatty acid form of omega-3 (comprised of 55% EPA and 20% DHA) which is being developed by Omthera Pharmaceuticals, which in April 2012 announced its top-line Phase 3 clinical trial results and indicated that it plans to submit an NDA during 2013 for the treatment of hypertriglyceridemia. In addition, Acasti Pharma, a subsidiary of Neptune Technologies & Bioresources Inc., announced in late 2012 that it intends to conduct a Phase 3 clinical program to assess the safety and efficacy of its omega-3 prescription drug candidate derived from krill oil for the treatment of hypertriglyceridemia. We believe Resolvyx Pharmaceuticals and Catabasis Pharmaceuticals are also developing potential treatments for hypertriglyceridemia based on omega-3 fatty acids but, to our knowledge, neither has initiated a Phase 2 clinical

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trial of its product. In addition, we are aware that Essentialis, Inc is developing a controlled release diazoxide product for the treatment of hypertriglyceridemia. Essentialis, Inc. has reported that they have completed Phase 2 clinical studies with this product.

Vascepa will also face competition from dietary supplement companies marketing naturally occurring omega-3 fatty acids as nutritional supplements. We cannot be sure physicians will view the FDA-approved prescription-only status, and EPA-only purity of Vascepa as having a superior therapeutic profile to naturally occurring omega-3 fatty acids and dietary supplements.

In addition, other drug companies (commonly known as generic drug companies) may challenge our patents and seek to design products around our issued patent claims and, after a period of FDA-granted regulatory exclusivity gain marketing approval for generic versions of Vascepa or gain marketing approval for branded competitive products based on new clinical studies.

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

Our only current product, Vascepa, is a prescription-only omega-3 fatty acid. Mixtures of omega-3 fatty acids are naturally occurring substances contained in various foods, including fatty fish. Omega-3 fatty acids are also marketed by others as non-prescription dietary supplements. We cannot be sure physicians will view the pharmaceutical grade purity of Vascepa as having a superior therapeutic profile to naturally occurring omega-3 fatty acids and dietary supplements. To the extent the price of Vascepa 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 may recommend these commercial alternatives instead of writing prescriptions for Vascepa or patients may elect on their own to take commercially available omega-3 fatty acids. Either of these outcomes may adversely impact our results of operations by limiting how we price our product and limiting the revenue we receive from the sale of Vascepa due to reduced market acceptance.

If we are not successful marketing and selling Vascepa on our own, we may need to find collaborative partners to help market and sell the product.

If we are not successful marketing and selling Vascepa on our own, we may need to find collaborative partners to help market and sell the product or otherwise outsource these functions to third parties. Until such time as we choose to, and actually do, complete a strategic transaction with a third party to market and sell Vascepa, if ever, we will continue to market and sell Vascepa on our own. We are actively exploring collaboration opportunities for the continued marketing and sale of Vascepa as we approach the potential approval of Vascepa in the ANCHOR indication, assuming its regulatory approval.

We may not be successful in finding a collaborative partner to help market and sell Vascepa, or may be delayed in doing so, if we determine such a collaborative partner is necessary, in which case we may not receive revenue to the extent that we currently anticipate. We face significant competition in seeking appropriate collaborators, and these collaborations are complex and time-consuming to negotiate and document. We may not be able to negotiate collaborations on acceptable terms, or at all. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If that were to occur, we may have to curtail the continued development of Vascepa for approval for additional indications beyond ANCHOR or increase our planned expenditures and undertake additional development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we will need to obtain additional capital, which may not be available to us on acceptable terms, or at all, or which may not be possible due to our other financing arrangements, including our Purchase and Sale Agreement with Biopharma Secured Debt Fund II Holdings Cayman, L.P., or Biopharma. If we cannot raise sufficient funds, we may not be able to market and sell Vascepa effectively, and generate as much product revenue, as we could under collaboration.

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Our ability to generate increased revenue depends, in part, on FDA approval for the use of Vascepa in the ANCHOR indication in the United States and potentially on other regulatory approvals outside the United States, and we may be delayed in obtaining, or never obtain, such approvals.

The costs involved in obtaining regulatory approvals for pharmaceutical products can be substantial. While we are currently marketing Vascepa for use in the MARINE indication in the United States, our ability to commercialize Vascepa in the ANCHOR indication in the United States or market Vascepa for either indication outside of the United States is dependent upon receiving additional regulatory approvals. Further, while we recently filed a Supplemental New Drug Application, or sNDA, with the FDA for the use of Vascepa in the ANCHOR indication, the acceptance of this submission is dependent on our first reaching, in the opinion of the FDA, substantial enrollment in our REDUCE-IT cardiovascular outcomes study. While we believe that we met this requirement before we submitted our sNDA, the FDA may not agree with us, and thus acceptance of the sNDA could be delayed. Additionally, the FDA could deny approval of our sNDA and require additional testing or data. If the FDA takes any of these actions, they could have a material adverse effect on our operations and financial condition, including our ability to reach profitability.

Even if we obtain additional regulatory approvals for Vascepa, the timing or scope of any approvals may prohibit or reduce our ability to commercialize the product successfully. For example, if the approval process for the ANCHOR indication takes too long, we may miss market opportunities and give other companies the ability to develop competing products or establish market dominance. Additionally, the terms of any approvals, including the approval received from the FDA in July 2012 for the MARINE indication, may prove to not have the scope or breadth needed for us to successfully commercialize Vascepa or become profitable.

Our SPAs with the FDA are not guarantees of FDA approval of Vascepa for the proposed ANCHOR and REDUCE-IT indications.

A Special Protocol Assessment, or SPA, is an evaluation by the FDA of a protocol with the goal of reaching an agreement that the Phase 3 trial protocol design, clinical endpoints, and statistical analyses are acceptable to support regulatory approval of the drug product candidate with respect to effectiveness for the indication studied. The ANCHOR trial was, and the REDUCE-IT trial is, being conducted under an SPA with the FDA. The FDA agreed that, based on the information we submitted to the agency, the design and planned analysis of the ANCHOR trial is adequate to support use of the conducted study as the primary basis for approval with respect to effectiveness. An SPA is generally binding upon the FDA except in limited circumstances, such as if the FDA identifies a substantial scientific issue essential to determining safety or efficacy after the study begins, or if the study sponsor fails to follow the protocol that was agreed upon with the FDA. Even though we have received regulatory approval of Vascepa for the MARINE indication, there is no assurance that the FDA will not identify a scientific issue and deem either or both of the ANCHOR or REDUCE-IT SPAs no longer binding. Moreover, any change to a study protocol after agreement with the FDA is reached can invalidate an SPA. While we amended the protocol for the ANCHOR trial after the initial SPA evaluation was completed, we obtained the FDA s evaluation of, and agreement to, the amendment. If, for example, the FDA does not consider the applicable SPA to be binding during its review of our regulatory approval applications, or if the FDA determines that we did not follow the SPAs appropriately, the agency could assert that additional studies or data are required to support approval of the application.

The commercial value to us of the MARINE and ANCHOR indications may be smaller than we anticipate.

There can be no assurance as to the adequacy for commercial success of the scope and breadth of the MARINE indication or, if approved, the ANCHOR indication. Even if we obtain marketing approval for additional indications, the FDA 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, with regard to the MARINE indication and any other indications for which we may gain approval, the number of actual patients with the condition included in such approved indication may be smaller than we anticipate. If any such approved indication is narrower than we anticipate, the market potential for our product would suffer.

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Our products will be 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. 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 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 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. If we participate in the U.S. Medicaid Drug Rebate Program, the Federal Supply Schedule of the U.S. Department of Veterans Affairs, or other government drug programs, we will be subject to complex laws and regulations regarding reporting and payment obligations. All of these activities are also potentially subject to U.S. federal and state consumer protection and unfair competition laws. Similar requirements exist in many of these areas in other countries.

Depending on the circumstances, failure to meet these 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. In addition, even if we or our potential partners 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. Adverse regulatory action, whether pre- or post-approval, can potentially lead to product liability claims and increase our product liability exposure. We or our potential partners must also compete against other products in qualifying for coverage and reimbursement under applicable third party payment and insurance programs.

The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products. If we are found to have improperly promoted off-label uses, we may become subject to significant fines and other liability.

The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products. In particular, a product may not be promoted for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product s approved labeling. Even though we received marketing approval for Vascepa for the MARINE indication only, physicians may nevertheless prescribe Vascepa to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label uses, we may become subject to significant government fines and other related liability. For example, 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.

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

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labeled claims. These incentives could also lead to suits that we have mischaracterized a competitor s product in the marketplace and 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.

The FDA may disagree with our assertion that our cardiovascular outcomes study, REDUCE-IT, was substantially underway at the time of our sNDA submission, thus delaying FDA review and approval of the ANCHOR indication and costing more than we expect.

Based on our communications with the FDA, to obtain FDA marketing approval of the ANCHOR indication, we believe that we must have a cardiovascular outcomes study, the REDUCE-IT study, substantially underway at the time of the sNDA submission for the ANCHOR indication. In August 2011, we reached an agreement with the FDA on an SPA for the design of the REDUCE-IT cardiovascular outcomes study of Vascepa, and we began dosing patients in December 2011. We submitted our sNDA for approval of the ANCHOR indication in late February 2013 based on our belief that the REDUCE-IT study was substantially underway. The FDA will make the final determination as to whether or not our REDUCE-IT study is sufficiently underway for the FDA to accept the submission of our ANCHOR sNDA.

In the event the FDA does not agree that our REDUCE-IT study is substantially underway, it may reject our submission, repeatedly, until such time as it determines that its study enrollment requirement is met. If we then experience delays in initiating or achieving what the FDA would determine to be substantial enrollment for the REDUCE-IT study or the FDA requires that we enroll still more patients beyond our own expectation of what substantial enrollment entails, our re-submission of an sNDA seeking approval of the ANCHOR indication may be rejected again, or delayed.

Any delay in the acceptance of our submission of the ANCHOR sNDA could have a material adverse effect on our business by delaying the possible approval of Vascepa for use in the ANCHOR indication. In addition, to the extent that we experience delays or need to take actions to prevent delays in the REDUCE-IT cardiovascular outcomes study, the cost of this study will increase. The cost of this study is based on estimates and is not capped.

The REDUCE-IT cardiovascular outcomes trial may fail to show that Vascepa can reduce major cardiovascular events in an at-risk patient population on statin therapy, and the long-term clinical results of Vascepa may not be consistent with the clinical results we observed in our Phase 3 clinical trial, in which case our sales of Vascepa may then suffer.

In accordance with the SPA for our MARINE and ANCHOR trials, efficacy was evaluated in these trials compared to placebo at twelve weeks. No placebo-controlled studies have been conducted regarding the long-term effect of Vascepa on lipids, and no outcomes study has been conducted evaluating Vascepa. The REDUCE-IT study is designed to evaluate the efficacy of Vascepa in reducing major cardiovascular events in an at-risk patient population on statin therapy.

Outcomes studies of certain other lipid modifying therapies have failed to achieve the endpoints of such studies. For example, in September 2012, researchers published in the *Journal of the American Medical Association,* or *JAMA,* the results of a retrospective meta-analysis of twenty previously conducted studies regarding the use of omega-3 supplements across various patient populations. This meta-analysis suggested that the use of such supplements was not associated with a lower risk of all-cause death, cardiac death, sudden death, heart attack, or stroke. We believe the results of the JAMA meta-analysis may not be directly applicable to the use of Vascepa over time. For instance, nineteen of the twenty studies included in the JAMA meta-analysis involved the use of omega-3 supplements containing a mixture of EPA and DHA, and most were evaluated at relatively lower doses. Vascepa is comprised of highly-pure ethyl-EPA, and has been approved by the FDA for use in patients with severe hypertriglyceridemia at a dose of 4 grams per day. The only other outcomes study involving the use of a highly-pure formulation of ethyl-EPA, called the Japan EPA Lipid Intervention Study (JELIS), suggested that use of a highly-pure formulation of ethyl-EPA in Japan, when used in conjunction with statins, reduced cardiovascular events by 19% compared to the use of statins alone.

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Although we believe the results of the JAMA meta-analysis and other studies are not directly applicable to the potential long-term clinical experience with Vascepa, there can be no assurance that the endpoints of the REDUCE-IT cardiovascular outcomes study will be achieved or that the lipid modifying effects of Vascepa in REDUCE-IT or any other study of Vascepa will not be subject to variation beyond twelve weeks. If the REDUCE-IT trial fails to achieve its clinical endpoints or if the results of these long-term studies are not consistent with the 12-week clinical results, it could prevent us from expanding the label of any approved product or even call into question the efficacy of any approved product.

We may not be successful in developing or marketing future products if we cannot meet the extensive regulatory requirements of the FDA and other regulatory agencies for quality, safety and efficacy.

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, the European Union, Japan and elsewhere. In the United States, the FDA generally requires pre-clinical 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:

- the lack of efficacy during clinical trials;
- the inability to manufacture sufficient quantities of qualified materials under current good manufacturing practices 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 or preclinical studies;
- the emergence of unforeseen safety issues in clinical 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; and
- government or regulatory delays or clinical holds requiring suspension or termination of a trial.

Even if we obtain positive results from early stage pre-clinical or clinical trials, we may not achieve the same success in future trials. 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, the efficacy results of our Vascepa Phase 3 clinical trials for the treatment of Huntington s disease were negative. As a result, we stopped development of that

product candidate, revised our clinical strategy and shifted our focus to develop Vascepa for use in the treatment of cardiovascular disease.

Any approvals that are obtained may be limited in scope, may require additional post-approval studies or may require the addition of labeling statements 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 earn revenues from the sale of such products. Even in circumstances where products are approved by a regulatory

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body for sale, 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 product or in connection with the manufacturer of products may result in restrictions on that product or manufacturer, including withdrawal of the product from the market, which would have a negative impact on our potential revenue stream.

Legislative or regulatory reform of the health care 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 health care services to contain or reduce health care 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 proposals to change the health care system in ways that could affect our ability to sell our products profitably. For example, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the PPACA, enacted in March 2010, substantially changes the way healthcare is financed by both governmental and private insurers. Among other cost-containment measures, PPACA 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.

We expect further federal and state proposals and health care reforms to continue to be proposed by legislators, which could limit the prices that can be charged for the products we develop and may limit our commercial opportunity.

The continuing efforts of government and other third-party payors to contain or reduce the costs of health care through various means may limit our commercial opportunity. It will be 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 PPACA and by other health care 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. 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.

In some foreign countries, including major markets in the European Union and Japan, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take 6 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.

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As we 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.

We only recently hired and trained a professional sales force of approximately 275 sales representatives and commenced our commercial launch of Vascepa in the MARINE indication in the United States in early January 2013. The process of establishing a commercial infrastructure is difficult, expensive and time-consuming. As our operations expand, 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. 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. 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 commercial supply and clinical trials is dependent upon relationships with third party manufacturers and key suppliers.

We have no in-house manufacturing capacity and rely on contract manufacturers for our clinical and commercial product supply. We cannot assure you 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 any manufacturer 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.

Any manufacturing problem, natural disaster affecting manufacturing facilities, or the loss of a contract manufacturer could be disruptive to our operations and result in lost sales. Additionally, we will be reliant on third parties to supply the raw materials needed to manufacture our potential products. 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 result in lost sales. If our suppliers were unable to supply us with adequate supply of ethyl-EPA it would have a material adverse effect on our ability to continue to commercialize Vascepa.

We currently purchase all of our supply of the bulk compound (ethyl-EPA), which constitutes the only active pharmaceutical ingredient, or API, of Vascepa, from a single supplier, Nisshin Pharma, or Nisshin, located in Japan. Nisshin currently obtains its supply of the key raw material to manufacture API from another third party single source of supply. While we have contractual freedom to source the API for Vascepa elsewhere and have entered into supply agreements with additional suppliers who rely on other third party suppliers of the key raw material to manufacture the API for Vascepa, Nisshin is the only supplier approved with our NDA to the FDA.

We intend to purchase increasing amounts of API to support our commercialization of Vascepa. Our strategy is to expand manufacturing capacity and to partially mitigate the risk of reliance on too few suppliers by having multiple API suppliers beyond Nisshin. In December 2012, we announced our submissions of sNDAs to the FDA seeking approval for both Chemport, Inc. and BASF (formerly Equateq Limited) as additional Vascepa API suppliers. Both Chemport and BASF continue to expand their API manufacturing capacity and bring to three the potential number of qualified worldwide supplies of API for Vascepa. Also in December 2012 we announced the addition of an exclusive consortium of companies led by Slanmhor Pharmaceutical, Inc., or Slanmhor, to our planned API global supply chain for Vascepa. Slanmhor was spun-out from Ocean Nutrition Canada, or ONC,

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prior to the May 2012 acquisition of ONC by Royal DSM N.V., a global leader in life sciences and materials sciences. Amarin now has a total of four suppliers for Vascepa API to utilize in supporting the global commercialization of Vascepa, subject to appropriate regulatory approvals. We intend to submit an additional sNDA for Slanhmor after it successfully completes the qualification process.

Expanding manufacturing capacity and qualifying such capacity is difficult and subject to numerous regulations and other operational challenges. The resources of our suppliers are limited and costs associated with projected expansion and qualification can be significant. The resources of our suppliers vary. For example, Chemport, which is one of the API suppliers that we see to qualify, is a privately-held company and their commitment to Vascepa supply has required them to seek additional resources. 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 qualification of our API suppliers. Each of our API suppliers has outlined plans for potential further capacity expansion. If no additional API supplier is approved by the FDA, our API supply will be limited to the API we purchase from Nisshin. If our third party manufacturing capacity is not expanded and compliant with application regulatory requirements, we may not be able to supply sufficient quantities of Vascepa to meet anticipated demand. We cannot assure you 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.

We cannot assure you 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.

We currently rely on two suppliers, Banner and Catalent, for the encapsulation of API for all capsules of Vascepa. While we have contractual freedom to source the API encapsulation for Vascepa elsewhere, Banner and Catalent are the only encapsulators approved by the FDA for encapsulation of API for Vascepa. There can be no guarantee that additional other suppliers with which we have contracted to encapsulate API will be qualified to manufacture the product to our specifications or that these and any future suppliers will have the manufacturing capacity to meeting anticipated demand for Vascepa. We cannot assure you 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.

We do not have sufficient experience with the commercial sale of Vascepa, and such inexperience may cause us to 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.

Our agreements with our suppliers typically include minimum purchase obligations and limited exclusivity provisions. These purchases are generally made on the basis of rolling twelve-month forecasts which in part are binding on us and the balance of which are subject to adjustment by us subject to certain limitations. We have no experience with the commercial sale of Vascepa, and as such expectations regarding expected demand may be wrong. 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.

The manufacture and packaging of pharmaceutical products such as Vascepa are subject to FDA requirements 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 and packaging 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 and comparable requirements of foreign regulatory bodies. There are a limited number of manufacturers that operate under these current good manufacturing practices regulations who are both capable

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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 recalls of product, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business. For example, our NDA approved by the FDA had only one supplier of API for Vascepa, Nisshin, and Nisshin plans to expand it capacity to supply API to us by further expanding their current facility. If we are not able to manufacture Vascepa to required specifications through Nisshin, 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 approval of the manufacturing process and procedures in accordance with the FDA s current good manufacturing practices, or 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. This review may be costly and time consuming and could delay or prevent the launch of a product. For example, in December 2012, we filed two supplemental NDAs to add new manufacturing facilities for each of BASF and Chemport, and have plans to file another for Slanmhor, to manufacture API for Vascepa. If these third parties cannot establish, to the satisfaction of the FDA, that they are in substantial compliance with cGMPs, and that the products manufactured at the new site meet FDA requirements, we may not be able to manufacture API from that site, our supply of API for Vascepa may be delayed, and our anticipated future revenues and financial results may be materially adversely affected.

Furthermore, the FDA and foreign regulatory agencies require that we be able to consistently produce the active pharmaceutical ingredient and the finished product in commercial quantities and of specified quality on a repeated basis, including proven product stability, and document our ability to do so. This requirement is referred to as process validation. We have not yet completed all of the steps and documentation necessary to validate the process for API manufacturing for Vascepa at any API contract supplier other than Nisshin. Each of our potential API suppliers uses a different method to manufacture API than that used by Nisshin, which has the potential to increase the risk to us that our manufacturers will not meet applicable regulatory requirements. 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 standards, or change their interpretation and enforcement of existing standards and requirements, for manufacture, packaging or testing of products at any time. If we are unable to comply, we may be subject to regulatory, civil actions or penalties which could significantly and adversely affect our business.

During 2013, we are increasing our purchases of API and finished capsules of Vascepa to further expand purchase levels of supply. We may elect to make API purchases from certain of our suppliers after we are satisfied that the material they produce and their facilities are qualified. However, in the event that we make such purchases from other suppliers, we will not be able to use such material for commercial sale until the sNDA for the applicable supplier is approved by the FDA. Similarly, if we are not compliant with other regulations with regard to this intended purchase of supply, our reaching profitability may be delayed.

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

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in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with standards, commonly referred to as good clinical practices, for conducting, recording, and reporting the results of clinical trials to assure 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 and Regulatory Exclusivity

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

Because of the significant time and expense involved in developing new products and obtaining regulatory approvals, it is very important to obtain patent and preserve trade secret protection for new technologies, products and processes. Our ability to successfully implement our business plan 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.

As of the date of this Annual Report, we have announced that 18 patent applications in the United States have been either issued or allowed and more than 30 additional patent applications are pending in the United States. Of such 18 allowed and issued applications, we currently have 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 highly pure EPA which expires in 2021, eight additional U.S. patents covering the use of Vascepa and potentially competitive products in either the MARINE or anticipated ANCHOR indication that have terms that expire in 2030, and have announced Notices of Allowance from the United States Patent and Trademark Office, or USPTO, for seven additional patent applications that have terms that expire in 2030 and are related to the use of Vascepa and potentially competitive products in either the MARINE or anticipated ANCHOR indication. 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 our issued patents and our pending patents, if and when issued, will prevent competitors from competing with Vascepa.

We are also pursuing patent applications related to Vascepa in multiple jurisdictions outside the United States, including an application for our MARINE method of use patent in Europe for which we received an Intention to Grant letter from the European Patent Office. 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. 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 go 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,

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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 upon 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, even if the opposition or challenge has little or no merit. Patent opposition proceedings and challenges are generally highly technical, time consuming and expensive to pursue. Were we to be subject to one or more patent oppositions or challenges, that effort could consume substantial time and resources, with no assurances of success, even when holding an issued patent.

Our issued patents and our pending patents, if and when issued, may not prevent competitors from competing with Vascepa.

We plan to vigorously defend our rights under issued patents. Other drug companies may challenge the validity, enforceability or both of the 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. 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 and ANCHOR trials. If granted, many of the resulting granted patents would expire in 2030 or beyond. However, no assurance can be given that any of our pending patent applications 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

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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 supplemental NDA 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. Providing such additional evidence 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.

If Vascepa is not granted new chemical entity exclusivity protection from the FDA our business may be materially harmed.

Under Sections 505(c)(3)(E)(ii) and 505(j)(5)(F)(ii) of the Food Drug and Cosmetic Act, or FDCA, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, as amended, or the Hatch-Waxman Amendments, a drug that is granted regulatory approval may be eligible for five years of marketing exclusivity in the United States following regulatory approval if that drug is classified as a new chemical entity, or NCE. A drug can be classified as a NCE if the FDA has not previously approved any other drug containing the same active moiety.

The FDA typically publishes a determination on the marketing exclusivity of recently approved products in a cumulative supplement to its Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the Orange Book, mid-month in the month following the drug s approval. Vascepa was approved by the FDA in July 2012, but we have not yet been informed of a determination by the FDA on our pending exclusivity request for Vascepa. Since prior to FDA approval of the Vascepa new drug application, we have had an active dialogue with the FDA related to our marketing exclusivity request for Vascepa, which requested NCE status for Vascepa. In recent months, we have repeatedly followed up with the FDA seeking a determination. While we continue to believe our arguments in support of an NCE determination for Vascepa are strong, the FDA may not agree with our arguments. Based on our discussions with the FDA, we have not been told and do not know what determination the FDA will reach regarding the pending exclusivity request for Vascepa or when the FDA will make such determination. Based on our communications with the FDA, we cannot make a reliable prediction as to when the FDA will communicate a determination on the matter. There can be no assurance that Vascepa will be granted NCE exclusivity, or that the FDA will make a determination on the pending exclusivity request in a timely manner.

NCE marketing exclusivity, if granted, would preclude approval during the five-year exclusivity period of certain 505(b)(2) applications or certain abbreviated new drug applications submitted by another company for another version of the drug. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement. In this case, Amarin may be afforded the benefit of a 30-month stay against the launch of such a competitive product that would extend from the end of the five-year exclusivity period, and may also be afforded other extensions under applicable regulations, including a six-month pediatric exclusivity extension or a judicial extension if applicable requirements are met. If we are not able to gain or exploit the period of marketing exclusivity, we may face significant competitive threats to our commercialization of these compounds from other manufacturers, including the manufacturers of generic alternatives. Further, even if Vascepa is considered to be a NCE and we are able to gain five-year marketing exclusivity, another company could challenge that decision to seek to overturn FDA s determination. Another company could also gain such marketing exclusivity under the provisions of the FDCA, as amended by the Hatch-Waxman Amendments, if such company can, under certain circumstances, complete a human clinical trial process and obtain regulatory approval of its product.

If Vascepa is not granted NCE marketing exclusivity, we expect it will be granted three years of new product exclusivity under the Hatch-Waxman Amendments. Such exclusivity protection would preclude the FDA from approving a marketing applics required to apply its judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Changes in Internal Controls Over Financial Reporting.

In evaluating whether there were any reportable changes in our internal control over financial reporting during the quarter ended December 31, 2016, we determined that, other than the changes described above under “Remediation Efforts to Address Material Weaknesses”, there were no changes in internal control over financial reporting during the quarter ended December 31, 2016 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. However, we do anticipate further changes will be implemented to remedy the material weaknesses identified above.

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PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this item will be included in our definitive proxy statement with respect to our 2017 Annual Meeting of Stockholders to be filed with the SEC and is incorporated herein by reference as it appears under the headings, “Proposal 1: Election of Directors”, “Directors and Executive Officers”, “Section 16(a) Beneficial Ownership Reporting Compliance”, “Corporate Governance – Code of Business Conduct and Ethics” and “Corporate Governance – Committees – Audit Committee”.

Item 11. Executive Compensation.

The information required by this item will be included in our definitive proxy statement with respect to our 2017 Annual Meeting of Stockholders to be filed with the SEC and is incorporated herein by reference as it appears under the headings, “Director Compensation” and “Executive Compensation”.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this item will be included in our definitive proxy statement with respect to our 2017 Annual Meeting of Stockholders to be filed with the SEC and is incorporated herein by reference as it appears under the headings, “Executive Compensation – Equity Compensation Plan Information” and “Security Ownership of Certain Beneficial Owners and Management”.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this item will be included in our definitive proxy statement with respect to our 2017 Annual Meeting of Stockholders to be filed with the SEC and is incorporated herein by reference as it appears under the headings, “Transactions with Related Persons” and “Corporate Governance – Director Independence”.

Item 14. Principal Accounting Fees and Services.

The information required by this item will be included in our definitive proxy statement with respect to our 2017 Annual Meeting of Stockholders to be filed with the SEC and is incorporated herein by reference as it appears under the heading, “Principal Accounting Fees and Services”.

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PART IV

Item 15. Exhibits and Financial Statement Schedules

(a) Documents filed as a part of this Annual Report

1. Financial Statements:

Report of Independent Registered Public Accounting Firm	34
Consolidated Balance Sheets at December 31, 2016 and 2015	35
Consolidated Statements of Operations for the years ended December 31, 2016 and 2015	36
Consolidated Statements of Comprehensive Income (Loss) for the years ended December 31, 2016 and 2015	37
Consolidated Statements of Changes in Shareholders' Equity for the years ended December 31, 2016 and 2015	38
Consolidated Statements of Cash Flows for the years ended December 31, 2016 and 2015	39
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2. Financial Statement Schedules. Schedules are omitted because they are not required under the applicable accounting regulations of the SEC.

(b) Exhibits

The information required by the Item is set forth in the Exhibit Index that follows the signature page of this Annual Report.

Item 16. Form 10-K Summary.

None

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Report of Independent Registered Public Accounting Firm

The Board of Directors and Shareholders
PAR Technology Corporation
New Hartford, New York

We have audited the accompanying consolidated balance sheets of PAR Technology Corporation and subsidiaries (the "Company") as of December 31, 2016, and 2015, and the related consolidated statements of operations, comprehensive loss, changes in shareholders' equity, and cash flow for each of the years then ended. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of PAR Technology Corporation and subsidiaries at December 31, 2016 and 2015, and the results of their operations and their cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

/s/ BDO USA, LLP

New York, New York
April 17, 2017

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PAR TECHNOLOGY CORPORATION
CONSOLIDATED BALANCE SHEETS
(in thousands, except share amounts)

Assets	December 31, 2016	December 31, 2015
Current assets:		
Cash and cash equivalents	$ 9,055	$ 8,024
Accounts receivable-net	30,705	29,530
Inventories-net	26,237	21,499
Note receivable	3,510	-
Income taxes receivable	261	-
Deferred income taxes	7,767	6,741
Other current assets	4,027	3,431
Assets of discontinued operations	462	377
Total current assets	82,024	69,602
Property, plant and equipment - net	7,035	5,716
Note receivable	-	4,259
Deferred income taxes	9,650	11,038
Goodwill	11,051	11,051
Intangible assets - net	10,966	10,898
Other assets	3,785	3,687
Total Assets	$ 124,511	$ 116,251
Liabilities and Shareholders' Equity		
Current liabilities:		
Current portion of long-term debt	$ 187	$ 2,103
Accounts payable	16,687	11,729
Accrued salaries and benefits	5,470	5,727
Accrued expenses	4,682	7,644
Customer deposits and deferred service revenue	19,814	10,819
Income taxes payable	-	279
Liabilities of discontinued operations	-	441
Total current liabilities	46,840	38,742
Long-term debt	379	566
Other long-term liabilities	7,712	8,883
Total liabilities	54,931	48,191
Commitments and contingencies		
Shareholders' Equity:		
Preferred stock, $.02 par value, 1,000,000 shares authorized	-	-
Common stock, $.02 par value, 29,000,000 shares authorized; 17,479,454 and 17,352,838 shares issued; 15,771,345 and 15,644,729 outstanding at December 31, 2016 and December 31, 2015, respectively	350	347
Capital in excess of par value	46,203	45,753
Retained earnings	32,357	30,574
Accumulated other comprehensive loss	(3,494)	(2,778)
Treasury stock, at cost, 1,708,109 shares	(5,836)	(5,836)
Total shareholders' equity	69,580	68,060
Total Liabilities and Shareholders' Equity	$ 124,511	$ 116,251

See accompanying Notes to Consolidated Financial Statements

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PAR TECHNOLOGY CORPORATION
CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share amounts)

	Year ended December 31,	
	2016	2015
Net revenues:		
Product	$ 100,271	$ 94,397
Service	49,070	46,754
Contract	80,312	87,852
	229,653	229,003
Costs of sales:		
Product	73,976	68,223
Service	35,647	33,875
Contract	73,830	81,848
	183,453	183,946
Gross margin	46,200	45,057
Operating expenses:		
Selling, general and administrative	31,440	27,374
Research and development	11,581	10,067
Amortization of identifiable intangible assets	966	987
	43,987	38,428
Operating income from continuing operations	2,213	6,629
Other income (expense), net	1,316	(800)
Interest income (expense)	121	(308)
Income from continuing operations before provision for income taxes	3,650	5,521
Provision for income taxes	(1,147)	(1,500)
Income from continuing operations	2,503	4,021
Discontinued operations		
Loss on discontinued operations (net of tax)	(720)	(4,912)
Net income (loss)	$ 1,783	$ (891)
Basic Earnings per Share:		
Income from continuing operations	0.16	0.26
Loss from discontinued operations	(0.05)	(0.32)
Net income (loss)	$ 0.11	$ (0.06)
Diluted Earnings per Share:		
Income from continuing operations	0.16	0.26
Loss from discontinued operations	(0.05)	(0.32)
Net income (loss)	$ 0.11	$ (0.06)
Weighted average shares outstanding		
Basic	15,675	15,562
Diluted	15,738	15,666

See accompanying Notes to Consolidated Financial Statements

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PAR TECHNOLOGY CORPORATION
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)
(in thousands)

	Year ended December 31,	
	2016	2015
Net income (Loss)	$ 1,783	$ (891)
Other comprehensive loss net of applicable tax:		
Foreign currency translation adjustments	(716)	(1,462)
Comprehensive income (Loss)	$ 1,067	$ (2,353)

See accompanying Notes to Consolidated Financial Statements

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PAR TECHNOLOGY CORPORATION
CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY
(in thousands)

(in thousands)	Common Stock Shares	Common Stock Amount	Capital in excess of Par Value	Retained Earnings	Accumulated Other Comprehensive Loss	Treasury Stock Shares	Treasury Stock Amount	Total Shareholders' Equity
Balances at December 31, 2014	17,275	$ 346	$ 44,854	$ 31,465	$ (1,316)	(1,708)	$ (5,836)	$ 69,513
Net loss				(891)				(891)
Issuance of common stock upon the exercise of stock options	94	2	472					474
Net issuance of restricted stock awards	(17)	(1)						(1)
Equity based compensation	-	-	487					487
Stock options and awards tax benefits			(60)					(60)
Translation adjustments, net of tax of $476					(1,462)			(1,462)
Balances at December 31, 2015	17,352	$ 347	$ 45,753	$ 30,574	$ (2,778)	(1,708)	$ (5,836)	$ 68,060
Net income				1,783				1,783
Issuance of common stock upon the exercise of stock options	5	1	26					27
Net issuance of restricted stock awards	122	2						2
Equity based compensation			469					469
Stock options and awards tax benefits			(45)					(45)
Translation adjustments, net of tax of $944					(716)			(716)
Balances at December 31, 2016	17,479	$ 350	$ 46,203	$ 32,357	$ (3,494)	(1,708)	$ (5,836)	$ 69,580

See accompanying Notes to Consolidated Financial Statements

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PAR TECHNOLOGY CORPORATION
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Year ended December 31,	
	2016	2015
Cash flows from operating activities:		
Net income (Loss)	$ 1,783	$ (891)
Loss from discontinued operations	720	4,912
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:		
Insurance (recovery) loss on investment	(771)	776
Depreciation, amortization, and accretion	4,624	3,070
Provision for bad debts	401	772
Provision for obsolete inventory	1,249	1,293
Equity based compensation	469	487
Change in fair value of contingent consideration	(1,130)	90
Deferred income tax	708	(1,910)
Changes in operating assets and liabilities, net of acquisitions:		
Accounts receivable	(1,576)	(628)
Inventories	(5,987)	3,136
Income tax receivable/(payable)	(540)	(196)
Other current assets	(248)	587
Other assets	(194)	(644)
Accounts payable	4,958	(7,529)
Accrued expenses	(2,023)	214
Customer deposits	9,032	(1,062)
Deferred service revenue	(37)	251
Other long-term liabilities	(41)	(54)
Deferred tax equity based compensation	(45)	(60)
Net cash provided by operating activities-continuing operations	11,352	2,614
Net cash used in operating activities-discontinued operations	(356)	(2,020)
Net cash provided by operating activities	10,996	594
Cash flows from investing activities:		
Capital expenditures	(3,433)	(1,705)
Capitalization of software costs	(2,685)	(2,148)
Investment expenditure	-	(776)
Proceeds from sale of business	-	12,100
Working capital adjustment paid	(977)	-
Net cash (used in) provided by investing activities-continuing operations	(7,095)	7,471
Net cash used in investing activities-discontinued operations	-	(1,046)
Net cash (used in) provided by investing activities	(7,095)	6,425
Cash flows from financing activities:		
Payments of long-term debt	(181)	(173)
Payments of other borrowings	(214,980)	(222,156)
Proceeds from other borrowings	214,980	217,156
Payments for deferred acquisition obligations	(2,000)	(3,000)
Proceeds from stock awards	27	473
Net cash used in financing activities	(2,154)	(7,700)
Effect of exchange rate changes on cash and cash equivalents	(716)	(1,462)
Net increase (decrease) in cash and cash equivalents	1,031	(2,143)

Cash and cash equivalents at beginning of period	8,024	10,167
Cash and cash equivalents at end of period	9,055	8,024
Less cash and cash equivalents of discontinued operations at end of period	-	-
Cash and cash equivalents of continuing operations at end of period	$ 9,055	$ 8,024
Supplemental disclosures of cash flow information:		
Cash paid during the period for:		
Interest	$ 94	$ 206
Income taxes, net of refunds	$ 714	$ 310
Supplemental disclosures of non-cash information:		
Sale of business through note receivable	$	$ 4,259

See accompanying Notes to Consolidated Financial Statements

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 1 — Summary of Significant Accounting Policies

Basis of consolidation

The consolidated financial statements include the accounts of PAR Technology Corporation and its subsidiaries (ParTech, Inc., ParTech (Shanghai) Company Ltd., PAR Springer-Miller Systems, Inc., Springer-Miller Canada, ULC, PAR Canada ULC, Brink Software, Inc., PAR Government Systems Corporation and Rome Research Corporation), collectively referred to as the "Company." All significant intercompany transactions have been eliminated in consolidation.

During fiscal year 2015, the Company entered into an asset purchase agreement to sell substantially all of the assets of our Hotel/Spa technology business operated under PAR Springer-Miller Systems, Inc. ("PSMS"). The transaction closed on November 4, 2015. Accordingly, the results of operations of PSMS have been classified as discontinued operations in accordance with Accounting Standards Codification ("ASC") 205-20, Presentation of Financial Statements – Discontinued Operations. All prior period amounts have been reclassified to conform to the current period presentation. See Note 2 – Divestiture and Discontinued Operations - in the Notes to Consolidated Financial Statements for further discussion.

Business combinations

The Company accounts for business combinations pursuant ASC 805, Business Combinations, which requires that assets acquired and liabilities assumed be recorded at their respective fair values on the date of acquisition. The fair value of the consideration paid is assigned to the underlying net assets of the acquired business based on their respective fair values. Any excess of the purchase price over the estimated fair values of the net assets acquired is allocated to goodwill (the "Acquisition Method"). The purchase price allocation process requires the Company to make significant assumptions and estimates in determining the purchase price and the assets acquired and liabilities assumed at the acquisition date. The Company's assumptions and estimates are subject to refinement and, as a result, during the measurement period, which may be up to one year from the acquisition date, the Company records adjustments to the assets acquired and liabilities assumed with the corresponding offset to goodwill. Upon conclusion of the measurement period, any subsequent adjustments are recorded to the Company's consolidated statements of operations. The Company's consolidated financial statements and results of operations reflect an acquired business after the completion of the acquisition.

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Contingent Consideration

The Company determines the acquisition date fair value of contingent consideration using a discounted cash flow method, with significant inputs that are not observable in the market and thus represents a Level 3 fair value measurement as defined in ASC Topic 820, Fair Value Measurement. The significant inputs in the Level 3 measurement not supported by market activity included the Company's probability assessments of expected future cash flows related to the Company's acquisition of Brink Software Inc. during the contingent consideration period, appropriately discounted considering the uncertainties associated with the obligation, and calculated in accordance with the terms of the definitive agreement. The liabilities for the contingent consideration are established at the time of the acquisition and will be evaluated on a quarterly basis based on additional information as it becomes available. Any change in the fair value adjustment is recorded in the earnings of that period. During 2016, we recorded a $1.1 million adjustment to decrease the fair value of our contingent consideration related to the acquisition of Brink Software Inc., versus a $0.1 million adjustment to increase the fair value during 2015. This is reflected within other expense on the statement of operations. Changes in the fair value of the contingent consideration obligations may result from changes in probability assumptions with respect to the likelihood of achieving the various contingent payment obligations. Significant increases or decreases in the inputs noted above in isolation would result in a significantly lower or higher fair value measurement.

Revenue recognition policy

Restaurant/Retail Contracts

Our Restaurant/Retail segment's revenues consist of sales of the Company's standard POS system to the Restaurant/Retail segment. We derive revenue from the following sources: (1) hardware sales, (2) software license agreements, including perpetual licenses and software as a service, (3) professional services, (4) hosting services and (5) post-contract customer support ("PCS").

We recognize revenue when all four revenue recognition criteria have been met: persuasive evidence of an arrangement exists, we have delivered the product or performed the service, the fee is fixed or determinable and collection is probable. Determining whether and when some of these criteria have been satisfied often involves assumptions and judgments that can have a significant impact on the timing and amount of revenue we report.

Hardware

Revenue recognition on hardware sales occurs upon delivery to the customer site (or when shipped for systems that are not installed by the Company) when persuasive evidence of an arrangement exists, the price is fixed or determinable, and collectability is reasonably assured.

Software

Revenue recognition on software sales generally occurs upon delivery to the customer, when persuasive evidence of an arrangement exists, the price is fixed or determinable, and collectability is reasonably assured. For software sales sold as a perpetual license, typically our Pixel software offering, where the Company is the sole party that has the proprietary knowledge to install the software, revenue is recognized upon installation and when the system is ready to go live.

Service

Service revenue consists of installation and training services, field and depot repair, subscription software products, associated software maintenance, and software related hosted services. Installation and training service revenue are

based upon standard hourly/daily rates as well as contracted prices with the customer, and revenue is recognized as the services are performed. Support maintenance and field and depot repair are provided to customers either on a time and materials basis or under a maintenance contract. Services provided on a time and materials basis are recognized as the services are performed. Service revenues from maintenance contracts are recorded as deferred revenue when billed to and collected from the customer and are recognized ratably over the underlying contract period. Software sold as a service with our Brink and SureCheck software offerings, is recorded as deferred revenue when billed and collected and recognized ratably over the contract term.

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The Company frequently enters into multiple-element arrangements with our customers including hardware, software, professional consulting services and maintenance support services. For arrangements involving multiple deliverables, when deliverables include software and non-software products and services, we evaluate and separate each deliverable to determine whether it represents a separate unit of accounting based on the following criteria: (a) the delivered item has value to the customer on a stand-alone basis; and (b) if the contract includes a general right of return relative to the delivered item, delivery or performance of the undelivered items is considered probable and substantially in the control of PAR.

Multiple element arrangements which include hardware, service, and software offerings are separated based upon the stand-alone price for each individual hardware, service, or software sold in the arrangement irrespective of the combination of products and services which are included in a particular arrangement. As such, overall consideration is allocated to each unit of accounting based on the unit's relative selling prices. In such circumstances, the Company uses a hierarchy to determine the selling price to be used for allocating revenue to each deliverable: (i) vendor-specific objective evidence of selling price (VSOE), (ii) third-party evidence of selling price (TPE), and (iii) best estimate of selling price (BESP). VSOE generally exists only when the Company sells the deliverable separately and is the price actually charged by the Company for that deliverable. The Company uses BESP to allocate revenue when we are unable to establish VSOE or TPE of selling price. BESP is primarily used for elements such as products that are not consistently priced within a narrow range. The Company determines BESP for a deliverable by considering multiple factors including product and customer class, geography, average discount, and management's historical pricing practices. Amounts allocated to the delivered hardware and software elements are recognized at the time of sale provided the other conditions for revenue recognition have been met. Amounts allocated to the undelivered maintenance and other services elements are recognized as the services are provided or on a straight-line basis over the service period. In certain instances, customer acceptance is required prior to the passage of title and risk of loss of the delivered products. In such cases, revenue is not recognized until the customer acceptance is obtained. Delivery and acceptance generally occur in the same reporting period.

Software elements, generally software PCS, and professional services revenue are recognized in accordance with authoritative guidance on software revenue recognition. For the software and software-related elements of such transactions, revenue is allocated based on the relative fair value of each element, and fair value is determined by vender specific objective evidence, where available. If VSOE is not available for all elements, we will use the residual method to separate the elements as long as we have VSOE for the undelivered elements. If we cannot objectively determine the fair value of any undelivered element included in such multiple-element arrangements, we defer the revenue until all elements are delivered and services have been performed, or until fair value can objectively be determined for any remaining undelivered elements.

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Government Contracts

The Company's contract revenues generated by the Government segment result primarily from contract services performed for the U.S. Government under a variety of cost-plus fixed fee, time-and-material, and fixed-price contracts. Revenue on cost-plus fixed fee contracts is recognized based on allowable costs for labor hours delivered, as well as other allowable costs plus the applicable fee. Revenue on time and material contracts is recognized by multiplying the number of direct labor hours delivered in the performance of the contract by the contract billing rates and adding other direct costs as incurred. Revenue from fixed-price contracts is recognized as labor hours are delivered which approximates the straight-line basis of the life of the contract. The Company's obligation under these contracts is to provide labor hours to conduct research or to staff facilities with no other deliverables or performance obligations. Anticipated losses on all contracts are recorded in full when identified. Unbilled accounts receivable is stated in the Company's consolidated financial statements at their estimated realizable value. Contract costs, including indirect expenses, are subject to audit and adjustment through negotiations between the Company and U.S. Government representatives.

Warranty Provisions

Warranty provisions for product warranties are recorded in the period in which the Company becomes obligated to honor the related right, which generally is the period in which the related product revenue is recognized. The Company accrues warranty reserves based upon historical factors such as labor rates, average repair time, travel time, number of service calls per machine and cost of replacement parts. When a sale is consummated, a warranty reserve is recorded based upon the estimated cost to provide the service over the warranty period.

Cash and cash equivalents

The Company considers all highly liquid investments, purchased with a remaining maturity of three months or less, to be cash equivalents.

Accounts receivable – Allowance for doubtful accounts

Allowances for doubtful accounts are based on estimates of probable losses related to accounts receivable balances. The establishment of allowances requires the use of judgment and assumptions regarding probable losses on receivable balances. The Company continuously monitors collections and payments from our customers and maintain a provision for estimated credit losses based on our historical experience and any specific customer collection issues that we have identified. Thus, if the financial condition of our customers were to deteriorate, our actual losses may exceed our estimates, and additional allowances would be required.

Inventories

The Company's inventories are valued at the lower of cost or market, with cost determined using the first-in, first-out ("FIFO") method. The Company uses certain estimates and judgments and considers several factors including product demand, changes in customer requirements and changes in technology to provide for excess and obsolescence reserves to properly value inventory.

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Property, plant and equipment

Property, plant and equipment are recorded at cost and depreciated using the straight-line method over the estimated useful lives of the assets, which range from three to twenty-five years. Expenditures for maintenance and repairs are expensed as incurred.

Other assets

Other assets primarily consist of cash surrender value of life insurance related to the Company's Deferred Compensation Plan eligible to certain employees. The funded balance is reviewed on an annual basis.

Income taxes

The provision for income taxes is based upon pretax earnings with deferred income taxes provided for the temporary differences between the financial reporting basis and the tax basis of the Company's assets and liabilities. The Company records a valuation allowance when necessary to reduce deferred tax assets to their net realizable amounts. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date.

Other long-term liabilities

Other long-term liabilities represent amounts owed to certain employees who are participants in the Company's Deferred Compensation Plan and the estimated fair value of the contingent consideration payable related to the Brink Software Inc. acquisition. During 2016, we recorded a $1.1 million adjustment to decrease the fair value of our contingent consideration related to the acquisition of Brink Software Inc., versus a $0.1 million adjustment to increase the fair value during 2015. This is reflected within other expense on the statement of operations. Changes in the fair value of the contingent consideration obligations may result from changes in probability assumptions with respect to the likelihood of achieving the various contingent payment obligations.

Foreign currency

The assets and liabilities for the Company's international operations are translated into U.S. dollars using year-end exchange rates. Income statement items are translated at average exchange rates prevailing during the year. The resulting translation adjustments are recorded as a separate component of shareholders' equity under the heading Accumulated Other Comprehensive Income (Loss). Exchange gains and losses on intercompany balances of permanently invested long-term loans are also recorded as a translation adjustment and are included in Accumulated Other Comprehensive Loss. Foreign currency transaction gains and losses are recorded in other income in the accompanying statements of operations.

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Other income (expense)

The components of other (expense) income from continuing operations for the two years ending December 31 are as follows:

	Year ended December 31 (in thousands)	
	2016	2015
Foreign currency loss	$ (24)	$ (193)
Rental (loss) income-net	(662)	264
Insurance recovery / investment write off	771	(776)
Fair value adjustment contingent consideration	1,130	(90)
Other	101	(5)
Income (expense)	$ 1,316	$ (800)

During 2016, we recorded a $1.1 million adjustment to decrease the fair value of its contingent consideration related to the acquisition of Brink Software Inc. In addition, we recorded an insurance recovery of $0.8 million in 2016 relating to the unauthorized transfers of the Company's funds by its former chief financial officer. Also, during 2016, the Company incurred a net loss on rental contracts of approximately $0.7 million. During 2015, the investment write-off of $0.8 million represents the write-off of unauthorized investments that were made in contravention of the Company’s policies and procedures involving the Company’s funds. The unauthorized investments occurred during the period between September 25, 2015 and November 6, 2015.

Identifiable intangible assets

The Company’s identifiable intangible assets represent intangible assets acquired from the Brink Software Inc. acquisition as well as internally developed software costs. The Company capitalizes certain costs related to the development of computer software used in its Restaurant/Retail segment. Software development costs incurred prior to establishing technological feasibility are charged to operations and included in research and development costs. The technological feasibility of a computer software product is established when the Company has completed all planning, designing, coding, and testing activities that are necessary to establish that the product can be produced to meet its design specifications including functions, features, and technical performance requirements. Software development costs incurred after establishing feasibility (as defined within ASC 985-20 for software cost related to sold as a perpetual license and ASC-350-40 for software sold as a service) are capitalized and amortized on a product-by-product basis when the product is available for general release to customers. Software costs capitalized within continuing operations during the periods ended December 31, 2016 and 2015 were $2.7 million and $2.1 million, respectively.

Annual amortization, charged to cost of sales when the product is available for general release to customers, is computed using the greater of (a) the straight-line method over the remaining estimated economic life of the product, generally three to seven years or (b) the ratio that current gross revenues for a product bear to the total of current and anticipated future gross revenues for that product. Amortization of capitalized software costs from continuing operations amounted to $1.1 million and $0.8 million, in 2016 and 2015, respectively. The Company assessed its recoverability of capitalized software assets noting an impairment charge of $0.5 million to accelerate one of its software modules. There was no impairment charge recorded as of December 31, 2015.

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The components of identifiable intangible assets, excluding discontinued operations, are:

	December 31, (in thousands)		
	2016	2015	Estimated Useful Life
Acquired and internally developed software costs	$15,884	$13,702	3 - 7 years
Customer relationships	160	160	7 years
Non-compete agreements	30	30	1 year
	16,074	13,892	
Less accumulated amortization	(5,508)	(3,394)	
	$10,566	$10,498	
Trademarks, trade names (non-amortizable)	400	400	N/A
	$10,966	$10,898	

The expected future amortization of these intangible assets assuming straight-line amortization of capitalized software costs and acquisition related intangibles is as follows (in thousands):

2017	$2,219
2018	2,054
2019	1,616
2020	1,396
2021	1,031
Thereafter	2,250
Total	$10,566

The Company has elected to test for impairment of indefinite lived intangible assets during the fourth quarter of its fiscal year. To value the indefinite lived intangible assets, the Company utilizes the royalty method to estimate the fair values of the trademarks and trade names. During 2016, the Company recorded an impairment charge of $0.5 million to accelerate one of its software modules. There was no impairment charge recorded as of December 31, 2015.

Stock-based compensation

The Company recognizes all stock-based compensation to employees, including grants of employee stock options and restricted stock awards, in the financial statements as compensation cost over the vesting period using an accelerated expense recognition method, based on their fair value on the date of grant.

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Earnings per share

Basic earnings per share are computed based on the weighted average number of common shares outstanding during the period. Diluted earnings per share reflect the dilutive impact of outstanding stock options and restricted stock awards.

The following is a reconciliation of the weighted average shares outstanding for the basic and diluted earnings per share computations (in thousands, except share and per share data):

	December 31,	
	2016	2015
Income from continuing operations	$2,503	$4,021
Basic:		
Shares outstanding at beginning of year	15,645	15,592
Weighted average shares issued (cancelled) during the year, net	30	(30)
Weighted average common shares, basic	15,675	15,562
Income from continuing operations per common share, basic	$0.16	$0.26
Diluted:		
Weighted average common shares, basic	15,675	15,562
Dilutive impact of stock options and restricted stock awards	63	104
Weighted average common shares, diluted	15,738	15,666
Income from continuing operations per common share, diluted	$0.16	$0.26

At December 31, 2016 and 2015 there were 38,000 and 112,000 incremental shares, respectively, from the assumed exercise of stock options that were excluded from the computation of diluted earnings per share because of the anti-dilutive effect on earnings per share. There were no restricted stock awards excluded from the computation of diluted earnings per share for each of the fiscal years ended December 31, 2016 and 2015.

Goodwill

The Company tests goodwill for impairment on an annual basis, which is on the first day of the fourth quarter, or more often if events or circumstances indicate there may be impairment. The Company operates in two reportable operating segments - Restaurant/Retail and Government. Goodwill impairment testing is performed at the sub-segment level (referred to as a reporting unit). The two reporting units utilized by the Company are: Restaurant/Retail, and Government. Goodwill is assigned to reporting units at the date the goodwill is initially recorded. Once goodwill has been assigned to reporting units, it no longer retains its association with a particular acquisition, and all of the activities within a reporting unit, whether acquired or organically grown, are available to support the value of the goodwill. The amount outstanding for goodwill within continuing operations was $11.1 million at December 31, 2016 and 2015. There was no impairment of goodwill for the periods ending December 31, 2016 or 2015.

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Impairment of long-lived assets

The Company evaluates the accounting and reporting for the impairment of long-lived assets in accordance with the reporting requirements of ASC 360-10, Accounting for the Impairment or Disposal of Long-Lived Assets. The Company will recognize impairment of long-lived assets or asset groups if the net book value of such assets exceeds the estimated future undiscounted cash flows attributable to such assets. If the carrying value of a long-lived asset or asset group is considered impaired, a loss is recognized based on the amount by which the carrying value exceeds the fair market value of the long-lived asset or asset group for assets to be held and used, or the amount by which the carrying value exceeds the fair market value less cost to sell for assets to be sold. During 2016, the Company recorded an impairment charge of $0.5 million to accelerate one of its software modules. There was no impairment charge recorded as of December 31, 2015.

Reclassifications

Amounts in prior years' consolidated financial statements are reclassified whenever necessary to conform to the current year's presentation. The results of operations of PSMS have been classified as discontinued operations in accordance with Accounting Standards Codification ("ASC") 205-20, Presentation of Financial Statements – Discontinued Operations. All prior period amounts have been reclassified to conform to the current period presentation. See Note 3 – Discontinued Operations - in the Notes to Consolidated Financial Statements for further discussion.

Use of estimates

The preparation of the consolidated financial statements requires management of the Company to make a number of estimates and assumptions relating to the reported amount of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the period. Significant items subject to such estimates and assumptions include revenue recognition, stock based compensation, the recognition and measurement of assets acquired and liabilities assumed in business combinations at fair value, the carrying amount of property, plant and equipment, identifiable intangible assets and goodwill, valuation allowances for receivables, inventories and deferred income tax assets, and measurement of contingent consideration at fair value. Actual results could differ from those estimates.

Recently Issued Accounting Pronouncements Not Yet Adopted

In March 2016, the Financial Accounting Standards Board (FASB) issued ASU 2016-09 to simplify several aspects of the accounting for employee share-based payment transactions standard, including the classification of excess tax benefits and deficiencies and the accounting for employee forfeitures. The guidance is effective for the Company beginning in the first quarter of 2017 at which time we will adopt. The updates to the accounting standard will include the following:

- Excess tax benefits and deficiencies will no longer be recognized as a change in additional paid-in-capital in the equity section of the balance sheet, instead they are to be recognized in the income statement as a tax expense or benefit. In the statement of cash flows, excess tax benefits and deficiencies will no longer be classified as a financing activity, instead they will be classified as an operating activity. The impact of this change in accounting to future periods cannot be estimated, as it is dependent upon several variables not in control of the Company, such as the future timing and amount of employee option exercises, restricted stock vesting and the Company's future stock price.

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- Entities will have the option to continue to reduce share-based compensation expense during the vesting period of outstanding awards for estimated future employee forfeitures or they may elect to recognize the impact of forfeitures as they actually occur. The Company will continue to reduce the share-based compensation expense during the vesting period of outstanding awards for estimated future forfeitures.

- The ASU also provides new guidance to other areas of the standard including minimum statutory tax withholding rules and the calculation of diluted common shares outstanding.

Adoption approach varies based on the amendment topic and the Company does not expect a significant impact at this time.

In February 2016, the FASB issued ASU 2016-02 impacting the accounting for leases intending to increase transparency and comparability of organizations by requiring balance sheet presentation of leased assets and increased financial statement disclosure of leasing arrangements. The revised standard will require entities to recognize a liability for its lease obligations and a corresponding asset representing the right to use the underlying asset over the lease term. Lease obligations are to be measured at the present value of lease payments and accounted for using the effective interest method. The accounting for the leased asset will differ slightly depending on whether the agreement is deemed to be a financing or operating lease. For finance leases, the leased asset is depreciated on a straight-line basis and recorded separately from the interest expense in the income statement resulting in higher expense in the earlier part of the lease term. For operating leases, the depreciation and interest expense components are combined, recognized evenly over the term of the lease, and presented as a reduction to operating income. The ASU requires that assets and liabilities be presented or disclosed separately and classified appropriately as current and noncurrent. The ASU further requires additional disclosure of certain qualitative and quantitative information related to lease agreements. The new standard is effective for the Company beginning in the first quarter 2019 and early adoption is permitted, although unlikely at this time. We are currently evaluating the impact of these amendments on our financial statements.

In November 2015, the FASB issued new guidance related to the balance sheet classification of deferred taxes. This standard requires an entity to classify all deferred tax assets, along with any valuation allowance, as noncurrent on the balance sheet. As a result, each jurisdiction will have one net noncurrent deferred tax asset or liability. The new standard is effective for the Company for fiscal years beginning after December 15, 2016. The adoption of this standard in Q1 2017, which will be applied prospectively, is not expected to have a material impact on the Company’s consolidated financial statements.

In July 2015, the FASB issued new guidance related to the measurement of inventory. This standard changes the inventory valuation method from the lower of cost or market to the lower of cost or net realizable value for inventory valued under the first-in, first-out or average cost methods. The new standard is effective for the Company beginning in Q1 of 2017, and requires prospective adoption. We do not anticipate the adoption will have a material impact on the Company’s consolidated financial statements.

In August 2014, the FASB issued new guidance related to disclosures around going concern, including management’s responsibility to evaluate whether there is substantial doubt about an entity’s ability to continue as a going concern and to provide related disclosures when conditions or events raise substantial doubt about an entity’s ability to continue as a going concern. The new standard is effective for the Company beginning in Q1 2017, with early adoption permitted although the Company did not early adopt. The impact of adopting this guidance on January 1, 2017 is not expected to have a material impact on our consolidated financial statements.

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In May 2014, the FASB amended the existing accounting standards for revenue recognition. The amendments are based on the principle that revenue should be recognized to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The guidance provides a five-step analysis of transactions to determine when and how revenue is recognized. The guidance also requires enhanced disclosures regarding the nature, amount, timing and uncertainty of revenue and cash flows arising from an entity's contracts with customers. In July 2015, the FASB affirmed its proposal of a one-year deferral of the effective date of the new revenue standard. As a result, the new guidance will be effective for the Company beginning in Q1 2018. The amendments may be applied retrospectively to each prior period presented or with the cumulative effect recognized as of the date of initial application. PAR is currently evaluating the impact of these amendments and plans not to early adopt and to adopt in 2018. In the second quarter of 2017, we will commence a project to assess the potential impact of the new standard on our consolidated financial statements and related disclosures. This project will also include the assessment and enhancement of our internal processes and systems to address the new standard. At this time, we have not yet selected a transition method.

Recently Adopted Accounting Pronouncements

None noted in prior two years.

Note 2 — Divestiture and Discontinued Operations

On November 4, 2015, ParTech, Inc. ("PTI"), a wholly owned subsidiary of PAR Technology Corporation, PAR Springer-Miller Systems, Inc. ("PSMS"), Springer-Miller International, LLC ("SMI"), and Springer-Miller Canada, ULC ("SMC") (PTI, PSMS, SMI and SMC are collectively referred to herein as the "Group"), entered into an asset purchase agreement (the "APA") with Gary Jonas Computing Ltd., SMS Software Holdings LLC, and Jonas Computing (UK) Ltd. (the "Purchasers"), each of which is an affiliate of the Jonas Software Group of Constellation Software Inc. of Toronto, Ontario, for the sale of substantially all of the assets of PSMS. Total consideration to be received from the sale is $16.6 million in cash (the "Base Purchase Price"), with $12.1 million received at the time of closing, and $4.5 million receivable eighteen months after the closing date, a portion of which amount will be available to pay certain indemnification obligations of the group, and/or adjusted based on the net tangible asset calculation, as defined in the APA The estimated fair value of the remaining portion of the note receivable, less any estimated working capital adjustments, due on May 4, 2017 is approximately $3.5 million and is included within current assets in the Company consolidated balance sheets. During 2016, the Company reduced the receivable by $0.9 million based on the terms of the net tangible asset calculation as the working capital shortfall was greater than previously estimated.

In addition to the base purchase price, contingent consideration of up to $1.5 million could be received by the Company based on achievement of certain agreed-upon revenue and earnings targets for calendar years 2016 through 2018, as set forth in the APA. As of December 31, 2016, the Company has not recorded any amount associated with this contingent consideration as we do not believe achievement of the related targets is probable.

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Summarized financial information for the Company's discontinued operations is as follows (in thousands):

	December 31, (in thousands)	
	2016	2015
Assets		
Other current assets	$ 462	$ 377
Assets of discontinued operation	$ 462	$ 377
Liabilities		
Accrued salaries and benefits	$ -	$ 441
Liabilities of discontinued operation	$ -	$ 441

Summarized financial information for the Company's discontinued operations is as follows (in thousands):

	December 31, (in thousands)	
	2016	2015
Total revenues	$-	$14,545
Loss from discontinued operations before income taxes	$(1,131)	$(5,702)
Loss on disposition	-	(2,408)
Benefit from income taxes	411	3,198
Loss from discontinued operations, net of taxes	$(720)	$(4,912)

During 2016, the Company recognized a loss on discontinued operations of $0.7 million (net of tax) mainly due to a reduction of the note receivable of $0.6 million (net of tax) and $0.1 million (net of tax) adjustment due to a loss on foreign currency exposure. The reduction of the note receivable is reflected in the Company's earnings for 2016 and will reduce the amount the Company aniticipates collecting on May 4, 2017 to $3.5 million.

In addition to the adjustments above, the Company paid a $1.0 million working capital adjustment, of which $0.9 million was included in accrued expenses at December 31, 2015, that resulted in a loss (net of tax) of $26,000. The working capital payment was estimated and paid as it was defined in the Springer-Miller APA.

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Note 3 — Accounts Receivable, net

The Company's net accounts receivable consists of, excluding discontinued operations:

	December 31, (in thousands)	
	2015	2015
Government segment:		
Billed	$6,779	$9,400
Advanced billings	(1,599)	(1,266)
	5,180	8,134
Hospitality segment:		
Accounts receivable - net	25,525	21,396
	$30,705	$29,530

At December 31, 2016 and 2015, the Company had recorded allowances for doubtful accounts of $0.9 million and $0.9 million, respectively, against Restaurant/Retail segment accounts receivable. Write-offs of accounts receivable during fiscal years 2016 and 2015 were $0.3 million and $0.4 million, respectively. The provision for doubtful accounts recorded in the consolidated statements of operations was $0.4 million and $0.8 million in 2016 and 2015, respectively.

Note 4 — Inventories, net

Inventories are used in the manufacture and service of Restaurant/Retail products. The components of inventory, net consist of the following, excluding discontinued operations:

	December 31, (in thousands)	
	2016	2015
Finished Goods	$9,423	$8,775
Work in process	443	402
Component parts	10,386	5,068
Service parts	5,985	7,254
	$26,237	$21,499

At December 31, 2016 and December 31, 2015, the Company had recorded inventory reserves of $9.2 million and $8.8 million, respectively, against Restaurant/Retail inventories, which relates primarily to service parts.

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Note 5 — Property, Plant and Equipment

The components of property, plant and equipment, excluding discontinued operations, are:

	December 31, (in thousands)	
	2016	2015
Land	$253	$253
Building and improvements	5,816	5,645
Rental property	5,345	5,330
Furniture and equipment	13,890	11,804
	25,304	23,032
Less accumulated depreciation	(18,269)	(17,316)
	$7,035	$5,716

The estimated useful lives of buildings and improvements and rental property are twenty to twenty-five years. The estimated useful lives of furniture and equipment range from three to eight years. Depreciation expense from continuing operations was $2.1 million and $1.1 million for 2016 and 2015, respectively.

The Company leases a portion of its headquarters facility to various tenants. Net rent received from these leases totaled $0.3 million and $0.3 million for 2016 and 2015, respectively. Future minimum rent payments due to the Company under these lease arrangements are approximately $0.2 million, and $0.1 million 2017 and 2018, respectively.

The Company leases office space under various operating leases. Rental expense from continuing operations on operating leases was approximately $1.6 million and $1.4 million for 2016 and 2015, respectively. Future minimum lease payments under all non-cancelable operating leases are (in thousands):

2017	1,360
2018	1,109
2019	895
2020	328
2021	208
Thereafter	503
	$4,403

Note 6 — Debt

On November 29, 2016, the Company entered into a Credit Agreement (the “Credit Agreement”) by and among the Company, as the Borrower thereunder, together with certain of the Company’s US subsidiaries, as “Loan Guarantors” (together with the Company, the “Loan Parties”), and JPMorgan Chase Bank, N.A., as the “Lender”. The Credit Agreement provides for revolving loans in an aggregate principal amount of up to $15.0 million to be made available to the Company; availability at any time being equal to the lesser of (i) $15.0 million and (ii) a borrowing base (equal to the sum of 80% eligible accounts, 50% eligible raw materials inventory and 35% eligible finished goods inventory, with no more than 50% of total eligible inventory included in the borrowing base), less the aggregate principal amount outstanding (the “Credit Facility”). Interest accrues on outstanding principal balances at an applicable rate per annum determined, as of the end of each fiscal quarter of the Company, by reference to the CBFR Spread or the Eurodollar Spread based on the Company’s consolidated indebtedness ratio as at the determination date. The Credit Facility replaces the Company’s asset-based credit agreement dated September 9, 2014 with JPMorgan Chase, N.A. (the “2014 ABL Credit Agreement”) and a portion of the proceeds of the Credit Facility were used to pay-off all indebtedness

outstanding under the Company's 2014 ABL Credit Agreement.

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The Credit Facility matures three (3) years from the date of the Credit Agreement and is guaranteed by the Loan Guarantors. The Credit Facility is secured by substantially all of the assets of the Company and of the other Loan Parties; provided, that the Credit Facility is not secured by any liens on more than 65% of the voting stock of the Company's foreign subsidiaries. The Credit Agreement contains representations and warranties and affirmative and negative covenants that are usual and customary, including representations, warranties and covenants that, among other things, restrict the ability of the Company and its subsidiaries to incur additional indebtedness, incur or permit to exist liens on assets, make investments, loans, advances, guarantees and acquisitions, consolidate or merge with or into any other company, engage in asset sales and pay dividends and make distributions. The Credit Agreement requires that the Company's consolidated indebtedness ratio at the end of each of its fiscal quarters to be greater than 3.0 to 1.0 and maintain a fixed charge coverage ratio of not less than 1.15 to 1.0 for the Company's fiscal quarter ending December 31, 2016 (to be tested only in the event the Company's total consolidated indebtedness equaled or exceeded $5.0 million at the end of such fiscal quarter) and 1.25 to 1.0 for the quarter ending March 31, 2017 and each quarter thereafter. Obligations under the Credit Agreement may be accelerated upon certain customary events of default (subject to grace periods, as appropriate), including among others: nonpayment of principal, interest or fees; breach of the affirmative or negative covenants; breach of the representations or warranties in any material respect; event of default under, or acceleration of, other material indebtedness; bankruptcy or insolvency; material judgments entered against the Company or any of its subsidiaries; invalidity or unenforceability of any collateral documentation associated with the Credit Facility; and a change of control of the Company there was no outstanding balance on the line of credit at December 31, 2016. The Company was in compliance with these covenants as of December 31, 2016.

In addition to the Credit Facility, the Company has a mortgage loan, collateralized by certain real estate, with a balance of $0.6 million and $0.7 million as of December 31, 2016 and 2015, respectively. This mortgage matures on November 1, 2019. The Company's interest rate is fixed at 4.00% through the maturity date of the loan. The annual mortgage payment including interest through November 1, 2019 totals $0.2 million.

In connection with the acquisition of Brink Software on September 18, 2014, the Company recorded indebtedness to the former owners of Brink under the stock purchase agreement. As of December 31, 2016 and 2015, the principal balance of the note payable was zero and $2.0 million and it had a carrying value of zero and $4.8 million, respectively. The carrying value was based on the note's estimated fair value at the time of acquisition. The note did not bear interest and repayment terms are $3.0 million, which was paid on the first anniversary of close, September 18, 2015, and $2.0 million payable on the second anniversary of close, which was paid in September 2016.

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The Company's future principal payments under the stock purchase agreement and our mortgage are as follows (in thousands):

	Total	Less Than 1 Year	1-3 Years	3 - 5 Years	More than 5 Years
Debt obligations	$566	$187	$ 379	$ -	$ -
Operating lease	4,403	1,360	2,004	536	503
Total	$4,969	$1,547	$ 2,383	$536	$ 503

Note 7 — Stock Based Compensation

The Company recognizes all stock-based compensation to employees and directors, including grants of employee stock options and restricted stock awards, in the financial statements as compensation cost over the vesting period based on their fair value on the date of grant. Total stock-based compensation expense included in selling, general and administrative expense in 2016 and 2015 was $0.5 million and $0.5 million, respectively. The amount recorded for the twelve months ended December 31, 2016 and 2015 was recorded net of benefits of $0.3 million and $0.2 million, as the result of forfeitures of unvested stock awards prior to the completion of the requisite service period. The amount of total stock based compensation includes $0.1 million and $0.2 million in 2016 and 2015, respectively, relating to restricted stock awards. No compensation expense has been capitalized during 2016 and 2015.

The Company has reserved 1.0 million shares under its 2015 Equity Incentive Plan ("EIP"). Stock options under this Plan may be incentive stock options or nonqualified stock options. The Plan also provides for restricted stock awards, including performance based awards. Stock options are nontransferable other than upon death. Option grants generally vest over a one to three year period after the grant and typically expire ten years after the date of the grant. The EIP provides for the grant of several different forms of stock-based compensation, including stock options to purchase shares of PAR common stock. The Compensation Committee of the Board of Directors (Compensation Committee) has discretion to determine the material terms and conditions of option awards under the EIP, provided that (i) the exercise price must be no less than the fair market value of PAR common stock (defined as the closing price) on the date of grant, (ii) the term must be no longer than ten years, and (iii) in no event shall the normal vesting schedule provide for vesting in less than one year. Other terms and conditions of an award of stock options will be determined by the Compensation Committee as set forth in the agreement relating to that award. The Compensation Committee has authority to administer the EIP.

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Information with respect to stock options included within this plan is as follows:

	No. of Shares (in thousands)	Weighted Average Exercise Price	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2015	933	$ 5.14	$ 1,579
Options granted	133	5.48	
Options exercised	(5)	5.32	
Forfeited and cancelled	(82)	4.85	
Expired	(30)	4.63	
Outstanding at December 31, 2016	949	$ 5.22	$ 264
Vested and expected to vest at December 31, 2016	1,062	$ 5.26	$ 260
Total shares exercisable as of December 31, 2016	397	$ 5.22	$ 111
Shares remaining available for grant	701		

The weighted average grant date fair value of options granted during the years 2016 and 2015 was $1.81 and $1.44, respectively. The total intrinsic value of options exercised during the year ended December 31, 2016 was $5,800. The total intrinsic value of options exercised during the year ended December 31, 2015 was $119,000. New shares of the Company's common stock are issued as a result of stock option exercises in 2016 and for options exercised in 2015. The fair value of options at the date of the grant was estimated using the Black-Scholes model with the following assumptions for the respective period ending December 31:

	2016		2015	
Expected option life	5.7 years		5.1 years	
Weighted average risk-free interest rate	1.3	%	1.6	%
Weighted average expected volatility	33	%	30	%
Expected dividend yield	0	%	0	%

For the years ended December 31, 2016 and 2015, the expected option life was based on the Company's historical experience with similar type options. Expected volatility is based on historical volatility levels of the Company's common stock over the preceding period of time consistent with the expected life. The risk-free interest rate is based on the implied yield currently available on U.S. Treasury zero coupon issues with a remaining term equal to the expected life. Stock options outstanding at December 31, 2016 are summarized as follows:

Range of Exercise Prices	Number Outstanding (in thousands)	Weighted Average Remaining Life	Weighted Average Exercise Price
$4.72 - $7.08	1,082	7.52 years	$ 5.26

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At December 31, 2016, the aggregate unrecognized compensation cost of unvested equity awards, as determined using a Black-Scholes option valuation model, was $0.5 million (net of estimated forfeitures) which is expected to be recognized as compensation expense in fiscal years 2017 through 2019. The Company has not paid cash dividends on its common stock, and the Company presently intends to continue to retain earnings for reinvestment in growth opportunities. Accordingly, it is anticipated no cash dividends will be paid in the foreseeable future.

Current year activity with respect to the Company's non-vested restricted stock awards is as follows:

Non-vested restricted stock awards (in thousands)	Shares	Weighted Average grant-date fair value
Balance at January 1, 2016	85	$ 5.13
Granted	168	5.23
Vested	(44)	4.94
Forfeited and cancelled	(46)	5.31
Balance at December 31, 2016	163	$ 5.22

The EIP also provides for the issuance of restricted stock, as well as restricted stock units. These types of awards can have either service based or performance based vesting with performance goals being established by the Compensation Committee. Grants of restricted stock with service based vesting are subject to vesting periods ranging from 1 to 3 years. Grants of restricted stock with performance based vesting are subject to a vesting period of 1 to 3 years and performance conditions as defined by the Compensation Committee. The Company assesses the likelihood of achievement throughout the performance period and recognizes compensation expense associated with its performance awards based on this assessment. Other terms and conditions applicable to any award of restricted stock will be determined by the Compensation Committee and set forth in the agreement relating to that award.

During 2016 and 2015, the Company issued 168,000 and 34,000 restricted stock awards, respectively, at a per share price of $0.02. For the periods ended December 31, 2016 and 2015, the Company recognized compensation expense related to the performance awards based on its estimate of the probability of achievement in accordance with ASC Topic 718.

The fair value of restricted stock awards is based on the average price of the Company's common stock on the date of grant. The weighted average grant date fair value of restricted stock awards granted during the years 2016 and 2015 was $5.23 and $4.67, respectively. In accordance with the terms of the restricted stock award agreements, the Company released 85,000 and 110,000 shares during 2016 and 2015, respectively. During 2016, there were approximately 46,000 shares of restricted stock cancelled, of which 45,000 were performance based restricted shares. During 2015, there were 112,000 shares of restricted stock cancelled, of which 102,000 were performance based restricted shares.

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Note 8 — Income Taxes

The provision for income taxes from continuing operations consists of:

	Year ended December 31, (in thousands)	
	2016	2015
Current income tax:		
Federal	$ 61	$ 221
State	167	141
Foreign	211	267
	439	629
Deferred income tax:		
Federal	768	816
State	(60)	55
	708	871
Provision for income taxes	$ 1,147	$ 1,500

The deferred tax benefit related to discontinued operations was $0.4 million in fiscal year 2016 and $3.2 million recorded in fiscal year 2015.

Deferred tax liabilities (assets) are comprised of the following at:

	December 31, (in thousands)	
	2016	2015
Deferred tax liabilities:		
Software development costs	$2,223	$1,841
Acquired intangible assets	1,731	2,088
Gross deferred tax liabilities	3,954	3,929
Allowances for bad debts and inventory	(4,505)	(4,804)
Capitalized inventory costs	(104)	(75)
Intangible assets	(1,388)	(1,747)
Employee benefit accruals	(2,089)	(2,050)
Federal net operating loss carryforward	(5,820)	(6,215)
State net operating loss carryforward	(1,085)	(1,111)
Tax credit carryforwards	(6,888)	(8,760)
Foreign currency	(33)	(33)
Other	(1,333)	(334)
Gross deferred tax assets	(23,245)	(25,129)
Less valuation allowance	1,874	3,421
Net deferred tax assets	$(17,417)	$(17,779)

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The Company has Federal tax credit carryforwards of $6.7 million that expire in various tax years from 2017 to 2036. The Company has a Federal operating loss carryforward of $18.8 million that expires in various tax years through 2034. Of the operating loss carryforward, $1.7 million will result in a benefit within additional paid in capital when realized. The Company also has state tax credit carryforwards of $0.2 million and state net operating loss carryforwards of $7.2 million that expire in various tax years through 2034. In assessing the ability to realize deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which the temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities, projected future taxable income, and tax planning strategies in making this assessment. As a result of this analysis and based on the current year's taxable income, and utilization of certain carryforwards management determined that we should reduce our valuation allowance in the current year. A valuation allowance is still required to the extent it is more likely than not that the future benefit associated with the foreign tax credit carryforwards and certain state tax loss carryforwards will not be realized. As a result, the Company recorded a tax expense associated with an increase of the deferred tax asset valuation allowance of $0.1 million for 2016.

The Company records the benefits relating to uncertain tax positions only when it is more likely than not (likelihood of greater than 50%), based on technical merits, that the position would be sustained upon examination by taxing authorities. Tax positions that meet the more likely than not threshold are measured using a probability-weighted approach as the largest amount of tax benefit that is greater than 50% likely of being realized upon settlement. At December 31, 2016, the Company's reserve for uncertain tax positions is not material and we believe we have adequately provided for its tax-related liabilities. The Company is no longer subject to United States federal income tax examinations for years before 2013. The provision for (benefit from) income taxes differed from the provision computed by applying the Federal statutory rate to income (loss) from continuing operations before taxes due to the following:

	Year ended December 31,			
	2016		2015	
Federal statutory tax rate	34.0	%	34.0	%
State taxes	1.4		5.8	
Non deductible expenses	2.7		1.0	
Tax credits	(6.7	)	(4.8	)
Foreign income tax rate differential	(2.1	)	(1.3	)
Valuation allowance	0.1		(9.5	)
Tax return and audit adjustments	0.0		3.8	
Other	2.0		(1.8	)
	31.4	%	27.2	%

Note 9 — Employee Benefit Plans

The Company has a deferred profit-sharing retirement plan that covers substantially all employees. The Company's annual contribution to the plan is discretionary. The Company's did not make a contribution in 2016 or 2015. The plan also contains a 401(k) provision that allows employees to contribute a percentage of their salary up to the statutory limitation. These contributions are matched at the rate of 10% by the Company. The Company's matching contributions under the 401(k) component were $0.3 million and $0.4 million in 2016 and 2015, respectively.

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The Company also maintains an incentive-compensation plan. Participants in the plan are key employees as determined by the Board of Directors and executive management. Compensation under the plan is based on the achievement of predetermined financial performance goals of the Company and its subsidiaries. Awards under the plan are payable in cash. Awards under the plan totaled $0.5 million and $0.8 million, in 2016 and 2015, respectively.

The Company also sponsors a deferred compensation plan for a select group of highly compensated employees. Participants may make elective deferrals of their salary to the plan in excess of tax code limitations that apply to the Company's qualified plan. The Company invests the participants' deferred amounts to fund these obligations. The Company also has the sole discretion to make employer contributions to the plan on behalf of the participants, though we did not make any employer contributions in 2016 or 2015.

Note 10 — Contingencies

We are subject to legal proceedings, which arise in the ordinary course of business. Additionally, U.S. Government contract costs are subject to periodic audit and adjustment. Further, as disclosed in "Item 9A. Controls and Procedures", we are currently conducting an internal investigation into import/export and sales documentation activities at our China and Singapore offices. The investigation is being conducted under the oversight of our Audit Committee, with the assistance of outside counsel, and is focused on compliance with provisions of the U.S. Foreign Corrupt Practices Act, or FCPA, and other applicable laws, and certain of our policies, including our Code of Business Conduct and Ethics. We have voluntarily notified the U.S. Securities and Exchange Commission ("SEC") and the U.S. Department of Justice ("DOJ") of these matters, and are fully cooperating with these agencies. During the year ended December 31, 2016, we recorded $1.3 million of expenses relating to the investigation, including expenses of outside legal counsel and forensic accountants. We are currently unable to predict what actions the SEC, the DOJ, or other governmental agencies (including foreign governmental agencies) might take, or what the likely outcome of any such actions might be, or estimate the range of reasonably possible fines or penalties, which may be material. The SEC, DOJ, and other governmental authorities have a broad range of civil and criminal sanctions, and the imposition of sanctions, fines or remedial measures could have a material adverse effect on the Company's business, prospects, reputation, financial condition, liquidity, results of operations or cash flows.

Note 11 — Segment and Related Information

The Company is organized in two reporting units: Restaurant/Retail, and Government. Management views the Restaurant/Retail and Government segments separately in operating its business, as the products and services are different for each segment. The Company's chief operating decision maker is the Company's Chief Executive Officer. The Hotel/Spa reporting was sold as of November 4, 2015, and is classified as discontinued operations (see Note 2 – Divestiture and Discontinued Operations - of the Notes to Consolidated Financial Statements).

The Company has two reportable business segments - Restaurant/Retail segment and Government segment. The Restaurant/Retail segment offers integrated solutions to the restaurant and retail industry consisting of restaurants, grocery stores and specialty retail outlets. These offerings include industry leading hardware and software applications utilized at the point-of-sale, back of store and corporate office and includes the acquisition of Brink Software. This segment also offers customer support including field service, installation, and twenty-four-hour telephone support and depot repair. With our SureCheck solution, we continue to expand our business into retail, big box retailers, grocery stores, and contract food management organizations. The government segment performs complex technical studies, analysis, and experiments, develops innovative solutions, and provides on-site engineering in support of advanced defense, security, and aerospace systems. This segment also provides expert on-site services for operating and maintaining U.S. Government-owned communication assets.

Information noted as "Other" primarily relates to the Company's corporate, home office operations.

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Information as to the Company's segments is set forth below. Amounts below exclude discontinued operations.

	Year ended December 31, (in thousands)	
	2016	2015
Revenues:		
Restaurant/Retail	$ 149,341	$ 141,151
Government	80,312	87,852
Total	$ 229,653	$ 229,003
Operating income (loss) :		
Restaurant/Retail	$ 825	$ 1,721
Government	6,160	5,365
Other	(4,772)	(457)
	2,213	6,629
Other income, net	1,316	(800)
Interest income (expense)	121	(308)
Income from continuing operations before provision for income taxes	$ 3,650	$ 5,521
Identifiable assets:		
Restaurant/Retail	$ 87,672	$ 72,948
Government	6,504	10,052
Other	29,873	32,874
Total	$ 124,049	$ 115,874
Goodwill:		
Restaurant/Retail	$ 10,315	$ 10,315
Government	736	736
Total	$ 11,051	$ 11,051
Depreciation, amortization and accretion:		
Restaurant/Retail	$ 3,479	$ 2,673
Government	38	48
Other	1,107	349
Total	$ 4,624	$ 3,070
Capital expenditures including software costs:		
Restaurant/Retail	$ 3,285	$ 3,645
Government	41	-
Other	2,792	208
Total	$ 6,118	$ 3,853

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The following table presents revenues by country based on the location of the use of the product or services. Amounts below exclude discontinued operations.

	December 31,	
	2016	2015
United States	$210,821	$197,303
Other Countries	18,832	31,700
Total	$229,653	$229,003

The following table presents assets by country based on the location of the asset. Amounts below exclude discontinued operations.

	December 31,	
	2016	2015
United States	$110,369	$100,583
Other Countries	13,680	15,291
Total	$124,049	$115,874

Customers comprising 10% or more of the Company's total revenues, excluding discontinued operations, are summarized as follows:

	December 31,	
	2016	2015
Restaurant and Retail segment:		
McDonald's Corporation	25 %	19 %
Yum! Brands, Inc.	11 %	10 %
Government segment:		
U.S. Department of Defense	35 %	38 %
All Others	29 %	33 %
	100 %	100 %

No other customer within All Others represented more than 10% of the Company's total revenue for the years ended December 31, 2016 and 2015.

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Note 12 — Fair Value of Financial Instruments

The Company's financial instruments have been recorded at fair value using available market information and valuation techniques. The fair value hierarchy is based upon three levels of input, which are:

Level 1 – quoted prices in active markets for identical assets or liabilities (observable)

Level 2 – inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities, quoted prices in inactive markets, or other inputs that are observable market data for essentially the full term of the asset or liability (observable)

Level 3 – unobservable inputs that are supported by little or no market activity, but are significant to determining the fair value of the asset or liability (unobservable)

The Company's financial instruments consist primarily of cash and cash equivalents, trade receivables, trade payables, debt instruments and deferred compensation assets and liabilities. For cash and cash equivalents, trade receivables and trade payables, the carrying amounts of these financial instruments as of December 31, 2016, and 2015 were considered representative of their fair values. The estimated fair value of the Company's long-term debt and line of credit at December 31, 2016 and 2015 was based on variable and fixed interest rates at December 31, 2016 and 2015, respectively, for new issues with similar remaining maturities and approximates the respective carrying values at December 31, 2016 and 2015.

The deferred compensation assets and liabilities primarily relate to the Company's deferred compensation plan, which allows for pre-tax salary deferrals for certain key employees (see Note 9 – Employees Benefit Plans - of the Notes to Consolidated Financial Statements). Changes in the fair value of the deferred compensation liabilities are derived using quoted prices in active markets of the asset selections made by the participants. The deferred compensation liabilities are classified within Level 2, as defined under U.S. GAAP, because their inputs are derived principally from observable market data by correlation to the hypothetical investments. The Company holds insurance investments to partially offset the Company's liabilities under the deferred compensation plan, which are recorded at fair value each period using the cash surrender value of the insurance investments.

The Company has obligations, to be paid in cash, to the former owners of Brink Software, based on the achievement of certain conditions as defined in the definitive agreement (see Note 1 – Summary of Significant Accounting Policies - sub-footnote Contingent Consideration - of the Notes to Consolidated Financial Statements).

The fair value of this contingent consideration payable was estimated using a discounted cash flow method, with significant inputs that are not observable in the market and thus represents a Level 3 fair value measurement as defined in ASC 820, fair value measurements and disclosures. The significant inputs in the Level 3 measurement not supported by market activity included the Company's probability assessments of expected future cash flows related to the Company's acquisition of Brink during the contingent consideration period, appropriately discounted considering the uncertainties associated with the obligation, and calculated in accordance with the terms of the definitive agreement. The liabilities for the contingent consideration were established at the time of the acquisition and are evaluated on a quarterly basis based on additional information as it becomes available. Any change in the fair value adjustment is recorded in the earnings of that period. Changes in the fair value of the contingent consideration obligations may result from changes in probability assumptions with respect to the likelihood of achieving the various contingent payment obligations. Significant increases or decreases in the inputs noted above in isolation would result in a significantly lower or higher fair value measurement.

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The following table presents a summary of changes in fair value of the Company's Level 3 assets and liabilities that are measured at fair value on a recurring basis (in thousands):

	Level 3 Inputs Liabilities
Balance at December 31, 2015	$ 5,130
New level 3 liability	-
Change in fair value of contingent consideration liability	(1,130)
Transfers into or out of Level 3	-
Balance at December 31, 2016	$ 4,000

Note 13 — Related Party Transactions

The Company leases its corporate wellness facility to related parties at a current rate of $9,775 per month. The Company receives a complimentary membership to this facility which is provided to all employees. During 2016 and 2015 the Company received rental income amounting to $117,300 for the lease of the facility in each year.

Our director, Paul D. Eurek, is President of Xpanxion LLC. In October 2016, we entered into a software development agreement with Xpanxion. In 2016, we incurred approximated $0.2 million of fees to Xpanxion under the software development agreement, but made no payments. Mr. Eurek's successor has been announced, and he intends to be fully retired from Xpanxion on June 30, 2017.

Note 14 — Subsequent Events

None noted

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SIGNATURES

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.

PAR TECHNOLOGY CORPORATION

April 17, 2017 /s/ Donald H. Foley
Donald H. Foley
Chief Executive Officer & President
(Principal Executive Officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Signatures	Title	Date
/s/ Donald H. Foley Donald H. Foley	Chief Executive Officer, President & Director (Principal Executive Officer)	April 17, 2017
/s/ Bryan A. Menar Bryan A. Menar	Chief Financial Officer (Principal Financial Officer)	April 17, 2017
/s/ Cynthia A. Russo Cynthia A. Russo	Director	April 17, 2017
/s/ Paul D. Eurek Paul D. Eurek	Director	April 17, 2017
/s/ Todd E. Tyler Todd E. Tyler	Director	April 17, 2017
/s/ John W. Sammon John W. Sammon	Director	April 17, 2017

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List of Exhibits

Exhibit Index

Exhibit Number	Exhibit Description	Incorporated by reference into this Annual Report on Form 10-K: Form (File No.)	Exhibit	Date Filed/Furnished
2(i) ***	Stock Purchase Agreement, dated as of September 18, 2014, among Brink Software Inc., the Shareholders, ParTech, Inc. and PAR Technology Corporation	Quarterly Report on Form 10-Q (File No. 001-09720)	10.3	11/14/2014
2(ii)	Asset Purchase Agreement, dated as of November 4, 2015, among Gary Jonas Computing Ltd., SMS Software Holdings LLC, Jonas Computing (UK) Ltd., PAR Springer-Miller Systems, Inc., Springer-Miller International, LLC, Springer-Miller Canada, ULC, Partech, Inc., and Constellation Software, Inc.	Annual Report on Form 10-K (File No. (001-09720)	10.26	3/30/2016
3(i)	Certificate of Incorporation, as amended May 22, 2014	Current Report on Form 8-K (File No. 001-09720)	3(i)	5/29/2014
3(ii)	By-laws, as amended May 22, 2014	Current Report on Form 8-K (001-09720)	3(ii)	5/29/2014
4	Specimen Certificate for shares of common stock	Registration Statement on Form S-2 (File No. 333-04077)	4	5/20/1996
10.1	PAR Technology Corporation 2005 Equity Incentive Plan	Registration Statement on Form S-8 (File No. 333-137647)	4.2	9/28/2006

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Exhibit Number	Exhibit Description	Incorporated by reference into this Annual Report on Form 10-K		
		Form	Exhibit	Date Filed
10.2	PAR Technology Corporation 2005 Equity Incentive Plan, as amended	Registration Statement on Form S-8 (File No. 333-187246)	4.1	3/14/2013
10.3	PAR Technology Corporation Restricted Stock Agreement pursuant to the 2005 Equity Incentive Plan (Form)	Quarterly Report on Form 10-Q (File No. 001-09720)	10.1	8/8/2013
10.4	PAR Technology Corporation 2005 Equity Incentive Plan Notice of Award (Form)	Annual Report on Form 10-K (File No. 001-09720)	10.17	3/14/2014
10.5 ††	PAR Technology Corporation 2005 Equity Incentive Plan Outside Director Notice of Restricted Stock Award and Agreement (Form)	Annual Report on Form 10-K (File No. 001-09720)	10.21	3/31/2015
10.6	PAR Technology Corporation 2005 Equity Incentive Plan Notice of Award and Agreement (Form)	Annual Report on Form 10-K (File No. 001-09720)	10.23	3/31/2015
10.7 ***	Credit Agreement, dated as of September 9, 2014, among PAR Technology Corporation, the other Loan Parties, and JPMorgan Chase Bank, N.A.	Quarterly Report on Form 10-Q (File No. 001-09720)	10.1	11/14/2014
10.8	Pledge and Security Agreement entered into as of September 9, 2014, among PAR Technology Corporation, Ausable Solutions Inc., PAR Government Systems Corporation, PAR Springer-Miller Systems, Inc., Rome Research Corporation, Springer-Miller International, LLC, ParTech, Inc., and JPMorgan Chase Bank, N.A.	Quarterly Report on Form 10-Q (File No. 001-09720)	10.2	11/14/2014

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Exhibit Number	Exhibit Description	Incorporated by reference into this Annual Report on Form 10-K		
		Form	Exhibit	Date Filed
10.9 ***	Second Amendment to Credit Agreement and Other Loan Documents, dated as of March 19, 2015, among PAR Technology Corporation, Ausable Solutions Inc., PAR Government Systems Corporation, PAR Springer-Miller Systems, Inc., Rome Research Corporation, Springer-Miller International, LLC, ParTech, Inc., Brink Software, Inc, and JPMorgan Chase Bank, N.A.	Annual Report on Form 10-K (File No. 001-09720)	10.24	3/31/2015
10.10	Fourth Amendment to Credit Agreement, dated as of March 24, 2016, among PAR Technology Corporation, the other Loan Parties (as defined in the Credit Agreement dated September 9, 2014 (as amended)) and JPMorgan Chase Bank, N.A.	Annual Report on Form 10-K (File No. 001-09720)	10.29	3/30/2016
10.11	Fifth Amendment to Credit Agreement, dated as of August 5, 2016, among PAR Technology Corporation, the other Loan Parties (as defined in the Credit Agreement dated September 9, 2014 (as amended)) and JPMorgan Chase Bank, N.A.	Quarterly Report on Form 10-Q (File No. 001-09720)	10.1	8/8/2016
10.12	Sixth Amendment to Credit Agreement, dated as of November 14, 2016, among PAR Technology Corporation, the other Loan Parties (as defined in the Credit Agreement dated September 9, 2014 (as amended)) and JPMorgan Chase Bank N.A.	Quarterly Report on Form 10-Q (File No. 001-09720)	10.1	11/14/2016
10.13	PAR Technology Corporation 2015 Equity Incentive Plan	Registration Statement on Form S-8 (File No. 333-208063)	4.2	11/16/2015
10.14	PAR Technology Corporation 2015 Equity Incentive Plan Notice of Award (Form)	Registration Statement on Form S-8 (File No. 333-208063)	4.3	11/16/2015

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Exhibit Number	Exhibit Description	Incorporated by reference into this Annual Report on Form 10-K		
		Form	Exhibit	Date Filed
10.15 ††	PAR Technology Corporation 2015 Equity Incentive Plan Outside Director Notice of Restricted Stock Award and Agreement (Form)	Registration Statement on Form S-8 (File No. 333-208063)	4.4	11/16/2015
10.16††	Employment Offer Letter, dated March 21, 2013, between Ronald J. Casciano and PAR Technology Corporation	Quarterly Report on Form 10-Q (File No. 001-09720)	10.1	5/9/2013
10.17††	Employment Offer Letter, dated March 21, 2013, between Karen E. Sammon and PAR Technology Corporation	Quarterly Report on Form 10-Q (File No. 001-09720)	10.3	5/9/2013
10.18††	Employment Offer Letter, dated July 13, 2015, between Michael Bartusek and PAR Technology Corporation	Annual Report on Form 10-K (File No. 001-09720)	10.25	3/30/2016
10.19 ††	Employment Offer Letter, dated November 16, 2015, between Karen E. Sammon and PAR Technology Corporation	Annual Report on Form 10-K (File No. 001-09720)	10.27	3/30/2016
10.20 ††	Employment Offer Letter, dated December 10, 2015, between Matthew Cicchinelli and PAR Technology Corporation	Annual Report on Form 10-K (File No. 001-09720)	10.28	3/30/2016
10.21	Credit Agreement dated as of November 29, 2016, among PAR Technology Corporation, the other Loan Parties (as defined in the Credit Agreement) and JPMorgan Chase Bank N.A.			Filed herewith
10.22 ††	Employment Offer Letter, dated November 14, 2016, between Bryan Menar and PAR Technology Corporation			Filed herewith
21	Subsidiaries of PAR Technology Corporation			Filed herewith
23(ii)	Consent of BDO USA, LLP			Filed herewith
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934, as amended			Filed herewith
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934, as			Filed herewith

amended

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Exhibit Number	Exhibit Description	Incorporated by reference into this Annual Report on Form 10-K		
		Form	Exhibit	Date Filed
32.1	Certification of Principal Financial Officer pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350			Furnished herewith
32.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350			Furnished herewith
101.INS	XBRL Instance Document			Filed herewith
101.SCH	XBRL Taxonomy Extension Schema Document			Filed herewith
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document			Filed herewith
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document			Filed herewith
101.LAB	XBRL Taxonomy Extension Label Linkbase Document			Filed herewith
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document			Filed herewith

†† Indicates management contract or compensatory plan or arrangement.
*** Portions of this Exhibit were omitted pursuant to a request for confidential treatment. The omitted portions have been separately filed with the Securities and Exchange Commission.