
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended June 30, 2014.

OR

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

For the transition period from _____ to _____.

Commission File Number 001-16537

ORASURE TECHNOLOGIES, INC.

(Exact Name of Registrant as Specified in Its Charter)

DELAWARE
(State or Other Jurisdiction of
Incorporation or Organization)

220 East First Street, Bethlehem, Pennsylvania
(Address of Principal Executive Offices)

36-4370966
(IRS Employer
Identification No.)

18015
(Zip code)

(610) 882-1820
(Registrant's Telephone Number, Including Area Code)

Indicate by check mark whether the Registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ 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 ☒ No ☐

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.

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input checked="" type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input type="checkbox"/>

Indicate by checkmark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

Number of shares of Common Stock, par value \$.000001 per share, outstanding as of August 1, 2014: 55,987,346 shares.

PART I. FINANCIAL INFORMATION

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ORASURE TECHNOLOGIES, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
(Unaudited)
(in thousands, except per share amounts)

	<u>JUNE 30, 2014</u>	<u>DECEMBER 31, 2013</u>
ASSETS		
CURRENT ASSETS:		
Cash	\$ 75,832	\$ 93,191
Short-term investments	4,437	—
Accounts receivable, net of allowance for doubtful accounts of \$276 and \$299	14,152	12,957
Inventories	13,229	11,444
Prepaid expenses	1,458	1,712
Deferred income taxes	70	71
Other current assets	6,627	200
Total current assets	115,805	119,575
PROPERTY AND EQUIPMENT, net	18,471	17,933
INTANGIBLE ASSETS, net	20,443	22,226
GOODWILL	23,674	23,782
OTHER ASSETS	1,172	729
	<u>\$ 179,565</u>	<u>\$ 184,245</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	\$ 4,647	\$ 4,834
Deferred revenue	694	1,119
Accrued expenses	9,366	13,032
Total current liabilities	14,707	18,985
OTHER LIABILITIES	1,157	677
DEFERRED INCOME TAXES	3,381	3,437
COMMITMENTS AND CONTINGENCIES (Note 6)		
STOCKHOLDERS' EQUITY		
Preferred stock, par value \$.000001, 25,000 shares authorized, none issued	—	—
Common stock, par value \$.000001, 120,000 shares authorized, 55,984 and 55,632 shares issued and outstanding	—	—
Additional paid-in capital	341,106	338,674
Accumulated other comprehensive loss	(3,953)	(3,797)
Accumulated deficit	(176,833)	(173,731)
Total stockholders' equity	160,320	161,146
	<u>\$ 179,565</u>	<u>\$ 184,245</u>

See accompanying notes to the consolidated financial statements.

ORASURE TECHNOLOGIES, INC. AND SUBIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)
(in thousands, except per share amounts)

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2014</u>	<u>2013</u>	<u>2014</u>	<u>2013</u>
NET REVENUES:				
Product	\$ 25,626	\$ 24,063	\$ 49,163	\$ 45,025
Licensing and product development	775	274	775	476
	<u>26,401</u>	<u>24,337</u>	<u>49,938</u>	<u>45,501</u>
COST OF PRODUCTS SOLD	10,385	9,838	19,995	18,973
Gross profit	<u>16,016</u>	<u>14,499</u>	<u>29,943</u>	<u>26,528</u>
OPERATING EXPENSES:				
Research and development	2,771	2,693	5,252	6,050
Sales and marketing	10,272	12,369	21,612	26,243
General and administrative	5,976	5,013	11,700	10,400
Gain on contract termination settlement	(5,500)	—	(5,500)	—
	<u>13,519</u>	<u>20,075</u>	<u>33,064</u>	<u>42,693</u>
Operating income (loss)	2,497	(5,576)	(3,121)	(16,165)
OTHER INCOME (EXPENSE)	<u>(142)</u>	<u>42</u>	<u>(24)</u>	<u>(5)</u>
Income (loss) before income taxes	2,355	(5,534)	(3,145)	(16,170)
INCOME TAX BENEFIT	<u>(174)</u>	<u>(249)</u>	<u>(43)</u>	<u>(659)</u>
NET INCOME (LOSS)	<u>\$ 2,529</u>	<u>\$ (5,285)</u>	<u>\$ (3,102)</u>	<u>\$ (15,511)</u>
EARNINGS (LOSS) PER SHARE:				
BASIC	<u>\$ 0.05</u>	<u>\$ (0.10)</u>	<u>\$ (0.06)</u>	<u>\$ (0.28)</u>
DILUTED	<u>\$ 0.04</u>	<u>\$ (0.10)</u>	<u>\$ (0.06)</u>	<u>\$ (0.28)</u>
SHARES USED IN COMPUTING EARNINGS (LOSS) PER SHARE:				
BASIC	<u>55,907</u>	<u>55,559</u>	<u>55,846</u>	<u>55,504</u>
DILUTED	<u>57,243</u>	<u>55,559</u>	<u>55,846</u>	<u>55,504</u>

See accompanying notes to the consolidated financial statements.

ORASURE TECHNOLOGIES, INC. AND SUBIDIARIES
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)
(Unaudited)
(in thousands)

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2014</u>	<u>2013</u>	<u>2014</u>	<u>2013</u>
NET INCOME (LOSS)	\$ 2,529	\$ (5,285)	\$ (3,102)	\$ (15,511)
OTHER COMPREHENSIVE INCOME (LOSS)				
Currency translation adjustments	1,622	(1,460)	(156)	(2,585)
Other comprehensive income (loss)	1,622	(1,460)	(156)	(2,585)
COMPREHENSIVE INCOME (LOSS)	<u>\$ 4,151</u>	<u>\$ (6,745)</u>	<u>\$ (3,258)</u>	<u>\$ (18,096)</u>

See accompanying notes to the consolidated financial statements.

ORASURE TECHNOLOGIES, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)
(in thousands)

	Six Months Ended June 30,	
	2014	2013
OPERATING ACTIVITIES:		
Net loss	\$ (3,102)	\$ (15,511)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	2,869	2,835
Depreciation and amortization	3,108	3,221
Unrealized foreign currency loss	139	—
Deferred income taxes	(43)	(659)
Changes in assets and liabilities		
Accounts receivable	(1,196)	2,030
Inventories	(1,789)	229
Prepaid expenses and other assets	(5,981)	(977)
Accounts payable	(179)	40
Deferred revenue	(418)	(1,165)
Accrued expenses and other liabilities	(3,805)	679
Net cash used in operating activities	<u>(10,397)</u>	<u>(9,278)</u>
INVESTING ACTIVITIES:		
Purchases of short term investments	(4,430)	—
Purchases of property and equipment	(1,988)	(1,092)
Net cash used in investing activities	<u>(6,418)</u>	<u>(1,092)</u>
FINANCING ACTIVITIES:		
Proceeds from exercise of stock options	202	301
Repurchase of common stock	(639)	(801)
Net cash used in financing activities	<u>(437)</u>	<u>(500)</u>
EFFECT OF FOREIGN EXCHANGE RATE CHANGES ON CASH	<u>(107)</u>	<u>(54)</u>
NET DECREASE IN CASH	<u>(17,359)</u>	<u>(10,924)</u>
CASH, BEGINNING OF PERIOD	<u>93,191</u>	<u>87,888</u>
CASH, END OF PERIOD	<u><u>\$ 75,832</u></u>	<u><u>\$ 76,964</u></u>
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:		
Cash paid for:		
Income taxes	\$ 42	\$ 28

See accompanying notes to the consolidated financial statements.

ORASURE TECHNOLOGIES, INC. AND SUBSIDIARIES
Notes to the Consolidated Financial Statements
(Unaudited)
(in thousands, except per share amounts, unless otherwise indicated)

1. The Company

We develop, manufacture, market and sell oral fluid diagnostic products and specimen collection devices using our proprietary oral fluid technologies, as well as other diagnostic products, including immunoassays and other *in vitro* diagnostic tests that are used on other specimen types. Our diagnostic products include tests that are performed on a rapid basis at the point-of-care and tests that are processed in a laboratory. We sell the first and only rapid point-of-care HIV test approved for use in the domestic consumer retail or over-the-counter (“OTC”) market. We also manufacture and sell oral fluid collection devices used to collect, stabilize and store samples of genetic material for molecular testing in the consumer genetic, clinical genetic testing, academic research, pharmacogenomics, personalized medicine, and animal genetics markets. Lastly, we manufacture and sell medical devices used for the removal of benign skin lesions by cryosurgery, or freezing. Our products are sold in the United States and internationally to various clinical laboratories, hospitals, clinics, community-based organizations, public health organizations, research and academic institutions, distributors, government agencies, physicians’ offices, and commercial and industrial entities. Our OTC HIV and cryosurgical products are sold to retail pharmacies and mass merchandisers, and our OTC HIV product is also sold to consumers over the internet.

2. Summary of Significant Accounting Policies

Principles of Consolidation and Basis of Presentation. The consolidated financial statements include the accounts of OraSure Technologies, Inc. (“OraSure”) and its wholly-owned subsidiary, DNA Genotek, Inc. (“DNAG”). All intercompany transactions and balances have been eliminated. References herein to “we,” “us,” “our,” or the “Company” mean OraSure and its consolidated subsidiaries, unless otherwise indicated.

The accompanying consolidated financial statements are unaudited and, in the opinion of management, include all adjustments (consisting only of normal and recurring adjustments) necessary for a fair presentation of our financial position and results of operations for these interim periods. These financial statements should be read in conjunction with the financial statements and notes thereto included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2013. Results of operations for the three and six months ended June 30, 2014 are not necessarily indicative of the results of operations expected for the full year.

Use of Estimates. The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions about future events. These estimates and underlying assumptions affect the amounts of assets and liabilities reported, disclosures about contingent assets and liabilities, and reported amounts of revenues and expenses. Such estimates include the valuation of accounts receivable and inventories and assumptions utilized in impairment testing for intangible assets and goodwill, as well as calculations related to contingencies and accruals, among others. These estimates and assumptions are based on management’s best estimates and judgment. Management evaluates its estimates and assumptions on an ongoing basis, using historical experience and other factors which management believes to be reasonable under the circumstances, including the current economic environment. We adjust such estimates and assumptions when facts and circumstances dictate. Illiquid credit markets, volatile equity and foreign currency markets, reductions in government funding and declines in consumer spending have combined to increase the uncertainty inherent in such estimates and assumptions. As future events and their effects cannot be determined with precision, actual results could differ significantly from these estimates. Changes in those estimates resulting from continuing changes in the economic environment and other factors will be reflected in the financial statements in those future periods.

Short-Term Investments. We consider all short-term investments to be available-for-sale securities. These securities are comprised of guaranteed investment certificates with purchased maturities greater than ninety days. Available-for-sale securities are carried at fair value, based upon quoted market prices, with unrealized gains and losses, if any, reported in stockholders’ equity as a component of accumulated other comprehensive loss.

Our available-for-sale securities as of June 30, 2014 consisted of guaranteed investment certificates with amortized cost and fair value of \$4,437. As of December 31, 2013, we had no available-for-sale securities.

Fair Value of Financial Instruments. As of June 30, 2014, the carrying values of cash, short-term investments, accounts receivable, accounts payable and accrued expenses approximate their respective fair values based on their short-term nature.

Fair value measurements of all financial assets and liabilities that are being measured and reported on a fair value basis are required to be classified and disclosed in one of the following three categories:

Level 1: Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities;

Level 2: Quoted prices in markets that are not active, or inputs which are observable, either directly or indirectly, for substantially the full term of the asset or liability; and

Level 3: Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (i.e., supported by little or no market activity).

We offer a nonqualified deferred compensation plan for certain eligible employees and members of our Board of Directors. The assets of the plan are held in the name of the Company at a third-party financial institution. Separate accounts are maintained for each participant to reflect the amounts deferred by the participant and all earnings and losses on those deferred amounts. The assets of the plan are held in mutual funds and Company stock. The fair value of the plan assets as of June 30, 2014 and December 31, 2013 was \$1,313 and \$677, respectively, and was calculated using the quoted market prices of the assets as of those dates. All investments in the plan are classified as trading securities and measured as Level 1 instruments. The fair value of plan assets is included in other assets with the same amount included in other liabilities in the accompanying consolidated balance sheets.

All of our available-for-sale securities were classified and measured as Level 1 instruments as of June 30, 2014.

Inventories. Inventories are stated at the lower of cost or market determined on a first-in, first-out basis and are comprised of the following:

	<u>June 30, 2014</u>	<u>December 31, 2013</u>
Raw materials	\$ 6,894	\$ 6,700
Work in process	1,074	833
Finished goods	5,261	3,911
	<u>\$ 13,229</u>	<u>\$ 11,444</u>

Property and Equipment. Property and equipment are stated at cost. Additions or improvements are capitalized, while repairs and maintenance are charged to expense. Depreciation and amortization are provided using the straight-line method over the estimated useful lives of the related assets. Buildings are depreciated over twenty to forty years, while computer equipment, machinery and equipment, and furniture and fixtures are depreciated over two to ten years. Building improvements are amortized over their estimated useful lives. When assets are sold or otherwise disposed of, the related property amounts are relieved from the accounts, and any gain or loss is recorded in the consolidated statement of operations. Accumulated depreciation of property and equipment as of June 30, 2014 and December 31, 2013 was \$29,843 and \$28,390, respectively.

Intangible Assets. Intangible assets consist of the following:

	Amortization Period (Years)	June 30, 2014		
		Gross	Accumulated Amortization	Net
Customer list	10	\$ 11,741	\$ (3,250)	\$ 8,491
Patents and product rights	3-10	10,449	(7,732)	2,717
Acquired technology	7	9,120	(3,551)	5,569
Tradenname	15	4,500	(861)	3,639
Non-compete agreements	1-3	637	(610)	27
		<u>\$36,447</u>	<u>\$ (16,004)</u>	<u>\$20,443</u>

	Amortization Period (Years)	December 31, 2013		
		Gross	Accumulated Amortization	Net
Customer list	10	\$ 11,795	\$ (2,701)	\$ 9,094
Patents and product rights	3-10	10,449	(7,466)	2,983
Acquired technology	7	9,162	(2,952)	6,210
Tradenname	15	4,521	(715)	3,806
Non-compete agreements	1-3	787	(654)	133
		<u>\$36,714</u>	<u>\$ (14,488)</u>	<u>\$22,226</u>

Goodwill. Goodwill represents the excess of the purchase price we paid over the fair value of the net tangible and identifiable intangible assets acquired and liabilities assumed in our acquisition of DNAG in August 2011. Goodwill is not amortized but rather is tested annually for impairment or more frequently if we believe that indicators of impairment exist. Current U.S. generally accepted accounting principles permit us to make a qualitative evaluation about the likelihood of goodwill impairment. If we conclude that it is more likely than not that the fair value of a reporting unit is greater than its carrying amount, then we would not be required to perform the two-step quantitative impairment test. Otherwise, performing the two-step impairment test is necessary. The first step of the two-step quantitative impairment test involves comparing the fair value of the applicable reporting unit with its aggregate carrying value, including goodwill. If the carrying value of a reporting unit exceeds the reporting unit's fair value, we perform the second step of the test to determine the amount of the impairment loss, if any. The second step involves measuring any impairment by comparing the implied fair values of the affected reporting unit's goodwill and intangible assets with their respective carrying values.

We performed our last annual impairment assessment as of July 31, 2013 utilizing a qualitative evaluation and concluded that it was more likely than not that the fair value of our DNAG reporting unit is greater than its carrying amount. We performed our last quantitative impairment test for goodwill as of July 31, 2012 and determined there was no impairment. That quantitative assessment determined that our DNAG reporting unit had a fair value in excess of its carrying value (including goodwill of \$25,179) of approximately 13%. We believe we have made reasonable estimates and assumptions to calculate the fair value of our reporting unit. If actual future results are not consistent with management's estimates and assumptions, we may have to take an impairment charge in the future related to our goodwill. Future impairment tests will continue to be performed annually in the fiscal third quarter, or sooner if a triggering event occurs. As of June 30, 2014, we believe no indicators of impairment exist.

The change in goodwill from \$23,782 as of December 31, 2013 to \$23,674 as of June 30, 2014 is a result of foreign currency translation.

Revenue Recognition. We recognize product revenues when there is persuasive evidence that an arrangement exists, the price is fixed or determinable, title has passed and collection is reasonably assured. Product revenues are recorded net of allowances for any discounts or rebates. Other than for our OraQuick® In-Home HIV test, we do not grant price protection or product return rights to our customers, except for warranty returns. Historically, returns arising from warranty issues have been infrequent and immaterial. Accordingly, we expense warranty returns as incurred.

We began selling our OraQuick® In-Home HIV test in the third quarter of 2012. From launch through November 2013, our revenue recognition practices with respect to the OraQuick® In-Home HIV test were different than those customarily used in the consumer package goods industry. Under U.S. generally accepted accounting principles, product revenue cannot be recognized unless the amount of future returns can be reasonably estimated. Because our OraQuick® In-Home HIV test was a new product for which we did not have a historical record of returns, we did not believe we could reasonably determine a return rate. As a result, initially we did not recognize revenue when we shipped to the retail trade. For these product shipments, we invoiced the retailer or distributor, recorded deferred revenue at gross invoice sales price, and classified the cost basis of the product held by the retailer or distributor as a component of inventory. We then recognized revenue upon the consummation of a sale to the consumer either in a store or over the internet. With the passage of time, however, we concluded that we have sufficient data and visibility into our distribution channel to develop a reasonable estimate of the level of expected returns. As such, commencing in December 2013, we recognized previously deferred revenue and its related cost of goods sold, and began to recognize revenue for this product upon shipment to the retailers or distributors. Accordingly, revenues in the first half of 2014 were recorded based upon shipments into the distribution channel, while revenues in the first half of 2013 were recorded based upon the consummation of a sale to the consumer.

Our net revenues recorded on sales of the OraQuick® In-Home HIV test represent total gross revenues, less an allowance for expected returns, and customer allowances for cooperative advertising discounts, rebates, and chargebacks. All of these allowances are estimates established by management, based on currently available information and are adjusted to reflect known changes in the factors that impact those estimates. These allowances are recorded as a reduction of gross revenue when recognized in our statements of operations.

Royalty income from the grant of license rights is recognized during the period in which the revenue is earned and the amount is determinable from the licensee.

We record shipping and handling charges billed to our customers as product revenue and the related expense as cost of products sold. Taxes assessed by governmental authorities, such as sales or value-added taxes, are excluded from product revenues.

On June 10, 2014, we entered into a Master Program Services and Co-Promotion Agreement with AbbVie Bahamas Ltd., a wholly-owned subsidiary of AbbVie Inc. ("AbbVie"), to co-promote our OraQuick® HCV Rapid Test in the United States. The product will be used to test individuals at-risk for the hepatitis C virus (HCV). We will be responsible for manufacturing and selling the product into all markets.

Under the agreement, we have granted exclusive promotion rights to AbbVie for the OraQuick® HCV test in certain markets and will provide certain additional services in support of HCV testing. In exchange for these exclusive rights and other services we will provide to AbbVie, we will receive up to \$75,000 in payments over the term of the agreement, which runs through December 31, 2019. We plan to recognize the payments ratably on a monthly basis over the life of the agreement. In addition, if certain performance-based milestones are achieved, we will be eligible to receive additional payments annually ranging from \$3,500 to \$55,500 over the life of the agreement beginning in 2015. The agreement also contains certain termination, indemnification and other provisions, typical of agreements of this type. Payments received under this agreement will be recorded as licensing and product development revenue in our statements of operations.

Customer Sales Returns and Allowances. We do not grant return rights to our customers for any product, except for our OraQuick® In-Home HIV test. Accordingly, we have recorded an estimate of expected returns as a reduction of gross OraQuick® In-Home HIV product revenues in our consolidated statements of operations. This estimate reflects our historical sales experience to retailers and consumers, as well as other retail factors, and is reviewed regularly to ensure that it reflects potential product returns. As of June 30, 2014 and December 31, 2013, the reserve for sales returns and allowances was \$363 and \$279, respectively. If actual product returns differ materially from our reserve amount, or if a determination is made that this product's distribution would be discontinued in whole or in part by certain retailers, then we would need to adjust our reserve. Should the actual level of product returns vary significantly from our estimates, our operating and financial results could be materially affected.

Termination Settlement. On November 21, 2013, we terminated our assay collaboration agreement with Roche Diagnostics (“Roche”). Pursuant to this termination agreement, Roche paid us \$8,300 which was recorded as a reduction of operating expense in our consolidated statement of operations for the year ended December 31, 2013. Roche agreed to provide certain transitional product support services to us and to continue to supply certain of the assays developed under the collaboration on a transitional basis for up to five years following the termination. We had the right to stop the supply of assays prior to the end of this five-year period and to receive an additional payment from Roche of up to \$5,500 depending on how early in that five-year period the supply obligation was ended. During the second quarter of 2014, we issued our final purchase order for fully-automated assays previously developed under the terminated collaboration agreement and as such, have recorded \$5,500 as a reduction of operating expense in our consolidated statement of operations and a receivable equal to the same amount in other current assets on our consolidated balance sheet. The \$5,500 payment was made by Roche in July 2014.

Deferred Revenue. We record deferred revenue when funds are received prior to the recognition of the associated revenue. Deferred revenue at June 30, 2014 and December 31, 2013 included customer prepayments of \$694 and \$1,119, respectively.

Customer and Vendor Concentrations. One of our customers, Reckitt Benckiser, accounted for approximately 11% of our accounts receivable balance as of June 30, 2014. We had no significant concentrations in accounts receivable as of December 31, 2013. We had no significant concentrations (greater than 10%) in revenues for the three or six months ended June 30, 2014 or 2013.

We currently purchase certain products and critical components of our products from sole-supply vendors, and if these vendors are unable or unwilling to supply the required components and products, we could be subject to increased costs and substantial delays in the delivery of our products to our customers. Also, our subsidiary, DNAG, uses two third-party suppliers to manufacture its products. Our inability to have a timely supply of any of these components and products could have a material adverse effect on our business, as well as our financial condition and results of operations.

Earnings (Loss) Per Share. Basic earnings (loss) per share is computed by dividing net income (loss) by the weighted-average number of shares of common stock outstanding during the period. Diluted earnings (loss) per share is computed in a manner similar to basic earnings (loss) per share except that the weighted average number of shares outstanding is increased to include incremental shares from the assumed vesting or exercise of dilutive securities, such as common stock options and unvested restricted stock, unless the impact is antidilutive. The number of incremental shares is calculated by assuming that outstanding stock options were exercised and unvested restricted shares were vested, and the proceeds from such exercises or vesting were used to acquire shares of common stock at the average market prices during the reporting period.

The computations of basic and diluted earnings (loss) per share are as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
Net income (loss)	\$ 2,529	\$ (5,285)	\$ (3,102)	\$ (15,511)
Weighted average shares of common stock outstanding:				
Basic	55,907	55,559	55,846	55,504
Dilutive effect of stock options and restricted stock	1,336	—	—	—
Diluted	57,243	55,559	55,846	55,504
Earnings (loss) per share:				
Basic	\$ 0.05	\$ (0.10)	\$ (0.06)	\$ (0.28)
Diluted	\$ 0.04	\$ (0.10)	\$ (0.06)	\$ (0.28)

For the three-month periods ended June 30, 2014 and 2013, outstanding common stock options and unvested restricted stock, representing 3,594 and 5,684 shares, respectively, were excluded from the computation of diluted earnings (loss) per share, as their inclusion would have been anti-dilutive. For the six months ended June 30, 2014 and 2013, outstanding common stock options and unvested restricted stock, representing 3,646 and 5,237 shares, respectively, were similarly excluded from the computation of diluted earnings (loss) per share.

Foreign Currency Translation. The assets and liabilities of our foreign operations are translated into U.S. dollars at current exchange rates as of the balance sheet date, and revenues and expenses are translated at average exchange rates for the period. Resulting translation adjustments are reflected in accumulated other comprehensive loss, which is a separate component of stockholders' equity.

Transaction gains and losses resulting from exchange rate changes on transactions denominated in currencies other than functional currency are included in income in the period in which the change occurs.

Accumulated Other Comprehensive Loss. We classify items of other comprehensive loss by their nature and disclose the accumulated balance of other comprehensive loss separately from accumulated deficit and additional paid-in capital in the stockholders' equity section of our balance sheet.

We have defined the Canadian dollar as the functional currency of our Canadian subsidiary, DNAG, and as such, the results of its operations are translated into U.S. dollars, which is the reporting currency of the Company. The \$156 and \$2,585 currency translation adjustments recorded in the first six months of 2014 and 2013, respectively, are largely the result of the translation of our Canadian operation's balance sheets into U.S. dollars.

Recent Accounting Pronouncements. In May 2014, the Financial Accounting Standards Board ("FASB") issued converged guidance on recognizing revenue in contracts with customers, ASU 2014-09 *Revenue from Contracts with Customers*. The intent of the new standard is to improve financial reporting and comparability of revenue globally. The core principle of the standard is for a company to recognize revenue in a manner that depicts the transfer of goods or services to customers in an amount that reflects the consideration which the company expects to receive in exchange for those goods or services. The standard will be effective for the first interim period within annual reporting periods beginning after December 15, 2016, with no early adoption permitted. We will evaluate the effects, if any, which adoption of this guidance will have on our consolidated financial statements.

3. Stockholders' Equity

Stock-Based Awards

We grant stock-based awards under the OraSure Technologies, Inc. Stock Award Plan, as amended and restated (the "Stock Plan"). The Stock Plan permits stock-based awards to employees, outside directors and consultants or other third-party advisors. Awards which may be granted under the Stock Plan include qualified incentive stock options, nonqualified stock options, stock appreciation rights, restricted awards, performance awards and other stock-based awards. We recognize compensation expense for stock option and restricted stock awards issued to employees and directors on a straight-line basis over the requisite service period of the award. To satisfy the exercise of options or to issue new restricted stock, we normally issue new shares rather than purchase shares on the open market.

Total compensation cost related to stock options for the six months ended June 30, 2014 and 2013 was \$1,499 and \$1,363, respectively. Net cash proceeds from the exercise of stock options were \$202 and \$301 for the six months ended June 30, 2014 and 2013, respectively. As a result of the Company's net operating loss carryforward position, no actual income tax benefit was realized from stock option exercises during these periods.

Compensation cost of \$1,370 and \$1,472 related to restricted shares was recognized during the six months ended June 30, 2014 and 2013, respectively. In connection with the vesting of restricted shares, during the six months ended June 30, 2014 and 2013, 106 and 120 shares, respectively, with aggregate values of \$639 and \$801, respectively, were withheld and retired in satisfaction of minimum tax withholding obligations.

4. Accrued Expenses

	<u>June 30, 2014</u>	<u>December 31, 2013</u>
Payroll and related benefits	\$ 4,395	\$ 5,827
Royalties	2,163	4,374
Professional fees	1,043	749
Other	1,765	2,082
	<u>\$ 9,366</u>	<u>\$ 13,032</u>

5. Income Taxes

During the three and six months ended June 30, 2014, we recorded foreign deferred tax benefits of \$174 and \$43, respectively. During the three and six months ended June 30, 2013, we recorded foreign deferred tax benefits of \$249 and \$659, respectively. The foreign deferred tax benefits are associated with certain Canadian research and development and investment tax credits and DNAG's loss before income taxes. The income tax benefits associated with DNAG are considered realizable based upon the estimated scheduled reversal of the deferred tax liabilities recorded in connection with the acquisition of DNAG.

Deferred income taxes reflect the tax effects of temporary differences between the basis of assets and liabilities recognized for financial reporting and tax purposes, and net operating loss and tax credit carryforwards. The significant components of our total deferred tax liability as of June 30, 2014 relate to the tax effects of the basis differences between the intangible assets acquired in the DNAG acquisition for financial reporting and tax purposes.

In 2008, we established a full valuation allowance against our U.S. net deferred tax asset, and management believes the full valuation allowance is still appropriate as of June 30, 2014 and December 31, 2013 since the facts and circumstances necessitating the allowance have not changed. As a result, no U.S. federal or state income tax benefit was recorded for the three and six month periods ended June 30, 2014 and 2013.

6. Commitments and Contingencies

From time-to-time, we are involved in certain legal actions arising in the ordinary course of business. In management’s opinion, based upon the advice of counsel, the outcomes of such actions are not expected to have a material adverse effect on our future financial position or results of operations.

7. Business Segment Information

We operate our business within two reportable segments: our “OSUR” business, which consists of the development, manufacture and sale of oral fluid diagnostic products and specimen collection devices and the manufacture and sale of medical devices used for the removal of benign skin lesions by cryosurgery; and our molecular collection systems or “DNAG” business, which consists of the manufacture, development and sale of oral fluid collection devices that are used to collect, stabilize and store samples of genetic material for molecular testing. OSUR revenues are derived primarily from products sold in the United States and internationally to various clinical laboratories, hospitals, clinics, community-based organizations, public health organizations, distributors, government agencies, physicians’ offices, and commercial and industrial entities. Revenues from OSUR’s OTC products result from sales to retail pharmacies and mass merchandisers, and to consumers over the internet. OSUR also derives revenues from licensing and product development activities. DNAG revenues result primarily from products sold into the commercial market which consists of companies and other entities engaged in consumer genetics, clinical genetic testing, pharmacogenomics, personalized medicine, and animal and livestock genetic testing. DNAG products are also sold into the academic research market, which consists of research laboratories, universities and hospitals.

We organized our operating segments according to the nature of the products included in those segments. The accounting policies of the segments are the same as those described in the summary of significant accounting policies (see Note 2). We evaluate performance of our operating segments based on revenue and operating income (loss). We do not allocate interest income, interest expense, other income, other expenses or income taxes to our operating segments. Reportable segments have no inter-segment revenues.

The following table summarizes segment information for the three and six months ended June 30, 2014 and 2013:

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2014</u>	<u>2013</u>	<u>2014</u>	<u>2013</u>
Net revenues:				
OSUR	\$ 21,505	\$ 19,683	\$ 39,283	\$ 36,915
DNAG	4,896	4,654	10,655	8,586
Total	<u>\$ 26,401</u>	<u>\$ 24,337</u>	<u>\$ 49,938</u>	<u>\$ 45,501</u>
Operating income (loss):				
OSUR	\$ 2,203	\$ (5,456)	\$ (4,190)	\$ (15,496)
DNAG	294	(120)	1,069	(669)
Total	<u>\$ 2,497</u>	<u>\$ (5,576)</u>	<u>\$ (3,121)</u>	<u>\$ (16,165)</u>
Depreciation and amortization:				
OSUR	\$ 790	\$ 797	\$ 1,566	\$ 1,574
DNAG	779	822	1,542	1,647
Total	<u>\$ 1,569</u>	<u>\$ 1,619</u>	<u>\$ 3,108</u>	<u>\$ 3,221</u>
Capital expenditures:				
OSUR	\$ 1,131	\$ 484	\$ 1,570	\$ 727
DNAG	210	128	418	365
Total	<u>\$ 1,341</u>	<u>\$ 612</u>	<u>\$ 1,988</u>	<u>\$ 1,092</u>

	<u>June 30, 2014</u>	<u>December 31, 2013</u>
Total assets:		
OSUR	\$ 125,845	\$ 130,848
DNAG	53,720	53,397
Total	<u>\$ 179,565</u>	<u>\$ 184,245</u>

Our products are sold principally in the United States and Europe.

The following table represents total revenues by geographic area, based on the location of the customer:

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2014</u>	<u>2013</u>	<u>2014</u>	<u>2013</u>
United States	\$ 19,113	\$ 18,959	\$ 36,518	\$ 34,999
Europe	3,681	2,438	7,682	5,284
Other regions	3,607	2,940	5,738	5,218
	<u>\$ 26,401</u>	<u>\$ 24,337</u>	<u>\$ 49,938</u>	<u>\$ 45,501</u>

The following table represents total long-lived assets by geographic area:

	<u>June 30, 2014</u>	<u>December 31, 2013</u>
United States	\$ 17,205	\$ 16,925
Canada	1,244	975
Other regions	22	33
	<u>\$ 18,471</u>	<u>\$ 17,933</u>

Item 2. MANAGEMENT’S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Statements below regarding future events or performance are “forward-looking statements” within the meaning of the Federal securities laws. These may include statements about our expected revenues, earnings/loss per share, net income (loss), expenses, cash flow or other financial performance or developments, clinical trial or development activities, expected regulatory filings and approvals, planned business transactions, views of future industry, competitive or market conditions, and other factors that could affect our future operations, results of operations or financial position. These statements often include the words “believes,” “expects,” “anticipates,” “intends,” “plans,” “estimates,” “may,” “will,” “should,” “could,” or similar expressions. Forward-looking statements are not guarantees of future performance or results. Known and unknown factors that could cause actual performance or results to be materially different from those expressed or implied in these statements include, but are not limited to: ability to market and sell products, whether through our internal, direct sales force or third parties; ability to manufacture products in accordance with applicable specifications, performance standards and quality requirements; ability to obtain, and timing and cost of obtaining, necessary regulatory approvals for new products or new indications or applications for existing products; ability to comply with applicable regulatory requirements; ability to effectively resolve warning letters, audit observations and other findings or comments from the FDA or other regulators; changes in relationships, including disputes or disagreements, with strategic partners or other parties and reliance on strategic partners for the performance of critical activities under collaborative arrangements; our ability to achieve financial and performance objectives under the HCV collaboration with AbbVie; failure of distributors or other customers to meet purchase forecasts, historic purchase levels or minimum purchase requirements for our products; impact of replacing distributors; inventory levels at distributors and other customers; ability of DNA Genotek to achieve its financial and strategic objectives and continue to increase its revenues; ability to identify, complete, integrate and realize the full benefits of future acquisitions; impact of competitors, competing products and technology changes; impact of negative economic conditions, high unemployment and poor credit conditions; reduction or deferral of public funding available to customers; competition from new or better technology or lower cost products; ability to develop, commercialize and market new products, including the OraQuick® In-Home HIV test; market acceptance of oral fluid testing or other products; changes in market acceptance of products based on product performance or other factors, including changes in Centers for Disease Control and Prevention (“CDC”) or other testing guidelines, algorithms or other recommendations; ability to fund research and development and other products and operations; ability to obtain and maintain new or existing product distribution channels; reliance on sole supply sources for critical products and components; availability of related products produced by third parties or products required for use of our products; history of losses and ability to achieve sustained profitability; ability to utilize net operating loss carry forwards or other deferred tax assets; volatility of OraSure’s stock price; uncertainty relating to patent protection and potential patent infringement claims; uncertainty and costs of litigation relating to patents and other intellectual property; availability of licenses to patents or other technology; ability to enter into international manufacturing agreements; obstacles to international marketing and manufacturing of products; ability to sell products internationally, including the impact of changes in international funding sources and testing algorithms; adverse movements in foreign currency exchange rates; loss or impairment of sources of capital; ability to attract and retain qualified personnel; exposure to product liability and other types of litigation; changes in international, federal or state laws and regulations; customer consolidations and inventory practices; equipment failures and ability to obtain needed raw materials and components; the impact of terrorist attacks and civil unrest; and general political, business and economic conditions. These and other factors are discussed more fully in our Securities and Exchange Commission (“SEC”) filings, including our registration statements, Annual Report on Form 10-K for the year ended December 31, 2013, Quarterly Reports on Form 10-Q, and other filings with the SEC. Although forward-looking statements help to provide information about future prospects, readers should keep in mind that forward-looking statements may not be reliable. The forward-looking statements are made as of the date of this Report, and we undertake no duty to update these statements.

The following discussion should be read in conjunction with our consolidated financial statements contained herein and the notes thereto, along with the Section entitled “Critical Accounting Policies and Estimates,” set forth below.

Overview

We develop, manufacture, market and sell oral fluid diagnostic products and specimen collection devices using our proprietary oral fluid technologies, as well as other diagnostic products including immunoassays and other *in vitro* diagnostic tests that are used on other specimen types. Our diagnostic products include tests that are performed on a rapid basis at the point-of-care and tests that are processed in a laboratory. We sell the OraQuick® In-Home HIV test, the first and only rapid point-of-care HIV test approved for use in the domestic consumer retail market. We also manufacture and sell oral fluid collection devices used to collect, stabilize, and store samples of genetic material for molecular testing in the clinical genetic testing, academic research, pharmacogenomics, personalized medicine, and animal genetics markets. Lastly, we manufacture and sell medical devices used for the removal of benign skin lesions by cryosurgery, or freezing. Our products are sold in the United States and internationally to various clinical laboratories, hospitals, clinics, community-based organizations and other public health organizations, research and academic institutions, distributors, government agencies, physicians' offices, and commercial and industrial entities. Our over-the-counter ("OTC") HIV and cryosurgery products are sold to retail pharmacies and mass merchandisers, and our OTC HIV product is also sold to consumers over the internet.

Recent Developments

HCV Co-Promotion Agreement

On June 10, 2014, we entered into a Master Program Services and Co-Promotion Agreement with AbbVie Bahamas Ltd., a wholly-owned subsidiary of AbbVie Inc. ("AbbVie"), to co-promote our OraQuick® HCV Rapid Test in the United States. The product will be used to test individuals at-risk for the hepatitis C virus ("HCV"). We will be responsible for manufacturing and selling the product into all markets.

Under the agreement, we have granted exclusive promotion rights to AbbVie for the OraQuick® HCV test in certain markets and will provide certain additional services in support of HCV testing. In exchange for these exclusive rights and other services we will provide to AbbVie, we will receive up to \$75.0 million in aggregate payments over the term of the agreement, which runs through December 31, 2019. We plan to recognize the payments ratably on a monthly basis over the life of the agreement. As of June 30, 2014, we recognized \$775,000 in revenues from payments due from AbbVie. The first \$15.0 million payment was received in July 2014. In addition, if certain performance-based milestones are achieved, we will be eligible to receive additional payments annually ranging from \$3.5 to \$55.5 million over the life of the agreement beginning in 2015. The agreement also contains certain termination, indemnification and other provisions typical of agreements of this type. Payments received under this agreement will be recorded as licensing and product development revenue in our statements of operations.

Drugs-of-Abuse Assay Collaboration Agreements

We continue to make progress under our agreement with Thermo Fisher Scientific ("Thermo Fisher") to develop and supply homogenous fully-automated oral fluid drugs of abuse assays to be used with a new version of our Intercept® oral fluid specimen collection device. As a result of this progress, in late June 2014 we issued our final purchase order for fully-automated assays previously developed under our now terminated collaboration agreement with Roche Diagnostics ("Roche"). Under the terms of the termination of our Roche collaboration, we received \$5.5 million as a result of the submission of our final purchase order. This payment was recorded as a receivable on our balance sheet and as a reduction of operating expense on our consolidated statement of operations for the second quarter. The \$5.5 million payment was received in July 2014.

Current Consolidated Financial Results

During the six months ended June 30, 2014, our consolidated net revenues were \$49.9 million compared to \$45.5 million in the six months ended June 30, 2013. Net product revenues during the six months ended June 30, 2014 increased 9% when compared to the first six months of 2013, primarily due to higher sales of our OraQuick® HCV, Oragene®, and cryosurgical systems products. Licensing and product development revenues for the first six months of 2014 increased 63% due to the recognition of \$775,000 in exclusivity payments from AbbVie. Licensing and product development revenues for the first six months of 2013 represent royalties related to sales of Merck's OTC cryosurgical wart removal product.

Our consolidated net loss for the six months ended June 30, 2014 was \$3.1 million, or \$0.06 per share, compared to a net loss of \$15.5 million, or \$0.28 per share, for the six months ended June 30, 2013. Results for the six months end June 30, 2014 include the \$5.5 million payment received pursuant to the termination of our collaboration agreement with Roche.

Cash used in operating activities for the six months ended June 30, 2014 was \$10.4 million, compared to \$9.3 million used during the six months ended June 30, 2013. As of June 30, 2014, we had \$80.3 million in cash and short-term investments compared to \$93.2 million at December 31, 2013.

Economic Outlook

Many of our customers rely on public funding provided by federal, state and local governments, and this funding has been and may continue to be reduced or deferred as a result of current economic conditions. These circumstances may adversely impact our customers and suppliers, which, in turn, could adversely affect their ability to purchase our products or supply us with necessary equipment, raw materials or components. In addition, these circumstances could adversely affect our access to liquidity that may be needed to conduct or expand our business, conduct future acquisitions or make other discretionary investments.

In 2011, President Obama signed into law the Budget Control Act of 2011, which was designed to reduce federal spending over the next 10 years by \$2.5 trillion. Under that law, certain automatic cuts to discretionary, national defense and Medicare spending (often referred to as Federal sequestration) have become effective. We cannot predict whether Congress will attempt to suspend or restructure the automatic budget cuts or what other deficit reduction initiatives may be proposed by Congress. Although the full impact of sequestration is difficult to ascertain, the spending cuts implemented under this new law have adversely affected, and are expected to continue to adversely affect, our customers' ability to purchase our products. In addition, other legislative or regulatory changes may be adopted which could adversely affect our ability to sell our current products or successfully develop and commercialize new products.

Business Segments

We operate our business within two reportable segments: our "OSUR" business, which consists of the development, manufacture and sale of oral fluid diagnostic products, specimen collection devices, and medical devices used for the removal of benign skin lesions by cryosurgery; and our "DNAG" or molecular collection systems business, which consists primarily of the development, manufacture and sale of oral fluid collection devices that are used to collect, stabilize, and store samples of genetic material for molecular testing. OSUR revenues are derived primarily from products sold into the United States and internationally to various clinical laboratories, hospitals, clinics, community-based organizations, public health organizations, distributors, government agencies, physicians' offices, and commercial and industrial entities. Revenues from OSUR's OTC products result from sales to retail pharmacies and mass merchandisers and to consumers over the internet. DNAG revenues result primarily from products sold into the commercial market, which consists of companies and other entities engaged in consumer genetics, clinical genetic testing, pharmacogenomics, personalized medicine, and animal genetic testing, as well as products sold into the academic research market which consists of research laboratories, universities and hospitals.

Results of Operations

Three months ended June 30, 2014 compared to June 30, 2013

CONSOLIDATED NET REVENUES

The table below shows the amount of total net product revenues (dollars in thousands) generated by each of our business segments and net revenues from licensing and product development activities for the three months ended June 30, 2014 and 2013.

	Three Months Ended June 30,				
	Dollars		% Change	Percentage of Total Net Revenues	
	2014	2013		2014	2013
OSUR	\$20,730	\$19,409	7%	78%	80%
DNAG	4,896	4,654	5	19	19
Net product revenues	25,626	24,063	6	97	99
Licensing and product development	775	274	183	3	1
Net revenues	<u>\$26,401</u>	<u>\$24,337</u>	8%	<u>100%</u>	<u>100%</u>

Consolidated net revenues increased 8% to \$26.4 million in the second quarter of 2014 from \$24.3 million in the comparable period of 2013, primarily as a result of higher sales of our OraQuick® HCV, cryosurgical systems, and molecular collection systems products. These increases were partially offset by lower domestic sales of our OraQuick® professional HIV product, OraQuick® In-Home HIV test and insurance risk assessment products. Licensing and product development revenues increased to \$775,000 in the second quarter of 2014 from \$274,000 in the second quarter of 2013. Licensing and product development revenues for the current quarter represent the recognition of payments from AbbVie for exclusive promotion rights and certain services we will provide under our HCV collaboration, while second quarter 2013 licensing and product development revenues represent royalties received on sales of Merck's OTC cryosurgical wart removal product.

Consolidated net revenues derived from products sold to customers outside the U.S. were \$7.3 million and \$5.4 million, or 28% and 22% of total net revenues, in the second quarters of 2014 and 2013, respectively. Because the majority of our international sales are denominated in U.S. dollars, the impact of fluctuating foreign currency exchange rates was not material to our total net revenues.

Net Revenues by Segment

OSUR Segment

The table below shows the amount of total net revenues (dollars in thousands) generated by our OSUR segment in each of our principal markets and by licensing and product development activities.

Market	Three Months Ended June 30,				
	Dollars		% Change	Percentage of Total Net Revenues	
	2014	2013		2014	2013
Infectious disease testing	\$12,668	\$11,966	6%	59%	61%
Substance abuse testing	2,208	2,113	4	10	11
Cryosurgical systems	4,920	4,177	18	23	21
Insurance risk assessment	934	1,153	(19)	4	6
Net product revenues	20,730	19,409	7	96	99
Licensing and product development	775	274	183	4	1
Net revenues	<u>\$21,505</u>	<u>\$19,683</u>	9%	<u>100%</u>	<u>100%</u>

Infectious Disease Testing Market

Sales to the infectious disease testing market increased 6% to \$12.7 million in the second quarter of 2014 from \$12.0 million in the second quarter of 2013, primarily due to higher sales of our OraQuick® HCV test in both domestic and international markets and our OraQuick® professional HIV product in the international market.

The table below shows a breakdown of our total net OraQuick® revenues (dollars in thousands) during the second quarters of 2014 and 2013.

Market	Three Months Ended June 30,		
	2014	2013	% Change
Domestic HIV	\$ 7,720	\$ 8,088	(5)%
International HIV	848	745	14
Domestic OTC HIV	1,669	1,993	(16)
Net HIV revenues	10,237	10,826	(5)
Domestic HCV	1,221	690	77
International HCV	974	247	294
Net HCV revenues	2,195	937	134
Net OraQuick® revenues	\$12,432	\$11,763	6%

Domestic OraQuick® HIV sales decreased 5% to \$7.7 million for the three months ended June 30, 2014 from \$8.1 million for the three months ended June 30, 2013. This decrease was primarily the result of some customer migration to automated 4th generation immunoassay HIV tests performed in a laboratory as recommended under new testing guidelines issued by the CDC. Also contributing to the lower domestic OraQuick® HIV sales were changes in customer ordering patterns. We anticipate that future sales of our professional HIV product will continue to be negatively affected as a result of the CDC's recommended use of automated laboratory-based blood tests and by reductions in government funding. International sales of our OraQuick® HIV test during the second quarter of 2014 increased 14% to \$848,000 from \$745,000 primarily due to sales in support of a significant African testing program.

During the second quarter of 2014, we recorded \$1.9 million in gross revenues from sales of our OraQuick® In-Home HIV test. These revenues were partially offset by \$196,000 in customer allowances, including cooperative advertising, cash discounts, and other allowances, which were netted against gross revenues in accordance with U.S. generally accepted accounting principles. Thus, net revenues from this product were \$1.7 million for the second quarter of 2014 as compared to net revenues of \$2.0 million in the second quarter of 2013 (\$2.1 million in gross revenues, partially offset by \$133,000 of allowances and discounts).

OraQuick® In-Home HIV revenues recorded in the current and prior year periods are not readily comparable due to the December 2013 change in our revenue recognition policy related to this product. Since the product launch in late 2012, revenues had been recognized upon consummation of a purchase by consumers either in a store or over the internet. In December 2013, as a result of our growing experience with this product and improved ability to estimate potential product returns, we began recognizing revenues upon shipment of product to the retailers or distributors. Based on available point-of-sale data, consumer purchases declined 1% in the second quarter of 2014 as compared to the second quarter of 2013 which we believe was due to a decrease in broad-based media advertising.

Sales of our OraQuick® In-Home HIV test in both the second quarter of 2014 and 2013 included approximately \$67,000 and \$255,000, respectively, of direct sales to public health customers. We anticipate that some public health entities may choose to use a portion of their funding to purchase our OTC product in lieu of professional rapid HIV testing products.

Domestic OraQuick® HCV sales increased 77% to \$1.2 million in the second quarter of 2014 from \$690,000 in the second quarter of 2013, primarily due to the addition of new HCV customers and higher sales to current customers who have expanded their HCV testing programs. International OraQuick® HCV sales increased 294% to \$974,000 in the second quarter of 2014 from \$247,000 in the second quarter of 2013, primarily as a result of purchases by a multi-national humanitarian organization that did not purchase product during the second quarter of 2013. We expect that purchases by this customer will be at a reduced rate over the balance of the year.

We believe our HCV product represents an opportunity for future sales growth, especially as new therapies for treating HCV come to market. We also expect that sales of our HCV product will be positively impacted as we implement our HCV collaboration with AbbVie. However, demand for our HCV product, particularly in the public health marketplace, has been, and will likely continue to be, tempered by the limited availability of government funding allocated to HCV testing efforts and the time and effort required to build awareness and demand for rapid HCV testing.

International orders for both our HIV and HCV products can be sporadic in nature and are often predicated upon the availability of governmental funding, the impact of competition and other factors. As such, there is no assurance that such sales will continue at the same levels in future periods.

Substance Abuse Testing Market

Sales to the substance abuse testing market increased 4% to \$2.2 million in the second quarter of 2014 from \$2.1 million in the second quarter of 2013, primarily as a result of higher sales of our Intercept® drug testing system. The table below shows a breakdown of our total net Intercept® revenues (dollars in thousands) generated in each market during the second quarters of 2014 and 2013.

Market	Three Months Ended June 30,		
	2014	2013	% Change
Domestic	\$1,616	\$1,342	20%
International	33	98	(66)
Net Intercept® revenues	<u>\$1,649</u>	<u>\$1,440</u>	15%

Domestic Intercept® sales for the second quarter of 2014 increased to \$1.6 million compared to \$1.3 million for the second quarter of 2013 largely due to the recovery of customers that were previously lost to competition. International Intercept® sales decreased 66% to \$33,000 in the second quarter of 2014 from \$98,000 in 2013 largely due the discontinuance of purchases by our UK distributor who in 2012 began selling its own competing oral specimen collection device. Sales to this distributor were \$46,000 in the second quarter of 2013.

Cryosurgical Systems Market

Sales of our cryosurgical systems products (which includes both the physicians' office and OTC markets) increased 18% to \$4.9 million in the second quarter of 2014, compared to \$4.2 million in the same period of the prior year.

The table below shows a breakdown of our total net cryosurgical systems revenues (dollars in thousands) generated in each market during the second quarters of 2014 and 2013.

Market	Three Months Ended June 30,		
	2014	2013	% Change
Domestic professional	\$1,469	\$1,497	(2)%
International professional	229	257	(11)
International OTC	3,222	2,423	33
Net cryosurgical systems revenues	<u>\$4,920</u>	<u>\$4,177</u>	18%

Sales of our Histofreezer® product to physicians' offices in the United States remained relatively flat at \$1.5 million in both the second quarters of 2014 and 2013. International sales of Histofreezer® decreased slightly to \$229,000, compared to \$257,000 in the same period of the prior year. Our long-term supply agreement for the Histofreezer® product with Koninklijke Utermöhlen, N.V., the party from whom we acquired the Histofreezer® business in 1998, terminated in late 2013, and Utermöhlen has indicated that it plans to sell a competing product similar to Histofreezer®. If Utermöhlen is successful in commercializing this product, we believe sales of our Histofreezer® product could be negatively impacted.

Sales of our OTC cryosurgical products during the second quarter of 2014 increased 33% to \$3.2 million compared to \$2.4 million in the second quarter of 2013, largely due to higher sales to both our European distributor, Reckitt Benckiser, and our Latin American distributor, Genomma.

Current quarter sales to Reckitt Benckiser increased to \$1.7 million, compared to \$1.2 million during the second quarter of 2013, primarily due to the launch of our product into new geographic territories and continued market penetration. Sales to Genomma increased to \$1.5 million in the second quarter of 2014 from \$1.2 million in the second quarter of 2013 due to customer ordering patterns.

Insurance Risk Assessment Market

Sales to the insurance risk assessment market decreased 19% to \$934,000 in the second quarter of 2014 from \$1.2 million in the second quarter of 2013, as a result of continued reduced demand in the domestic life insurance market, as well as the adoption by some underwriters of a "Simplified Issues" policy, pursuant to which testing for risk factors is replaced by having applicants respond to a questionnaire about their behaviors.

Licensing and Product Development

Licensing and product development revenues increased to \$775,000 in the second quarter of 2014 from \$274,000 in the second quarter of 2013. Licensing and product development revenues in the second quarter of 2014 represent the recognition of payments from AbbVie for exclusive promotion rights and certain services we will provide under our HCV collaboration. The first such payment of \$15.0 million as required by the agreement was received in July 2014. Licensing and product development revenues in the second quarter of 2013 represent royalties paid on domestic outsales of Merck's OTC cryosurgical wart removal product, pursuant to a license and settlement agreement executed in January 2008. We stopped receiving royalties under this license when certain of our cryosurgical patents expired in August 2013.

DNAG Segment

Molecular Collection Systems

Net molecular collection systems revenues, which primarily represent sales of our Oragene® product line, increased 5% to \$4.9 million in the second quarter of 2014 from \$4.7 million in the second quarter of 2013. Sales of Oragene® in the commercial market remained flat at \$2.8 million in both periods. Revenues in the second quarter of 2014 did not include any sales to DNAG's largest commercial customer, whereas revenues in the second quarter of 2013 included approximately \$1.7 million in sales to this customer. Sales of Oragene® in the academic market increased 12% largely due to the timing of orders placed by our distributors and studies performed by several larger academic customers.

CONSOLIDATED OPERATING RESULTS

Consolidated gross margin was 61% for the second quarter of 2014 compared to 60% for the second quarter of 2013. Gross margin for the current quarter primarily benefited from a more favorable product mix driven largely by increased DNAG sales to higher margin customers.

Consolidated operating income for the second quarter of 2014 was \$2.5 million, an \$8.1 million improvement from the \$5.6 million operating loss reported in the second quarter of 2013. The second quarter 2014 operating income was primarily the result of the \$5.5 million payment received under the terms of the termination of our drug assay collaboration with Roche. Also contributing to this improvement in operating performance were increased revenues and lower HIV OTC marketing costs during the current quarter.

OPERATING INCOME (LOSS) BY SEGMENT

OSUR Segment

OSUR's gross margin was 58% in the second quarter of 2014 compared to 59% in the second quarter of 2013. OSUR's 2014 margin was negatively impacted by less efficient manufacturing, a shift in product mix to sales of product with lower gross margin partially offset by higher licensing and product development revenues.

Research and development expenses increased slightly to \$2.1 million in the second quarter of 2014 from \$2.0 million in the second quarter of 2013 largely due to higher supply costs. Sales and marketing expenses decreased 21% to \$8.4 million in the second quarter of 2014 from \$10.7 million in the second quarter of 2013. This decrease was primarily the result of lower advertising and promotional costs for our OraQuick® In-Home HIV test which totaled \$3.0 million in the second quarter of 2014, compared to \$5.4 million in second quarter of 2013. This reduction was the result of our decision to focus our marketing and promotional efforts at the retail outlet level and transition away from broad-based consumer advertising by the end of the second quarter of 2014. General and administrative expenses increased 21% to \$5.2 million in the second quarter of 2014 from \$4.3 million in the second quarter of 2013 due to higher legal expenses, staffing related costs and consulting costs.

All of the above, along with the \$5.5 million payment from Roche, contributed to OSUR's second quarter 2014 operating income of \$2.2 million, which included non-cash charges of \$790,000 for depreciation and amortization and \$1.4 million for stock-based compensation.

DNAG Segment

DNAG's gross margin was 72% in the second quarter of 2014 compared to 62% in the second quarter of 2013. This increase was directly attributable to an increased volume of high margin sales experienced in the second quarter of 2014 when compared to the second quarter of 2013.

DNAG operating expenses increased to \$3.3 million in the second quarter of 2014 from \$3.0 million in the second quarter of 2013. Research and development expenses remained relatively flat at \$623,000 in the second quarter of 2014 compared to \$655,000 in the second quarter of 2013. Sales and marketing expenses increased 12% to \$1.9 million in the second quarter of 2014 from \$1.7 million in the second quarter of 2013 due to higher staffing costs. General and administrative expenses increased to \$761,000 in the second quarter of 2014 compared to \$704,000 in the second quarter of 2013, also due to higher staffing costs.

All of the above contributed to DNAG's second quarter 2014 operating income of \$294,000, which included non-cash charges of \$779,000 for depreciation and amortization and \$109,000 for stock-based compensation.

CONSOLIDATED INCOME TAXES

We continue to believe the full valuation allowance established in 2008 against OSUR's total U.S. net deferred tax asset is appropriate as the facts and circumstances necessitating the allowance have not changed. As a result, no U.S. income tax expense or benefit was recorded for OSUR's pre-tax income or loss in the second quarter of 2014 or 2013, respectively. A Canadian income tax benefit of \$174,000 and \$249,000 was recorded in the second quarter of 2014 and 2013, respectively, which was associated with certain Canadian research and development and investment tax credits and DNAG's loss before income taxes. The Canadian income tax benefits are considered realizable based upon the scheduled reversal of the deferred tax liabilities recorded in connection with the acquisition of DNAG.

Six months ended June 30, 2014 compared to June 30, 2013

CONSOLIDATED NET REVENUES

The table below shows the amount of total net product revenues (dollars in thousands) generated by each of our business segments and net revenues from licensing and product development activities for the six months ended June 30, 2014 and 2013.

	Six Months Ended June 30,				
	Dollars		% Change	Percentage of Total Net Revenues	
	2014	2013		2014	2013
OSUR	\$38,508	\$36,439	6%	77%	80%
DNAG	10,655	8,586	24	21	19
Net product revenues	49,163	45,025	9	98	99
Licensing and product development	775	476	63	2	1
Net revenues	<u>\$49,938</u>	<u>\$45,501</u>	10%	<u>100%</u>	<u>100%</u>

Consolidated net revenues increased 10% to \$49.9 million in the first half of 2014 from \$45.5 million in the comparable period of 2013, primarily as a result of higher sales of our OraQuick® HCV, molecular collection systems products, and cryosurgical systems products. These increases were partially offset by lower sales of our OraQuick® professional product in the domestic market and lower substance abuse and insurance risk assessment product sales. Licensing and product development revenues increased to \$775,000 in the first six months of 2014 from \$476,000 in the first six months of 2013. Licensing and product development revenues for the current six-month period represent the recognition of payments from AbbVie for exclusive promotion rights and certain services we will provide under our HCV collaboration, while 2013 licensing and product development revenues represent royalties received on sales of Merck's OTC cryosurgical wart removal product.

Consolidated net revenues derived from products sold to customers outside the U.S. were \$13.4 million and \$10.5 million, or 27% and 23% of total net revenues, during the six months ended June 30, 2014 and 2013, respectively. Because the majority of our international sales are denominated in U.S. dollars, the impact of fluctuating foreign currency exchange rates was not material to our total net revenues.

Net Revenues by Segment

OSUR Segment

The table below shows the amount of total net revenues (dollars in thousands) generated by our OSUR segment in each of our principal markets and by licensing and product development activities.

Market	Six Months Ended June 30,					
	Dollars			Percentage of Total Net Revenues		
	2014	2013	%	2014	2013	
Infectious disease testing	\$23,732	\$22,654	5%	60%	61%	
Substance abuse testing	4,038	4,362	(7)	10	12	
Cryosurgical systems	8,887	7,261	22	23	20	
Insurance risk assessment	1,851	2,162	(14)	5	6	
Net product revenues	38,508	36,439	6%	98	99%	
Licensing and product development	775	476	63	2	1	
Net revenues	<u>\$39,283</u>	<u>\$36,915</u>	6%	<u>100%</u>	<u>100%</u>	

Infectious Disease Testing Market

Sales to the infectious disease testing market increased 5% to \$23.7 million in the first half of 2014 from \$22.7 million in the first half of 2013, primarily due to higher sales of our OraQuick® HCV product and OraQuick® In-Home HIV test and higher sales of our OraQuick® professional HIV product in the international market.

The table below shows a breakdown of our total net OraQuick® revenues (dollars in thousands) during the six months ended June 30, 2014 and 2013.

Market	Six Months Ended June 30,		
	2014	2013	% Change
Domestic HIV	\$14,339	\$15,761	(9)%
International HIV	1,405	1,300	8
Domestic OTC HIV	3,622	3,435	5
Net HIV revenues	19,366	20,496	(6)
Domestic HCV	1,884	1,119	68
International HCV	1,870	486	285
Net HCV revenues	3,754	1,605	134
Net OraQuick® revenues	<u>\$23,120</u>	<u>\$22,101</u>	5%

Domestic OraQuick® HIV sales decreased 9% to \$14.3 million for the six months ended June 30, 2014 from \$15.8 million for the six months ended June 30, 2013. This decrease was primarily caused by our customers' migration to automated 4th generation immunoassay HIV tests performed in a laboratory as recommended under new CDC testing guidelines. Also contributing to the lower domestic OraQuick® HIV sales were changes in customer ordering patterns. We anticipate that future sales of our professional HIV product will continue to be negatively affected as a result of the CDC's recommended use of automated laboratory-based blood tests and by reductions in government funding. International sales of our OraQuick® HIV test during the first half of 2014 increased slightly to \$1.4 million from \$1.3 million in the first half of 2013.

During the first half of 2014, we recorded \$4.0 million in gross revenues from sales of our OraQuick® In-Home HIV test. These revenues were partially offset by \$407,000 in customer allowances, including cooperative advertising, cash discounts, and other allowances, which were netted against gross revenues in accordance with U.S. generally accepted accounting principles. Thus, net revenues from this product were \$3.6 million for the first half of 2014 as compared to net revenues of \$3.4 million in the first half of 2013 (\$3.7 million in gross revenues, partially offset by \$242,000 of allowances and discounts).

OraQuick® In-Home HIV revenues recorded in the current and prior year periods are not readily comparable due to the December 2013 change in our revenue recognition policy related to this product. Since the product launch in late 2012, revenues had been recognized upon consummation of a purchase by consumers either in a store or over the internet. In December 2013, as a result of our growing experience with this product and improved ability to estimate potential product returns, we began recognizing revenues upon shipment of product to the retailers or distributors. Based on available point-of-sale data, consumer purchases increased 9% in the first half of 2014 as compared to the first half of 2013 due to increased awareness about the product.

Sales of our OraQuick® In-Home HIV test in both the first six months of 2014 and 2013 included approximately \$250,000 and \$383,000, respectively, of direct sales to public health customers. We anticipate that some public health entities may choose to use a portion of their funding to purchase our OTC product in lieu of professional rapid HIV testing products.

Domestic OraQuick® HCV sales increased 68% to \$1.9 million in the first half of 2014 from \$1.1 million in the first half of 2013, primarily due to the addition of new HCV customers and higher sales to current customers who have expanded their HCV testing programs. International OraQuick® HCV sales increased 285% to \$1.9 million in the first half of 2014 from \$486,000 in the first half of 2013, primarily as a result of purchases by a multi-national humanitarian organization which did not purchase product during the first six months of 2013. We expect that purchases by this customer will be at a reduced rate over the balance of the year.

We believe our HCV product represents an opportunity for future sales growth, especially as new therapies for treating HCV come to market. We also expect that sales of our HCV product will be positively impacted as we implement our HCV collaboration with AbbVie. However, demand for our HCV product, particularly in the public health marketplace, has been, and will likely continue to be, tempered by the limited availability of government funding allocated to HCV testing efforts and the time and effort required to build awareness and demand for rapid HCV testing.

International orders for both our HIV and HCV products can be sporadic in nature and are often predicated upon the availability of governmental funding, the impact of competition and other factors. As such, there is no assurance that such sales will continue at the same levels in future periods.

Substance Abuse Testing Market

Sales to the substance abuse testing market decreased 7% to \$4.0 million in the first six months of 2014 from \$4.4 million in the first six months of 2013, primarily as a result of lower sales of our Intercept® drug testing system. The table below shows a breakdown of our total net Intercept® revenues (dollars in thousands) generated in each market during the six months ended June 30, 2014 and 2013.

Market	Six Months Ended June 30,		
	2014	2013	% Change
Domestic	\$2,866	\$2,745	4%
International	73	356	(79)
Net Intercept® revenues	<u>\$2,939</u>	<u>\$3,101</u>	(5)%

Domestic Intercept® sales for the first six months of 2014 decreased to \$2.9 million compared to \$3.1 million for the first six months of 2013, primarily because of lower international sales. International Intercept® sales decreased 79% to \$73,000 in the first half of 2014 from \$356,000 in 2013 largely due the discontinuance of purchases by our UK distributor who in 2012 began selling its own competing oral specimen collection device. Sales to this distributor were \$283,000 in the first half of 2013.

Cryosurgical Systems Market

Sales of our cryosurgical systems products (which includes both the physicians' office and OTC markets) increased 22% to \$8.9 million in the first half of 2014, compared to \$7.3 million in the same period of the prior year.

The table below shows a breakdown of our total net cryosurgical systems revenues (dollars in thousands) generated in each market during the six months ended June 30, 2014 and 2013.

Market	Six Months Ended June 30,		
	2014	2013	% Change
Domestic professional	\$3,011	\$2,388	26%
International professional	538	605	(11)
International OTC	5,338	4,268	25
Net cryosurgical systems revenues	<u>\$8,887</u>	<u>\$7,261</u>	22%

Sales of our Histofreezer® product to physicians' offices in the United States increased 26% to \$3.0 million in the first half of 2014, compared to \$2.4 million in the first half of 2013. This increase reflects below normal sales in the early months of 2013, resulting from higher distributor purchases in the fourth quarter of 2012 in advance of a price increase implemented in January 2013. During the first half of 2014, international sales of Histofreezer® decreased slightly to \$538,000, compared to \$605,000 in the same period of the prior year. Our long-term supply agreement for the Histofreezer® product with Koninklijke Utermöhlen, N.V., the party from whom we acquired the Histofreezer® business in 1998, terminated in late 2013, and Utermöhlen has indicated that it plans to sell a competing product similar to Histofreezer®. If Utermöhlen is successful in commercializing this product, we believe sales of our Histofreezer® product could be negatively impacted.

Sales of our OTC cryosurgical products during the first six months of 2014 increased 25% to \$5.3 million compared to \$4.3 million in the first six months of 2013, largely due to higher sales to both our European distributor, Reckitt Benckiser, and our Latin American distributor, Genomma.

Sales to Reckitt Benckiser increased to \$3.0 million, compared to \$2.2 during the first half of 2013, primarily due to the launch of our product into new geographic territories and new market segments. Sales to Genomma increased to \$2.2 million in the first half of 2014 from \$1.9 million in the first half of 2013 due to customer ordering patterns.

Insurance Risk Assessment Market

Sales to the insurance risk assessment market decreased 14% to \$1.9 million in the first six months of 2014 from \$2.2 million in the first six months of 2013, as a result of continued reduced demand in the domestic life insurance market, as well as the adoption by some underwriters of a "Simplified Issues" policy, pursuant to which testing for risk factors is replaced by having applicants respond to a questionnaire about their behaviors.

Licensing and Product Development

Licensing and product development revenues increased to \$775,000 in the first half of 2014 from \$476,000 in the first half of 2013. Licensing and product development revenues in 2014 represent the recognition of payments from AbbVie for exclusive promotion rights and certain services we will provide under our HCV collaboration. The first such payment of \$15.0 million as required by the agreement was received in July 2014. Licensing and product development revenues in 2013 represent royalties paid on domestic outsales of Merck's OTC cryosurgical wart removal product, pursuant to a license and settlement agreement executed in January 2008. We stopped receiving royalties under this license when certain of our cryosurgical patents expired in August 2013.

DNAG Segment

Molecular Collection Systems

Net molecular collection systems revenues, which primarily represent sales of our Oragene® product line, increased 24% to \$10.7 million in the first six months of 2014 from \$8.6 million in the first six months of 2013. Sales of Oragene® in the commercial market increased approximately 31% in the first half of 2014 primarily as a result of the ordering patterns of a few of our larger commercial customers. Revenues in the first half of 2014 included approximately \$1.3 million in sales to DNAG's largest commercial customer while revenues in the first half of 2013 included approximately \$2.4 million in sales to this customer. Sales of Oragene® in the academic market increased 21% largely due to the timing of orders placed by our distributors and studies performed by several larger academic customers.

CONSOLIDATED OPERATING RESULTS

Consolidated gross margin was 60% for the first half of 2014 compared to 58% for the first half of 2013. Gross margin for the current period primarily benefited from a more favorable product mix driven largely by increased DNAG sales to higher margin customers.

Consolidated operating loss for the first half of 2014 was \$3.1 million, a \$13.1 million improvement from the \$16.2 million operating loss reported in the first half of 2013. The current period operating results include the \$5.5 million payment received under the terms of the termination of our drug assay collaboration with Roche. Also contributing to this improvement in operating loss were higher revenues and lower HIV OTC sales and marketing costs during the first six months of 2014.

OPERATING INCOME (LOSS) BY SEGMENT

OSUR Segment

OSUR's gross margin was 57% in both the first half of 2014 and 2013.

Research and development expenses decreased 17% to \$4.0 million in the first half of 2014 from \$4.8 million in the first half of 2013 largely due to lower clinical trial and staffing costs. Sales and marketing expenses decreased 21% to \$17.9 million in the first half of 2014 from \$22.8 million in the first half of 2013. This decrease was primarily the result of lower advertising and promotional costs for our OraQuick® In-Home HIV test which totaled \$7.6 million in the first half of 2014, compared to \$12.3 million in the first half of 2013. This reduction was the result of our decision to focus our marketing and promotional efforts at the retail outlet level and transition away from broad-based consumer advertising by the end of the first half of 2014. General and administrative expenses increased 13% to \$10.1 million in the first half of 2014 from \$8.9 million in the first half of 2013 due to higher legal expenses, staffing related costs and consulting costs.

All of the above, along with the \$5.5 million payment from Roche, contributed to OSUR's operating loss of \$4.2 for the first half of 2014, million, which included non-cash charges of \$1.6 million for depreciation and amortization and \$2.7 million for stock-based compensation.

DNAG Segment

DNAG's gross margin was 72% in the first half of 2014 compared to 65% in the first half of 2013. This increase was directly attributable to an increased volume of high margin sales experienced in the first half of 2014 when compared to the first half of 2013.

DNAG operating expenses increased to \$6.6 million in the first half of 2014 from \$6.2 million in the first half of 2013. Research and development expenses remained relatively flat at \$1.3 million in the first half of 2014 and 2013. Sales and marketing expenses increased 6% to \$3.7 million in the first half of 2014 from \$3.5 million in the first half of 2013 largely due to higher staffing costs. General and administrative expenses increased 7% to \$1.6 million in the first half of 2014 from \$1.5 million in the first half of 2013 also due to higher staffing expenses.

All of the above contributed to DNAG's operating income of \$1.1 million for the first half of 2014, which included non-cash charges of \$1.5 million for depreciation and amortization and \$206,000 for stock-based compensation.

CONSOLIDATED INCOME TAXES

We continue to believe the full valuation allowance established in 2008 against OSUR's total U.S. net deferred tax asset is appropriate as the facts and circumstances necessitating the allowance have not changed. As a result, no U.S. income tax benefit was recorded for OSUR's pre-tax loss in the first half of 2014 or 2013. For the six months ended June 30, 2014 and 2013, we recorded Canadian income tax benefits of \$43,000 and \$659,000, respectively, associated with certain Canadian research and development and investment tax credits and DNAG's loss before income taxes. The Canadian income tax benefits are considered realizable based upon the scheduled reversal of the deferred tax liabilities recorded in connection with the acquisition of DNAG.

Liquidity and Capital Resources

	June 30, 2014	December 31, 2013
	(In thousands)	
Cash	\$ 75,832	\$ 93,191
Working capital	101,098	100,590

Our cash balances decreased \$17.4 million to \$75.8 million at June 30, 2014 from \$93.2 million at December 31, 2013. Our working capital increased to \$101.1 million at June 30, 2014 from \$100.6 million at December 31, 2013.

During the first six months of 2014, we used \$10.4 million in cash to finance our operating activities. Our net loss of \$3.1 million was partially offset by non-cash stock-based compensation expense of \$2.9 million, depreciation and amortization expense of \$3.1 million and unrealized foreign currency loss of \$139,000. An additional large use of cash in operating activities included a \$6.0 million increase in prepaid expenses and other current assets largely due to the \$5.5 million receivable from Roche and the \$775,000 exclusivity payment due from AbbVie. Also contributing to the use of cash was a \$3.8 million decrease in accrued expenses and other liabilities associated with payment of our 2013 management incentive bonuses, royalty obligations, and certain year-end accruals, a \$1.8 million increase in inventory associated with our infectious disease products, a \$1.2 million increase in accounts receivable resulting from the timing of orders during the current quarter, a \$418,000 increase in deferred revenues associated with increased customer prepayments, and a \$179,000 decrease in accounts payable.

We used a total of \$6.4 million in investing activities during the first six months of 2014 to purchase \$4.4 million in short-term investments and \$2.0 million to acquire property and equipment.

Net cash used in financing activities was \$437,000 for the six months ended June 30, 2014, which resulted from the use of \$639,000 for the repurchase of common stock related to the vesting of restricted shares, partially offset by \$202,000 in proceeds received from the exercise of stock options.

Our current cash balance is expected to be sufficient to fund our current operating and capital needs through at least the next twelve months. Our cash requirements, however, may vary materially from those now planned due to many factors, including, but not limited to, the scope and timing of future strategic acquisitions, the progress of our research and development programs, the scope and results of clinical testing, the cost of any future litigation, the magnitude of capital expenditures, changes in existing and potential relationships with business partners, the timing and cost of obtaining regulatory approvals, the costs involved in obtaining and enforcing patents, proprietary rights and any necessary licenses, the cost and timing of expansion of sales and marketing activities, market acceptance of new products, competing technological and market developments, the impact of the current economic environment and other factors.

Summary of Contractual Obligations

A summary of our obligations to make future payments under contracts existing at December 31, 2013 is included in Item 7, Management's Discussion and Analysis of Financial Condition and Results of Operations, of our Annual Report on Form 10-K for the year ended December 31, 2013. As of June 30, 2014, there were no significant changes to this information, including the absence of any off-balance sheet arrangements.

Critical Accounting Policies and Estimates

This Management's Discussion and Analysis of Financial Condition and Results of Operations discusses our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these consolidated financial statements requires that we make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. On an on-going basis, we evaluate our judgments and estimates, including those related to the valuation of accounts receivable, inventories and intangible assets, as well as calculations related to contingencies and accruals. We base our judgments and estimates on historical experience and on various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

A more detailed review of our critical accounting policies is contained in our 2013 Annual Report on Form 10-K filed with the SEC. During the first six months of 2014, there were no material changes in our critical accounting policies.

Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We do not hold any amounts of derivative financial instruments or derivative commodity instruments and, accordingly, we have no material derivative risk to report under this Item.

As of June 30, 2014, we did not have any foreign currency exchange contracts or purchase currency options to hedge local currency cash flows. We have operations in Canada and Europe, which are subject to foreign currency fluctuations. As currency rates change, translation of revenues and expenses for these operations from foreign currencies to U.S. dollars affects year-to-year comparability of operating results. Sales denominated in a foreign currency comprised 7% of our total revenues for the six months ended June 30, 2014 (including revenues from DNAG). We expect our international business will continue to grow and our exposure to fluctuations in foreign currency exchange rates may increase.

Item 4. CONTROLS AND PROCEDURES

(a) Evaluation of Disclosure Controls and Procedures. The Company's management, with the participation of the Company's Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934) as of June 30, 2014. Based on that evaluation, the Company's management, including such officers, concluded that the Company's disclosure controls and procedures were adequate and effective as of June 30, 2014 to ensure that information required to be disclosed by the Company in the reports that we file or submit under the Securities Exchange Act of 1934 was accumulated and communicated to the Company's management, including the Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosure and was recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the SEC.

(b) Changes in Internal Control Over Financial Reporting. There was no change in the Company's internal control over financial reporting that occurred during the three months ended June 30, 2014 that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

PART II. OTHER INFORMATION**Item 1A. RISK FACTORS**

There have been no material changes to the factors disclosed in Item 1A., entitled “Risk Factors,” in our Annual Report on Form 10-K for the year ended December 31, 2013.

Item 2. UNREGISTERED SALE OF EQUITY SECURITIES AND USE OF PROCEEDS

During the quarter ended June 30, 2014, pursuant to the OraSure Technologies, Inc. Stock Award Plan, and in connection with the vesting of restricted shares, we retired 17,418 shares of our common stock to satisfy minimum tax withholding obligations at an average price paid per share of \$6.76.

Item 6. EXHIBITS

Exhibits are listed on the Exhibit Index following the signature page of this Report.

SIGNATURES

Pursuant to the requirements 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.

ORASURE TECHNOLOGIES, INC.

/s/ Ronald H. Spair

Ronald H. Spair
Chief Operating Officer and
Chief Financial Officer
(Principal Financial Officer)

Date: August 6, 2014

/s/ Mark L. Kuna

Mark L. Kuna
Senior Vice President, Finance and Controller
(Principal Accounting Officer)

Date: August 6, 2014

EXHIBIT INDEX

Exhibit

10.1	Master Program Services and Co-Promotion Agreement, dated as of June 10, 2014, between OraSure Technologies, Inc. and AbbVie Bahamas Ltd.*
10.2	Amendment to OraSure Technologies, Inc. Stock Award Plan, effective May 22, 2014.**
31.1	Certification of Douglas A. Michels required by Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended.
31.2	Certification of Ronald H. Spair required by Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended.
32.1	Certification of Douglas A. Michels required by Rule 13a-14(b) or Rule 15d-14(b) under the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Ronald H. Spair required by Rule 13a-14(b) or Rule 15d-14(b) under the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

* Portions of this exhibit have been redacted pursuant to a confidential treatment request filed with the SEC on August 6, 2014.

** Compensation plan or arrangement.

CERTAIN INFORMATION IN THIS DOCUMENT HAS BEEN OMITTED AND FILED
SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.
SUCH OMISSIONS DENOTED WITH [***].

Execution Version
[Redacted]

MASTER PROGRAM SERVICES AND PRODUCT CO-PROMOTION AGREEMENT

This Master Program Services and Product Co-Promotion Agreement (this “**Agreement**”) is made and entered into effective as of June 10, 2014 (the “**Effective Date**”) by and between **ORASURE TECHNOLOGIES, INC.**, a Delaware corporation having a principal place of business at 220 East First Street, Bethlehem, Pennsylvania 18015 (“**OraSure**”), and **ABBVIE BAHAMAS LTD.** a Bahamian limited corporation having a principal place of business at Sassoon House, Shirley Street & Victoria Avenue, PO Box SS-5383, Nassau, New Providence, Bahamas (“**AbbVie**”). OraSure and AbbVie are sometimes referred to herein individually as a “**Party**” and collectively as the “**Parties**.”

RECITALS

WHEREAS, OraSure has developed, and manufactures, markets, distributes and sells, the OraQuick® HCV Rapid Antibody Test (U.S. Food and Drug Administration (“**FDA**”) Premarket Approval No. P080027, as amended), an FDA-approved, CLIA-waived point of care diagnostic test utilized for detecting HCV antibodies in humans (the “**Product**”);

WHEREAS, AbbVie has a sales force of a size and nature suitable for effective promotion of the Product in the Field in the Territory;

WHEREAS, AbbVie has developed a continuity of care model that involves a variety of community outreach initiatives developed consistent with AbbVie internal policies and procedures and intended to address HCV patient education, testing, diagnosis, and treatment needs (the “**Care Model**”);

WHEREAS, the Care Model is intended to help improve clinical outcomes by providing individuals the information and understanding necessary to participate in the detection and management of HCV through the use of FDA-approved therapies for the treatment of such condition;

WHEREAS, OraSure and AbbVie desire to co-promote the Product in order to promote education and the early diagnosis, testing, and detection to appropriate individuals in the Field in the Territory with respect to HCV;

WHEREAS, in furtherance of the foregoing: (A) AbbVie desires to engage OraSure to provide certain services, and OraSure desires to provide such services, on the terms and conditions set forth in this Agreement and in each individual statement of work for engagements set forth in a statement of work (each such statement of work a “**Statement of Work**”) executed

by both Parties (individually and collectively referred to herein as the “**OraSure Services**”); and (B) OraSure desires to engage AbbVie to provide certain services, and AbbVie desires to provide such services, on the terms and conditions set forth in this Agreement and any Statement of Work (individually and collectively referred to herein as the “**AbbVie Services**”); and

WHEREAS, a primary component of the OraSure Services, which is essential to the implementation and success of the Care Model, is OraSure’s development and ongoing maintenance of a proprietary database into which data relating to individuals who are tested with the Product in the Field in the Territory and who choose to opt-in to the Care Model, indicating interest and consent to receive materials from AbbVie regarding HCV generally and regarding FDA-approved therapies (“**Patient Care Database**”).

NOW, THEREFORE, in consideration of the premises and the mutual promises and conditions hereinafter set forth, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, do hereby agree as follows:

ARTICLE 1 DEFINITIONS

Unless otherwise specifically provided herein, the following terms shall have the following meanings:

1.1 “AbbVie” has the meaning set forth in the preamble, and shall include its successors and permitted assigns.

1.2 “AbbVie Competitors” has the meaning set forth in Exhibit A.

1.3 “AbbVie Indemnitees” has the meaning set forth in Section 7.1.

1.4 “AbbVie Services” has the meaning set forth in the Recitals.

1.5 “AbbVie Trademarks” has the meaning set forth in Section 2.11.

1.6 “Accounting Standards” means United States Generally Accepted Accounting Principles (“**G.A.A.P.**”) or International Financial Reporting Standards (“**IFRS**”), in each case consistently applied.

1.7 “Accrued Exclusivity Amount” has the meaning set forth in Section 4.2(a).

1.8 “Acquiror Product” has the meaning set forth in Section 2.2(c).

1.9 “ADR” has the meaning set forth in Section 9.4(c).

1.10 “Affiliate” means, with respect to a Party, any Person that, directly or indirectly, through one (1) or more intermediaries, controls, is controlled by or is under common control with such Party. For purposes of this definition, “control” and, with correlative meanings, the terms “controlled by” and “under common control with” means: (a) the possession, directly or

indirectly, of the power to direct the management or policies of a Person, whether through the ownership of voting securities, by contract relating to voting rights or corporate governance, or otherwise; or (b) the ownership, directly or indirectly, of more than fifty percent (50%) of the voting securities or other comparable ownership interest of a Person (or, with respect to a limited partnership or other similar entity, its general partner or controlling entity).

1.11 “Agreement” has the meaning set forth in the preamble, and shall include this Agreement as amended or modified.

1.12 “Aggregate Exclusivity Amount” has the meaning set forth in Section 4.2(a).

1.13 “Annual Minimum Patient Care Database Threshold” has the meaning set forth in Section 8.1(b).

1.14 “Applicable Law(s)” means federal, state, local, national and supra-national laws, statutes, rules, and regulations, including any rules, regulations, guidelines, or other requirements of the Regulatory Authorities, major national securities exchanges or major securities listing organizations, that may be in effect from time to time during the Term and applicable to a particular activity hereunder.

1.15 “Audit Arbitrator” has the meaning set forth in Section 4.5.

1.16 “Breaching Party” has the meaning set forth in Section 8.2.

1.17 “Business Day” means a day other than a Saturday or Sunday on which banking institutions in New York, New York are open for business.

1.18 “Calendar Quarter” means each successive period of three (3) calendar months commencing on January 1, April 1, July 1 and October 1, except that the first Calendar Quarter of the Term shall commence on the Effective Date and end on the day immediately prior to the first to occur of January 1, April 1, July 1 or October 1 after the Effective Date, and the last Calendar Quarter shall end on the last day of the Term.

1.19 “Calendar Year” means each successive period of twelve (12) calendar months commencing on January 1 and ending on December 31, except the first Calendar Year of the Term shall commence on the Effective Date and end on December 31, 2015 and the last Calendar Year of the Term shall commence on January 1 of the year in which the Term ends and end on the last day of the Term.

1.20 “Care Model” has the meaning set forth in the Recitals and shall include the Care Model as amended or modified.

1.21 “Change of Control” means: (a) the acquisition, directly or indirectly, by any Person or group of related Persons (other than any Person that controls, is controlled by or is under common control with a party) of beneficial ownership (as such term is defined in Rule 13d-3 promulgated under the Securities Exchange Act of 1934, as amended) of securities possessing more than fifty percent (50%) of the total combined voting power of a Party’s outstanding securities; (b) a merger or consolidation in which securities possessing more than

fifty percent (50%) of the total combined voting power of such Party's outstanding securities are transferred to a Person or Persons different from the Persons holding those securities immediately prior to such transaction; or (c) the sale, transfer, exclusive license or other disposition of all or substantially all of such Party's assets (determined on a consolidated basis). For purposes of this definition, the term "control" including the term "controlling" means the possession of, directly or indirectly, the capability to control the direction of the management and policies of a Party, whether through the ownership of shares, by contract or otherwise. For purposes of this definition of "Change of Control" a Person shall not be deemed to have either "voting power" in clause (b) above or "beneficial ownership" in clause (a) above if such "voting power" or "beneficial ownership" (as applicable) is the result of an agreement, arrangement or understanding to vote such applicable securities where such agreement, arrangement or understanding arises solely from a revocable proxy given in response to a proxy or consent solicitation made pursuant to, and in accordance with, the applicable provisions of the Securities Exchange Act of 1934 and the regulations thereunder, as amended from time to time.

1.22 "Change of Laws" has the meaning set forth in [Section 8.6](#).

1.23 "Commercially Reasonable Efforts" means, where applied to carrying out specific tasks and obligations of a Party under this Agreement, expending (on its own and/or acting through any of its Affiliates, agents or subcontractors) reasonable, diligent, good faith efforts and resources to accomplish such task or obligation as a similarly situated company would normally use to accomplish a similar task or obligation under similar circumstances.

1.24 "Complaint" means a written, electronic or oral communication or expression of dissatisfaction that alleges deficiencies related to the Product, including the identity, quality, labeling, safety, accuracy or performance of the Product.

1.25 "Confidential Information" means any and all non-public information provided orally, visually, in writing or other form by or on behalf of one (1) Party (or an Affiliate or Representative of such Party) to the other Party (or to an Affiliate or Representative of such Party) in connection with this Agreement, including information relating to the terms of this Agreement, the disclosing Party's (or its Affiliate's or Representative's) business, financial information and data, research and development plans, methods, concepts, know-how and data, scientific and technical data, technology, manufacturing and production data, product information, customer and supplier information, business development, marketing and sales plans and data and any other materials that have not been made to the general public by the disclosing Party (or an Affiliate or Representative of such Party). Confidential Information does *not* include patient information or other personal medical information or data obtained pursuant to this Agreement.

1.26 "Control", "Controls" or "Controlled" means, with respect to any Intellectual Property Rights, material or item of a Person, the ability of such Person (whether through ownership or license (other than a license granted in this Agreement) to grant to the other Party and/or its Affiliates, as applicable, the licenses, sublicenses or rights as provided herein without violating the terms of any then-existing agreement with any Third Party and without creating or increasing any payment obligation to a Third Party, including any royalty or milestone payment.

1.27 “Convicted Entity” has the meaning set forth in Section 5.2(i).

1.28 “Convicted Individual” has the meaning set forth in Section 5.2(i).

1.29 “Co-Payment Assistance” has the meaning set forth in Section 2.4(b).

1.30 “Co-Payment Assistance Program” has the meaning set forth in Section 2.4(b).

1.31 “Co-Promotion” means the activities associated with the promotion, marketing and Detailing of the Product in the Field in the Territory as contemplated by this Agreement.

1.32 “Co-Promotion Committee” has the meaning set forth in Section 2.6(a).

1.33 “Co-Promotion Fees” has the meaning set forth in Section 4.1.

1.34 “Co-Promotion Plan” means, for any period during the Term, a written plan mutually agreed upon by the Parties pursuant to Section 2.5 that sets forth the key elements of the sales and marketing strategy for the Product in the Field in the Territory, including, but not limited to, plans for promotional materials, advertising and number of Details.

1.35 “Current Good Manufacturing Practices” or “CGMP” means the current standards for manufacture, as set forth in the FFDCA and applicable regulation and guidelines promulgated thereunder or successors thereto and any Applicable Law, as shall be in effect from time to time during the Term.

1.36 “Database Establishment, Ownership and Exclusivity Fees” has the meaning set forth in Section 4.2(a).

1.37 “Database Exclusivity” has the meaning set forth in Section 2.2(a)(i).

1.38 “Debarred Entity” has the meaning set forth in Section 5.2(i).

1.39 “Debarred Individual” has the meaning set forth in Section 5.2(i).

1.40 “Default Notice” has the meaning set forth in Section 8.2.

1.41 “Detail” or “**Detailing Activities**” means a face-to-face contact between a sales representative and a physician or other medical or health care professional licensed or authorized under Applicable Law to administer the Product, during which a secondary position detail is made to such Person in order to market and promote the Product, during which contact (i) approved Product Promotional Materials and (ii) scientific or medical information about the Product are discussed in an effort to educate HCPs regarding the administering of the Product for its Labeled Use; it being understood and agreed that (a) a Detail does not include a reminder or sample drop (or other comparable activity), and (b) Details shall be measured by each Party’s internal recording of such activity (provided that such measurement shall be on the same basis as the recording Party’s measurement for its sales representatives detailing of such recording Party’s other products, consistently applied through the Term); *provided*, that such meeting is consistent with and in accordance with the requirements of Applicable Law and this Agreement. A

“secondary position detail” is one in which the promotional message involving the Product is presented in the second position and is a principal topic of discussion. When used as a verb, “Detail” means to engage in a Detail.

1.42 “Dispute” has the meaning set forth in Section 9.4(c).

1.43 “Dollars” or “\$” means United States Dollars.

1.44 “Effective Date” has the meaning set forth in the preamble.

1.45 “Excluded Entity” has the meaning set forth in Section 5.2(i).

1.46 “Excluded Individual” has the meaning set forth in Section 5.2(i).

1.47 “Exclusivity” has the meaning set forth in Section 2.2(b).

1.48 “Exclusivity Period” has the meaning set forth in Section 4.2(a).

1.49 “Exclusivity Refund” has the meaning set forth in Section 4.2(a).

1.50 “Exclusivity Shortfall” has the meaning set forth in Section 4.2(a).

1.51 “FDA” means the United States Food and Drug Administration and any successor agency(ies) or authority having substantially the same function.

1.52 “FDA’s Disqualified/Restricted Lists” has the meaning set forth in Section 5.2(i).

1.53 “FFDCA” means the United States Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, as amended from time to time, together with any rules, regulations and requirements promulgated thereunder (including all additions, supplements, extensions, and modifications thereto).

1.54 “Field” means the following: (a) physician- or nurse-administered clinics at retail pharmacies; (b) primary care physician offices; (c) specialist care offices consisting of gastroenterologists, hepatologists and infectious disease specialists; (d) employers or employer groups mutually agreed by the Parties in writing; and (e) physician- or nurse-administered clinics organized by the Healthy Truckers Association of America and/or, if mutually agreed in writing by the Parties, other Third Parties.

1.55 “Future Product” means any product, other than the Product, and all improvements to such product, that OraSure Controls at any time during the Term, that is used for the point-of-care detection of HCV antibodies in humans.

1.56 “Good Manufacturing Practice” or “GMP” means the current good manufacturing practices applicable from time to time to the manufacturing of the Product, any Product intermediate or components or accessories of the Product pursuant to Applicable Law.

1.57 “Guiding Principles” means the principles for determining the Parties’ respective responsibilities for the co-promotion of the Product and the terms of each Statement of Work, as set forth in Exhibit F.

1.58 “HCP” means: (a) health care providers qualified to prescribe, recommend, or administer the Product, in each case who are authorized by Applicable Law to authorize, utilize, or prescribe the Product; and (b) any associated staff who need to be educated about the Product (including logistics related to the Product), including nurses, laboratory technicians, physician assistants, and administrative staff.

1.59 “HCV” means the hepatitis C virus.

1.60 “HIPAA” has the meaning set forth in Section 5.2(a).

1.61 “HIPAA Authorization Form” has the meaning set forth in Section 2.4(b)(i).

1.62 “HTAA Statement of Work” has the meaning set forth in Section 2.4(a).

1.63 “Indemnified Claim Notice” has the meaning set forth in Section 7.3.

1.64 “Indemnified Party” has the meaning set forth in Section 7.3.

1.65 “Intellectual Property Rights” means all rights, privileges and priorities provided under federal, state, foreign and multinational law relating to intellectual property, including all: (a) (i) U.S. and foreign patents and patent applications, inventions, discoveries, machines, manufactures, compositions of matter, processes, formulae, designs, methods, techniques, procedures, concepts, developments, technology, new and useful improvements thereof and know-how relating thereto, whether or not patented or patentable; (ii) copyrights and works of authorship, including computer applications, programs, software, hardware, files, mask works, compilations, databases, documentation and related items; (iii) Trademarks; and (iv) trade secrets, drawings, lists and all other proprietary, nonpublic or confidential information, documents or materials in any media; and (b) all registrations, applications, recordings and other legal protections or rights related to the foregoing.

1.66 “Labeled Uses” means the diagnostic indications covered by the Marketing Authorization for the Product.

1.67 “Litigation Conditions” has the meaning set forth in Section 7.4(a).

1.68 “Losses” has the meaning set forth in Section 7.1.

1.69 “Maintenance Services Payment” has the meaning set forth in Section 4.2(b).

1.70 “Marketing Authorization” means the regulatory authorization required to market, promote and sell the Product in the Field in the Territory.

1.71 “Marketing Consent Form” has the meaning set forth in Section 2.4(b)(i).

1.72 “Non-Breaching Party” has the meaning set forth in Section 8.2.

1.73 “Non-Governmental Payor Patients” has the meaning set forth in Section 2.4(b).

1.74 “OraSure” has the meaning set forth in the preamble and shall include its successors and permitted assigns.

1.75 “OraSure Indemnitees” has the meaning set forth in Section 7.2.

1.76 “OraSure Exclusivity” has the meaning set forth in Section 2.2(b)(i).

1.77 “OraSure Intellectual Property” means any and all Intellectual Property Rights exclusively or non-exclusively Controlled by OraSure or its Affiliates during the Term that are required for AbbVie to carry out its obligations to promote, market and Detail the Product under this Agreement.

1.78 “OraSure Services” has the meaning set forth in the Recitals.

1.79 “OraSure Trademarks” has the meaning set forth in Section 2.11(a).

1.80 “Paid Exclusivity Fees” has the meaning set forth in Section 4.2(a).

1.81 “Party” or **“Parties”** has the meaning set forth in the preamble.

1.82 “Patient(s)” means those individuals who are tested for HCV through the administration of the Product by an HCP in the Field in the Territory.

1.83 “Patient Care Database” has the meaning set forth in the Recitals.

1.84 “Patient Forms” has the meaning set forth in Section 2.4(b)(i).

1.85 “Patient Information” has the meaning set forth in Section 2.4(b)(i).

1.86 “Person” means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, unincorporated association, joint venture or other similar entity or organization, including a government or political subdivision, department or agency of a government.

1.87 “Personal Data” has the meaning set forth in Section 3.3.

1.88 “Process” or **“Processing”** has the meaning set forth in Section 3.3.

1.89 “Product” has the meaning set forth in the recitals and includes any future modifications, variations, revisions or improvements thereto, to the extent such modified, varied, revised or improved product is covered by the same FDA premarket approval identified in the recitals, as such approval may be supplemented from time to time, and, subject to Section 2.2(c), Future Products.

1.90 “Product Promotional Materials” has the meaning set forth in Section 2.7(b).

1.91 “Regulatory Authority” means any applicable supra-national, federal, national, regional, state, provincial, or local governmental or regulatory authority, agency, department, bureau, commission, council, or other entities regulating or otherwise exercising authority with respect to activities contemplated in this Agreement.

1.92 “Representatives” of a Party or any of its Affiliates means the officers, directors, employees and agents of such Party or Affiliate.

1.93 “Right of First Refusal” has the meaning set forth in Section 2.2(c).

1.94 “Sales Force” means the field-based sales representatives employed by or on behalf of AbbVie or OraSure, as the case may be, for Co-Promoting the Product in the Field in the Territory to the HCPs. Either Party’s Sales Force may include sales representatives engaged through an arrangement with a contract sales organization or other Third Party.

1.95 “Samples” mean free samples of the Product distributed by OraSure to a HCP.

1.96 “Security Breach” has the meaning set forth in Section 3.3(d).

1.97 “Senior Officer” means, with respect to OraSure, its Chief Executive Officer or his/her designee, and with respect to AbbVie, its VP of Specialty Brands or his/her designee.

1.98 “Statement of Work” has the meaning set forth in the Recitals and shall include any modifications or amendments thereto.

1.99 “Term” has the meaning set forth in Section 8.1.

1.100 “Territory” means the United States of America (including the District of Columbia) and its territories and possessions, including but not limited to Puerto Rico.

1.101 “Third Party” means any Person other than OraSure, AbbVie and their respective Affiliates.

1.102 “Third Party Claim” has the meaning set forth in Section 7.1.

1.103 “Third Party Provider” has the meaning set forth in Section 3.2.

1.104 “Trademark” means any word, name, symbol, color, designation or device or any combination thereof that functions as a source identifier, including any trademark, trade dress, brand mark, service mark, trade name, brand name, logo, business symbol or domain names, whether or not registered.

ARTICLE 2
SERVICES AND CO-PROMOTION OF THE PRODUCT

2.1 Grant of Co-Promotion Rights. During the Term, OraSure hereby grants to AbbVie and its Affiliates (to the extent such Affiliates are Co-Promoting the Product), the co-exclusive right (solely with OraSure and its Affiliates) to Co-Promote the Product in the Field in the Territory and to conduct its obligations under this Agreement, as permitted under and subject to the terms and conditions set forth in this Agreement.

2.2 Exclusivity.

(a) Patient Care Database Exclusivity.

(i) During the Term, and subject to Section 2.2(a)(iii), OraSure will develop and establish the Patient Care Database for, and on behalf of, and for the sole and exclusive benefit of, AbbVie, and hereby grants AbbVie exclusivity with respect to the Patient Care Database and the Intellectual Property Rights therein (such exclusivity, the “**Database Exclusivity**”). OraSure shall not, and shall cause its Affiliates and Representatives to not, directly or indirectly, enter into any arrangement with any Third Party (other than with Third Party Provider(s) engaged by OraSure or its Affiliates to develop, operate and maintain the Patient Care Database) to provide access to, allow the reverse engineering of, or otherwise permit or facilitate the ability of any Third Party (except as permitted above) to use or access the Patient Care Database or, except as may be required by Applicable Law or the order of a court or Regulatory Authority, provide any list, data or other information from the Patient Care Database to any such Third Party or otherwise commercialize the Patient Care Database.

(ii) Additionally, upon the termination or nonrenewal of this Agreement at any time, for any reason, subject to the terms of Section 8.7(d) and AbbVie fulfilling its payment obligations pursuant to Section 4.2 below, OraSure and its Affiliates shall no longer access or use the Patient Care Database or, subject to Section 2.2(a)(iii), any data or information therefrom, and AbbVie shall have such rights with respect thereto, including Intellectual Property Rights, as set forth in Section 8.7(d).

(iii) Notwithstanding Sections 2.2(a)(i) and (ii), OraSure shall have the right to use any data or information from the Patient Care Database as follows: (A) to verify the amount of Maintenance Services Payments required to be paid by AbbVie hereunder, (B) to administer and maintain the Patient Care Database, and (C) in anonymized form not containing Personal Data for OraSure’s marketing purposes.

(b) Product Exclusivity.

(i) For the duration of the Term, OraSure and its Affiliates shall not, directly or indirectly, enter into any arrangement in the Territory to co-promote, market, Detail or sell the Product in the Field in the Territory (“**OraSure Exclusivity**” and, collectively, with the Database Exclusivity, sometimes referred to herein as the “**Exclusivity**”). Notwithstanding the foregoing, the OraSure Exclusivity does not prohibit or restrict OraSure from (A) promoting, marketing, Detailing or selling the Product directly or through or with any distributor, subcontractor, agent, sales representative or other Third Party that is not an AbbVie Competitor, (B) engaging in or undergoing a Change of Control, or (C) entering into any arrangement to sell Product to Persons that are provided grants or other funding, directly or indirectly, by an AbbVie Competitor.

(ii) For the duration of the Term, AbbVie and its Affiliates shall not, directly or indirectly, on their own or through any arrangement with any Person, promote, co-promote, market, Detail or sell any diagnostic test in the Territory that is utilized for detecting HCV antibodies in humans (other than the Product with OraSure).

(c) *Future Products*. If during the Term OraSure Controls a Future Product and OraSure decides to commercialize such Future Product in the Field in the Territory, AbbVie shall have the right of first refusal to co-promote such Future Product in the Field in the Territory (the “**Right of First Refusal**”). In such case, OraSure shall promptly notify AbbVie in writing setting forth information about such Future Product as is reasonably requested by AbbVie. For clarity, this Section 2.2(c) shall not apply in the event a Third Party acquires OraSure and the Third Party (or any of such Third Party’s then-existing Affiliates) already has a product that would constitute a Future Product and would otherwise fall within the scope of this Section 2.2(c) (an “**Acquiror Product**”), and such Acquiror Product shall not be subject to this Section 2.2(c) or otherwise be included in the definition of “**Product**” hereunder.

(i) If AbbVie wishes to co-promote such Future Product in the Territory, AbbVie shall, within thirty (30) days following receipt of OraSure’s written notification, deliver to OraSure written notice of AbbVie’s intent to co-promote such Future Product.

(ii) If AbbVie does not deliver to OraSure written notice of its intent to co-promote a Future Product within such thirty (30) day period, then OraSure shall be free to negotiate and enter into a co-promotion agreement or similar agreement for the relevant Future Product in the Field in the Territory with any Third Party.

2.3 AbbVie Obligations.

(a) AbbVie shall utilize Commercially Reasonable Efforts to (in all cases in accordance with the terms and conditions of this Agreement, Applicable Law, and AbbVie policies and procedures regarding interactions with HCPs and use of promotional materials) (i) Co-Promote the Product in the Field in the Territory through the AbbVie Sales Force pursuant to its respective responsibilities set forth in the Co-Promotion Plan; (ii) develop, deploy, make available to Patients and maintain the Care Model during the Term in the Field in the Territory in accordance with the terms and conditions of this Agreement and Applicable Law; and (iii) introduce physicians and other HCPs in the Field to, and obtain the participation of physicians and other HCPs in the Field in, the Care Model; in each case subject to and in accordance with the Guiding Principles. In addition, as part of its Co-Promotion efforts, AbbVie agrees to Detail the Product to primary care physicians, gastroenterologists, hepatologists and infectious disease specialists in the Territory and provide the minimum number of Details set forth in Section 4.1(b), in the approximate proportions set forth in the Guiding Principles. Notwithstanding the foregoing, AbbVie shall have the sole discretion with respect to determining the deployment of the AbbVie Sales Force, subject to the terms and conditions of this Agreement, including the Co-Promotion Plan.

2.4 OraSure Obligations.

(a) AbbVie and OraSure are entering into this Agreement with the understanding that OraSure will provide OraSure Services as further set forth in Article 3 and for each engagement set forth in each Statement of Work, in substantially the form attached hereto as Exhibit C. In furtherance thereof, the Parties have entered into the Statement of Work attached hereto as Exhibit C-1 (the “**HTAA Statement of Work**”). Specifically, during the Term, OraSure shall utilize Commercially Reasonable Efforts (in all cases in accordance with the terms and conditions of this Agreement, Applicable Law and OraSure policies and procedures regarding interactions with HCPs and use of sales and marketing materials) to: (i) Co-Promote the Product in the Field in the Territory through the OraSure Sales Force pursuant to its respective responsibilities set forth in the Co-Promotion Plan; (ii) obtain or cause to be obtained and maintain or cause to be maintained from each Patient enrolling and participating in the Patient Care Database the relevant Marketing Consent Form and HIPAA Authorization Form; (iii) obtain or cause to be obtained and maintain or cause to be maintained the relevant Marketing Authorization and any other applicable regulatory approvals reasonably necessary to market and sell the Product in the Field in the Territory to the HCPs; (iv) distribute Patient Forms to HCPs; (v) manufacture and supply the Product to meet market demand all in accordance with CGMP and all Applicable Law; (vi) sell the Product to HCPs desiring to purchase Product in the Field in the Territory; and (vii) distribute the Product in the Field in the Territory; in each case subject to and in accordance with the Guiding Principles. OraSure shall also build and maintain the Patient Care Database pursuant to Section 3.1 and provide Care Model-related data reasonably requested by AbbVie to AbbVie.

(b) *Co-Payment Assistance Program*. OraSure has developed or is developing a co-payment assistance program for the Product exclusively for Non-Governmental Payor Patients (the “**Co-Payment Assistance Program**”) as described herein. For the duration of the Term, to the extent permitted by Applicable Law, OraSure shall exercise Commercially Reasonable Efforts to implement and administer, through a Third Party Provider or otherwise, the Co-Payment Assistance Program in the Field in the Territory. The amount of such co-payment assistance will be up to [***] per eligible Patient per unit of Product (the “**Co-Payment Assistance**”) paid to the party administering the HCV test using the Product. Administration details of the Co-Payment Assistance Program shall be determined by OraSure consistent with the Guiding Principles. The Co-Pay Assistance Program shall only be made available to Patients who have commercial medical insurance or who are uninsured (collectively, the “**Non-Governmental Payor Patients**”) and Co-Payment Assistance shall not be payable to any Patient, but rather shall be paid on behalf of such Patient to reduce the cost that a Patient would otherwise have incurred in connection with the use of the Product to perform the HCV test on the Patient. No Patient that receives benefits under a Federal health care program as defined at 42 U.S.C. §1320a-7b(f), a State health care program as defined at 42 U.S.C. §1320a-7(h), or any other federal, state, or local government funded health care program, shall be eligible to participate in the Co-Payment Assistance Program. Subject to Applicable Law, OraSure shall exercise Commercially Reasonable Efforts to encourage HCPs in the Field in the Territory who administer or intend to administer the Product to offer the Co-Payment Assistance Program to eligible Patients (excluding those Patients specified above) prior to the administration of the Product. OraSure shall be solely responsible for all costs and expenses associated with the Co-Payment Assistance Program.

[***] Portions of this page have been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

(i) OraSure will provide Co-Payment Assistance only to Patients who agree to participate in the Patient Care Database and who complete the following forms and securely submit the Patient Forms into the Patient Care Database: (A) authorization to disclose Patient's HCV diagnosis, other health or medical information, demographic information, including name and address, financial information and any other information provided in connection with the Co-Payment Assistance Program ("**Patient Information**") subsequent to the administration of the Product, as set forth in Exhibit D ("**HIPAA Authorization Form**"); and (B) consent to receipt of AbbVie marketing communications as set forth in Exhibit E ("**Marketing Consent Form**," collectively with the HIPAA Authorization Form, the "**Patient Forms**", as such Patient Forms may be reasonably modified by the Parties to comply with Applicable Law).

For clarity, a Patient shall not be required to participate in the Co-Payment Assistance Program in order to participate in the Patient Care Database. Additionally, nothing in this Agreement shall prevent any individual from having access to the Product or otherwise be interpreted as conditioning an individual's access to the Product on such individual electing to receive Co-Payment Assistance or otherwise consenting to participate in the Patient Care Database or the Care Model or to receive AbbVie marketing communications.

(ii) Except as otherwise provided in the Co-Promotion Plan or otherwise agreed to in writing, OraSure shall be prohibited from Detailing, promoting, discussing, selling, advertising for sale and communicating in any way (including verbally, using written materials or online communication) about, AbbVie's pharmaceutical products with any Person, including healthcare professionals, patients or any other actual or potential customer for AbbVie's pharmaceutical products, including any AbbVie products currently in development, that would result in a violation by OraSure of Applicable Law.

2.5 Product Co-Promotion Plan. Within sixty (60) days following the Effective Date, the Parties shall make their best effort to agree upon a Co-Promotion Plan which shall be attached hereto as Exhibit B, and which Co-Promotion Plan will specify in reasonable detail all Co-Promotion activities the Parties shall undertake in the Field in the Territory during the Term. The Co-Promotion Plan shall include, among other things, subject to and in accordance with the Guiding Principles, the following: (a) the targeted number of annual Details by customer group to be provided by AbbVie in the Field in the Territory; (b) Product positioning, strategy and tactics with supporting marketing and promotional activity to be undertaken; (c) a determination of the HCP accounts that are appropriate for Details; (d) any training programs to be conducted; (e) appropriate awareness, medical and education programs to be conducted; (f) professional and trade relations activities; (g) specifications for the development of Product Promotional Materials and training materials (including the specific types of such materials to be developed); (h) subsequent to the Co-Promotion Committee's formation, such other information relating to the marketing and sales of the Product as deemed advisable by the Co-Promotion Committee; (i) the projected budget for all of the activities and materials anticipated under such plan and the Parties' respective financial obligations; (j) a process for OraSure to communicate to AbbVie aggregate data recorded by OraSure in accordance with its standard record keeping procedures and which is related to the Co-Promotion of the Product, including Product sales and any other information reasonably requested by AbbVie on a periodic schedule (which may vary by type of information required and shall be subject to distributor or other Third Party limitations where OraSure relies

on such Third Parties for such data); (k) a process for AbbVie to report on Details conducted by it in the Field in the Territory and recorded by AbbVie in accordance with its standard record keeping procedures based on data recorded by the Sales Force, including the number of Details and the names, addresses and other contact information for the Detail recipients; and (l) a process for AbbVie to provide information to OraSure regarding its Co-Promotion efforts and installation of its Care Model in the Field in the Territory, and any other information reasonably requested by OraSure on a periodic schedule (which may vary by type of information required). For clarity, OraSure shall have sole responsibility for establishing and setting the sales price of the Product in the Field in the Territory and booking, billing, invoicing, and submitting claims of receivables and amounts due resulting from the sale of the Product in the Field in the Territory, and consummating the sale of, and distributing and selling, the Product in the Field in the Territory.

2.6 Product Co-Promotion Committee.

(a) *Establishment; Composition.* Within thirty (30) days following the Effective Date, the Parties shall make their best effort to establish a joint Product co-promotion committee (the “**Co-Promotion Committee**”). The Co-Promotion Committee shall consist of an equal number of representatives from each of the Parties, each with the requisite experience and seniority to enable such person to make decisions on behalf of the Parties with respect to issues falling within the jurisdiction of the Co-Promotion Committee, with at least one (1) representative of each Party required at all times to be the senior executive responsible within such Party for this Agreement. From time to time, subject to the foregoing sentence, each Party may substitute one (1) or more of its representatives to the Co-Promotion Committee with written notice to the other Party.

(b) *Meetings; Responsibilities.* The Co-Promotion Committee shall meet at least quarterly to: (i) review and discuss the strategies related to the Co-Promotion of the Product in the Field in the Territory, including a review of Product Promotional Materials and any and all OraSure development and commercialization plans relating directly or indirectly to the Product in the Field in the Territory, AbbVie, the Patient Care Database or the Care Program; (ii) periodically (no less often than quarterly) review and serve as a forum for discussing the Co-Promotion Plan and review and approve amendments thereto, as well as the Parties’ performance of the Co-Promotion Plan; (iii) oversee at a high level all Detailing in the Field in the Territory with respect to the Product, including the number, frequency and location of Details; (iv) review updates regarding any Product development, clinical, regulatory, manufacturing/supply and quality matters; and (v) perform such other functions as are set forth herein or as the Parties may mutually agree in writing, except where in conflict with any provision of this Agreement. For purposes of clarity, the Co-Promotion Committee shall not have any oversight of management responsibility or authority with respect to: (x) the manufacturing/supply or pricing of the Product; (y) the Marketing Authorization related to the Product; or (z) the distribution and sales of the Product by OraSure. The first meeting of the Co-Promotion Committee shall be held as soon as practicable after the Effective Date. Notwithstanding the creation of the Co-Promotion Committee, each Party shall retain the rights, powers and discretions granted to it pursuant to this Agreement. The Co-Promotion Committee shall not be delegated or vested with any rights, power or discretions unless expressly provided for in this Agreement. Without limiting the generality of the foregoing, the Co-Promotion Committee may not amend or modify this Agreement, which may only be amended or modified as set forth in [Section 9.6](#).

(c) *Procedural Rules.* The Co-Promotion Committee shall have the right to adopt such standing rules as shall be necessary for its work, to the extent that such rules are not inconsistent with this Agreement. A quorum of the Co-Promotion Committee shall exist whenever there is present at a meeting at least the senior executive directly responsible within each Party for this Agreement. Representatives of the Parties on the Co-Promotion Committee may attend a meeting either in person or by telephone, video conference or similar means in which each participant can hear what is said by, and be heard by, the other participants. Representation by proxy shall be permitted (other than for the senior executive directly responsible within each Party for this Agreement). The Co-Promotion Committee shall take action by agreement of the representatives present at a meeting at which a quorum exists, with each Party having a single vote irrespective of the number of representatives of such Party in attendance, or by a written resolution signed by at least one (1) representative appointed by each Party. Employees or consultants of either Party that are not representatives of the Parties on the Co-Promotion Committee may attend meetings; *provided*, that such attendees: (i) shall not vote or otherwise participate in the decision-making process of the Co-Promotion Committee; and (ii) are bound by obligations of confidentiality and non-disclosure set forth in this Agreement.

(d) *Minutes.* A representative of each Party, alternating between the Parties for each meeting of the Co-Promotion Committee (with OraSure having responsibility for the initial Co-Promotion Committee meeting), shall be responsible for preparing and circulating minutes of each meeting of the Co-Promotion Committee, setting forth, *inter alia*, an overview of the discussions at the meeting and a list of any actions, decisions or determinations approved by the Co-Promotion Committee. Such minutes shall be effective only after such minutes have been approved by both Parties in writing. Definitive minutes of all Co-Promotion Committee meetings shall be finalized no later than ten (10) Business Days after the meeting to which the minutes pertain.

(e) *Expenses.* Each Party shall bear its own costs associated with its participation in the Co-Promotion Committee, including the costs of travel and lodging and expenses directly associated with participation on the Co-Promotion Committee.

(f) *Dispute Resolution.* If the Co-Promotion Committee cannot, or does not, reach agreement on an issue at a meeting or within such other period as the Parties may agree, then the dispute shall be referred to the Senior Officers of the Parties, who shall confer in good faith on the resolution of the issue. Any final decision mutually agreed to by the Senior Officers shall be conclusive and binding on the Parties. If the Senior Officers are not able to agree on the resolution of any such issue within thirty (30) days after such issue was first referred to them, then such dispute shall be resolved as follows: (i) the Senior Officer of OraSure shall have final decision making authority with respect to all matters pertaining to the Product, including, subject to Section 2.7(b)(ii), Product Promotional Materials, Product training materials and content, and scripts to be used by the Parties' Sales Forces with respect to the Product (but excluding matters pertaining to the deployment of the AbbVie Sales Force), and (ii) the Senior Officer of AbbVie shall have final decision making authority with respect to all matters pertaining to the development, implementation and maintenance of the Care Model.

(g) *Limits on Decision Making Authority.* Notwithstanding Section 2.6(f), the Senior Officer of a Party shall not have the right to exercise its final decision-making authority to unilaterally: (1) determine that any obligations have been fulfilled under this Agreement or that a Party has breached any obligation under this Agreement; (2) determine that a milestone event required for the payment of a milestone payment has or has not occurred including, without limitation, the payments set forth in Article 4 herein; (3) make a decision that is expressly stated to require the mutual agreement of the Parties; (4) amend the Co-Promotion Plan to require the other Party to conduct any activities; or (5) otherwise expand a Party's rights or reduce a Party's obligations under this Agreement, including, without limitation, the payments set forth in Article 4 herein.

2.7 Product Promotion Matters.

(a) *Detailing Costs.* Except as set forth in Section 2.8 (with respect to the initial training of AbbVie personnel), AbbVie shall be responsible for all costs and expenses related to (i) establishing, maintaining and training the AbbVie Sales Force and conducting AbbVie's Detailing Activities pursuant to the Co-Promotion Plan, (ii) the Care Model, and (iii) awareness raising and educational activities regarding HCV and available treatments in connection with the Care Model. OraSure shall be responsible for all costs and expenses related to (i) establishing, maintaining or training the OraSure Sales Force, (ii) conducting OraSure's promotional activities pursuant to the Co-Promotion Plan, and (iii) the Co-Payment Assistance Program. Each Party also shall bear such costs and expenses for activities as may be specified in the Guiding Principles, the Co-Promotion Plan or any Statement of Work.

(b) Product Promotional Materials.

(i) Promptly following the Effective Date, OraSure shall provide to AbbVie physical or electronic copies of existing artwork or training, sales and promotional materials relating to the Product ("**Product Promotional Materials**"). Subject to Section 2.7(b)(ii), AbbVie may create new Product Promotional Materials, based on the existing OraSure materials or otherwise.

(ii) All Product Promotional Materials created or to be used by AbbVie shall be reviewed and approved promptly by the Parties in accordance with the mutually agreed upon review protocols prior to their use by AbbVie. AbbVie shall not be required to use any Product Promotional Materials that are not reviewed by and reasonably acceptable to AbbVie. AbbVie may not use any Product Promotional Materials that are not reviewed by and acceptable to OraSure, other than the Product Promotional Materials provided by OraSure to AbbVie for its use. If, after its review of any Product Promotional Materials (including any new materials introduced after the Effective Date), a Party believes that changes to any such Product Promotional Materials are required to comply with Applicable Law or other regulatory requirements, such proposed changes shall be reviewed by the Co-Promotion Committee. OraSure shall be responsible for ensuring that all Product Promotional Materials prepared or approved by OraSure comply with the Labeled Use, Applicable Law or other regulatory requirements applicable to the Product.

(iii) OraSure, at its sole cost and expense, shall provide to AbbVie physical or electronic copies of current OraSure Product Promotional Materials as reasonably requested by AbbVie in order for AbbVie to fulfill its Co-Promotion activities set forth in the Co-Promotion Plan; provided, that, AbbVie may produce additional approved Product Promotional Materials at its own cost and expense.

(iv) OraSure shall own, and AbbVie hereby assigns (on behalf of itself and its Affiliates) to OraSure, all rights, including all copyrights, in and to all Product Promotional Materials created by either Party or any of their respective Affiliates (other than those items which are subject to Third Party copyrights). OraSure shall, and does hereby, grant to AbbVie a royalty-free, non-exclusive license in the Field in the Territory during the Term to use, reproduce and distribute Product Promotional Materials or any other Product-related materials made available to AbbVie by OraSure hereunder, in each case, solely for the performance of AbbVie's Co-Promotion obligations pursuant to this Agreement.

2.8 Training. (a) OraSure shall cooperate with AbbVie to educate and train AbbVie's and, to the extent AbbVie's Affiliates employ sales and marketing personnel used to Co-Promote the Product, such Affiliates' sales and marketing representatives regarding the Product; *provided*, that such training shall be completed by no later than ninety (90) days after the Effective Date, it being understood that: (i) OraSure shall provide AbbVie, free of charge, with reasonable quantities of training materials which have been created and developed by OraSure relating to the Product; and (ii) AbbVie and its Affiliates shall not permit any of their respective sales personnel to Co-Promote the Product unless such sales personnel have been trained by OraSure (or AbbVie as provided below in this Section 2.8). AbbVie and its Affiliates referenced above shall make their respective sales representatives available for such training and participate in conducting such training. Training shall be carried out at times and locations that are mutually acceptable to the Parties. As additional members are added to AbbVie's or its Affiliates' Sales Forces responsible for Co-Promoting the Product, training will be provided to such newly added members by either OraSure or AbbVie using solely the training materials initially developed by OraSure, as mutually agreed upon by the Parties. The Parties shall mutually decide where the training of such sales representatives will occur and, unless the Parties agree otherwise in writing, AbbVie and OraSure will be responsible for the costs of transporting, housing and maintaining their respective personnel conducting or receiving such training. Any and all training materials and training assistance shall, at a minimum, address: (w) the HCV disease state; (x) Product knowledge; (y) obligations under this Agreement; and (z) any other information the Parties reasonably believe is necessary to Co-Promote the Product in the Field in the Territory. OraSure shall be responsible for providing additional training in the event Product circumstances change (including, but not limited, to labeling revisions or issuance of new instructions for use) on substantially the same terms as this Section 2.8(a).

(a) On such date as shall be agreed to by the Parties, AbbVie shall provide OraSure with reasonable training regarding the Care Model, including the information regarding the Care Model that the OraSure Sales Force may convey to customers in the Field. AbbVie shall provide OraSure, free of charge, with reasonable quantities of training and other materials which have been created and developed by AbbVie relating to the Care Model. The Parties shall mutually decide where the training of such sales representatives will occur and, unless the Parties agree otherwise in writing, AbbVie and OraSure will be responsible for the costs of transporting, housing and maintaining their respective personnel conducting or receiving such training.

2.9 Compliance with Laws. Each of the Party's Co-Promotion activities with respect to the Product shall be conducted: (a) in a manner which is consistent with the FFDCA, the Marketing Authorization and/or other regulatory requirements which are then in effect with respect to the Product; and (b) in compliance with Applicable Law, including all restrictions and regulations promulgated by the FDA or any other applicable Regulatory Authority. In addition, in performing its Co-Promotion duties hereunder, AbbVie shall, and shall cause its employees and Sales Force to, comply with all regulatory, professional and legal requirements, including, without limitation, the American Medical Association's Guidelines on Gifts to Physicians, the PhRMA Guidelines for Marketing Practices, the AdvaMed Code, and the ACCME Standards for Commercial Support of Continuing Medical Education, which may be applicable to the services to be provided by Co-Promotion Partner hereunder. No employee or Sales Force member of either Party shall make any representation, statement, warranty or guaranty with respect to the Product that is not consistent with current labeling of the Product or Product Promotional Materials approved by the Co-Promotion Committee, that is deceptive or misleading or that disparages the Product or the good name, goodwill and reputation of either Party. Both Parties shall use Commercially Reasonable Efforts to ensure that its services hereunder will be provided in a professional, ethical and competent manner.

2.10 Sampling. OraSure shall be permitted to provide co-branded samples of the Product to HCPs in the Field in the Territory; *provided*, that the number of Product samples each HCP is entitled to receive shall be limited to the number of Product samples reasonably necessary for the HCP to learn how to properly administer and interpret the test results of the Product, in accordance with all Applicable Laws and the AdvaMed Code, but in no event more than [***] Product units, *provided further* that OraSure may provide additional co-branded samples of the Product (not to exceed [***]) to any HCP that previously has received such samples as may be reasonably necessary for such HCP to refresh the HCP's learning of the proper administration and interpretation of test results of the Product. In addition, OraSure agrees: (a) not to provide any Samples or other free product of any type to AbbVie for distribution in any way; and (b) except for the Co-Payment Assistance Program and Product samples as set forth above, not to provide any remuneration or any financial incentive or free or discounted products of any type, including Products, to healthcare practitioners to get Patients to enroll in the Patient Care Database. OraSure shall be responsible for all recordkeeping, registration and listing, and all other requirements related to Product sampling under all Applicable Laws.

AbbVie and OraSure agree that all samples will be distributed by OraSure. To the extent that the Parties desire to use a coupon or voucher to enable HCPs to obtain Samples, AbbVie shall be permitted to distribute such coupons or vouchers, provided that (i) OraSure has provided its prior written consent to the use of such coupons or vouchers, and (ii) all such coupons and vouchers shall not exceed an amount which enables OraSure to comply with its obligations under this Section 2.10 above which limits the number of free Samples that can be distributed.

[***] Portions of this page have been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

2.11 Trademarks.

(a) During the Term, OraSure hereby grants to AbbVie and its Affiliates a non-exclusive, royalty-free right and license to use the OraSure Trademarks specified in Schedule 2.11 (the “**OraSure Trademarks**”) solely in connection with performing its obligations under this Agreement. AbbVie and its Affiliates may use the OraSure Trademarks on leaflets, brochures, advertising and Product Promotional Materials. Notwithstanding the foregoing, any usage of OraSure Trademarks by AbbVie or its Affiliates must be approved in advance by OraSure, which approval shall not be unreasonably withheld, delayed or conditioned. AbbVie shall ensure that each use of the OraSure Trademarks by it and its Affiliates is accompanied by an acknowledgement that the OraSure Trademarks are owned by OraSure.

(b) During the Term, AbbVie hereby grants to OraSure and its Affiliates a non-exclusive, royalty-free right and license to use the AbbVie Trademarks specified in Schedule 2.11 (the “**AbbVie Trademarks**”) solely in connection with performing its obligations under this Agreement. OraSure and its Affiliates may use the AbbVie Trademarks on leaflets, brochures, advertising and Product Promotional Materials and Product samples. Notwithstanding the foregoing, any usage of AbbVie Trademarks by OraSure or its Affiliates must be approved in advance by AbbVie, which approval shall not be unreasonably withheld, delayed or conditioned. OraSure shall ensure that each use of the AbbVie Trademarks by it and its Affiliates is accompanied by an acknowledgement that the AbbVie Trademarks are owned by AbbVie.

(c) Neither Party shall (i) use the Trademarks of the other Party in a way that might prejudice their distinctiveness or validity or the goodwill of the owning Party therein, or (ii) use any Trademarks so resembling any of the other Party’s Trademarks as to be likely to cause confusion or deception.

(d) Each Party acknowledges the validity of the other Party’s right, title and interest in and to the other Party’s Trademarks. The Parties shall not have, assert or acquire any right, title or interest in or to any of the other Party’s Trademarks.

(e) Each Party shall determine in its sole discretion what action, if any, to take in response to the infringement or misappropriation or threatened infringement or misappropriation of its Trademarks.

2.12 Regulatory Affairs.

(a) *Complaints.* If AbbVie or any of its Affiliates becomes aware of any Complaint or concern regarding the Product (including related to the accuracy, quality or performance of the Product or any complaints or concerns regarding the sales, promotion, or marketing of the Product) in the Field in the Territory, then AbbVie shall submit a written report of such Complaint or concern, along with any documentation involved with the Complaint, if available, to OraSure within two (2) Business Days after receipt of such Complaint or concern by AbbVie. As between the Parties, OraSure shall have the sole authority and responsibility to respond to any Regulatory Authority, including the FDA, with respect to Complaints and concerns, and to handle all returns field alerts, recalls or market withdrawals of the Product in accordance with Applicable Law; *provided, however*, that the foregoing shall not be construed to

prevent AbbVie or its Affiliates in any way from complying with any Regulatory Authority or Applicable Laws, rules or regulations or from responding to Regulatory Authorities, including the FDA, with respect to Complaints regarding the conduct of AbbVie. AbbVie shall forward all Complaints and inquiries to OraSure in a timely manner as set forth in this Section 2.12 and shall follow any reasonable and timely directions OraSure may provide in that respect. If an investigation by OraSure is needed in response to a Complaint or inquiry, AbbVie shall assist OraSure as reasonably requested by OraSure, at OraSure's sole cost and expense for reasonable direct costs and expenses incurred by AbbVie in providing such assistance, and OraSure shall forward the results of the investigation to AbbVie within two (2) Business Days to allow AbbVie to comply with Applicable Law. OraSure shall have sole responsibility for direct, front-line customer support including, without limitation, medical information support for the Product. Such activities shall be at OraSure's sole cost and expense. OraSure shall be responsible for evaluating and reporting any Complaints to Regulatory Authorities as required by Applicable Law. In addition, OraSure shall provide AbbVie with any and all material Complaints relating to the accuracy of the Product to the extent permitted by Applicable Law. OraSure shall promptly provide AbbVie with: (i) reports to Regulatory Authorities in the Territory regarding patient result errors; and (ii) all corrective actions, preventative actions and similar communications to Regulatory Authorities that relate to matters that would reasonably be deemed material to the commercialization of the Product.

(b) *Medical Inquiries.* For all medical inquiries related to the Product, other than inquiries for information within the scope of the Labeled Use or Product Promotional Materials, AbbVie shall direct all such inquiries to OraSure and OraSure shall handle such requests in accordance with all Applicable Laws and FDA guidance. As between the Parties, any responses to such inquiries from a Third Party shall be provided solely by OraSure and OraSure is solely responsible for the content of such communications.

(c) *Recalls.* Each Party shall promptly (but in any case, not later than forty-eight (48) hours) notify the other Party in writing of any order, request or directive of a court or other Regulatory Authority to recall or withdraw the Product. OraSure shall be responsible and have sole authority for handling all inquiries, Complaints, or recalls of the Product at its sole cost and expense, keeping AbbVie fully informed as to its plans and actions related to any such recall. If requested by OraSure, AbbVie shall fully cooperate with a Product recall in the Field in the Territory and follow all reasonable instructions given by OraSure in that regard. If a Party (a) is contacted by any other Regulatory Authority for any purpose pertaining specifically to this Agreement or to the Product; or (b) becomes aware of an impending inspection or audit of the facilities or operations involved with the Product, such Party shall immediately notify the other Party in writing. AbbVie agrees that it shall not respond to any such Regulatory Authority making an inquiry of it until and only as reasonably directed by OraSure; *provided, however*, that the foregoing shall not be construed to prevent AbbVie in any way from complying with any Regulatory Authority or Applicable Laws. In the event that OraSure considers initiating a voluntary recall of the Product, OraSure shall promptly inform AbbVie of such deliberations (including the contributing facts and circumstances leading up to such deliberations) and of its final determination, and keep AbbVie fully informed as to its plans and actions related to any such voluntary recall.

2.13 Supply and Distribution. OraSure shall, at its sole cost and expense, use Commercially Reasonable Efforts to: (a) have the Product manufactured either directly or through a Third Party manufacturer for the Field in the Territory; and (b) handle Product inventory, returns and receivables for the Field in the Territory. OraSure shall utilize Commercially Reasonable Efforts to maintain, or cause its Third Party Providers to maintain, sufficient stock of the Product available in its inventory for prompt delivery to the HCPs in the Field and the Territory following receipt of Product purchase orders. OraSure shall manufacture or cause to be manufactured the Product for the Field and Territory in accordance with all Applicable Law, including the FFDCA and Current Good Manufacturing Practices, as applicable.

2.14 Completion of Exhibits. The Parties acknowledge that Exhibit B (Co-Promotion Plan) and Exhibit G (Patient Care Database Requirements) are not complete and final as of the Effective Date. The Parties shall use their best efforts to agree upon final forms of these Exhibits, consistent with this Agreement, no later than sixty (60) days after the Effective Date. Upon mutual agreement by the Parties, these Exhibits will be attached hereto and incorporated into this Agreement and become binding on the Parties.

2.15 Reservation of Rights. Except as expressly granted by OraSure in this Agreement, OraSure does not grant to AbbVie any license, right or immunity, whether by implication, estoppel or otherwise, with respect to any Intellectual Property Rights of OraSure or any of its Affiliates. For clarity, OraSure reserves the sole and exclusive right to pursue, obtain, maintain, defend and enforce the OraSure Intellectual Property and its other Intellectual Property Rights.

ARTICLE 3 SERVICES

3.1 OraSure Services. AbbVie desires to retain OraSure to perform the OraSure Services, including such services relating to the Patient Care Database, in furtherance of the Care Model as follows:

(a) *Patient Care Database.* For the duration of the Term, OraSure shall exercise Commercially Reasonable Efforts to design, develop, implement and administer the Patient Care Database and, subject to AbbVie's compliance with Section 3.3, maintain the security of the Patient Care Database and the Patient Information contained therein, in accordance with the mutually agreed requirements therefor. Any specifications with respect to the Patient Care Database that are set forth in an agreement to be entered into between OraSure and a Third Party vendor shall be subject to the prior written approval of AbbVie which approval shall not be unreasonably withheld, conditioned or delayed and which specifications shall be attached hereto as Exhibit G. OraSure shall provide training to AbbVie and its Representatives on access and use of the Patient Care Database in a manner consistent with Section 2.8. OraSure shall be solely responsible for all costs and expenses associated with carrying out the activities described in the first sentence of this Section 3.1(a) with respect to the Patient Care Database. No modifications to the Patient Care Database or requirements therefore shall be permitted without the Parties' prior written consent.

(b) *Additional Services.* OraSure shall perform any additional services as reasonably agreed to by the Parties and set forth in a Statement of Work to effectuate the OraSure Services and purpose of this Agreement. Each Statement of Work describing additional OraSure Services shall set forth, consistent with and subject to the Guiding Principles and the terms of this Agreement: (i) the scope of the relevant program, including a detailed explanation of such OraSure Services to be provided; (ii) a list of applicable documents or materials which are incorporated into the Statement of Work; (iii) performance requirements; (iv) OraSure's and AbbVie's responsibilities, including payment of costs; (v) a schedule for the program; (vi) both Parties' project contacts; (vii) change management; (viii) a listing of any Patient groups (grouped by state of residence, payer or otherwise) who shall be excluded from the Program; and (ix) a reference to this Agreement. With respect to any additional proposed OraSure Services not previously approved by the Parties in accordance with the terms of this Agreement, OraSure shall provide such OraSure Services only after the scope of such OraSure Services has been approved by AbbVie and agreed to by OraSure in writing in the form of a fully executed Statement of Work. In the event the terms of any Statement of Work are inconsistent with or are in conflict with the terms of this Agreement, the terms of this Agreement shall control, unless a term of this Agreement is expressly intended to be replaced or amended, as set forth in a fully executed Statement of Work.

3.2 Subcontracting of Services. Subject to Section 2.2(b), each Party shall have the right to subcontract any of the services it is to provide or its other obligations under this Agreement to a Third Party (a "**Third Party Provider**") without the prior written consent of the other Party. In the event a Party subcontracts certain services or other obligations, the subcontracting Party shall furnish the other Party with written notice identifying the Third Party Provider and specifying the work subcontracted. The subcontracting Party shall ensure that it obtains a written undertaking from the Third Party Provider that it shall be subject to the applicable terms and conditions of this Agreement, including compliance with Applicable Law, the data provisions of this Article 3 and the confidentiality provisions of Article 6. Notwithstanding the foregoing, the subcontracting Party shall remain responsible and liable to the other Party for any and all services and items furnished by such Third Party Provider and such Third Party Provider's breach of this Agreement.

3.3 Data Protection. A Party may be required to use, access, collect, retain, disclose or otherwise process individually identifiable health information or information, in combination with other information, identifiable to a living individual, including Patient Information obtained in connection with this Agreement (collectively, "**Personal Data**"). For purposes of this Agreement, "**Processing**" (and its conjugates, including without limitation "**Process**") shall mean any operation or set of operations that is performed upon Personal Data, including any collection, recording, retention, organization, storage, adaptation, alteration, retrieval, consultation, blocking erasure use, disclosure, access, transfer, or destruction, whether or not by electronic means.

(a) Each Party shall use Commercially Reasonable Efforts to keep secure any Personal Data in the possession or under the control of such Party or its Affiliates, Representatives or Third Party Providers.

(b) In that event, each Party agrees to use, access, collect, retain, transmit, disclose or otherwise process Personal Data solely as described in this Agreement and the applicable Patient Forms, which means OraSure shall only use, access, collect, retain, transmit, disclose or otherwise process Personal Data solely for the purpose of creating and maintaining the Patient Care Database, complying with its other obligations under this Agreement with respect thereto and as provided in Section 2.2(a)(iii), and AbbVie shall only use, access, collect, retain, disclose or otherwise process Personal Data solely for the purposes set forth in this Agreement and the Patient Forms. Neither Party shall use, access, collect, retain, transmit, disclose or otherwise process such Personal Data for any other purpose or in any other manner except where such further use is required by Applicable Law or Regulatory Authority.

(c) Each Party agrees to abide by all applicable data protection, privacy, and security laws and regulations in connection with its activities under this Agreement.

(d) Each Party will maintain appropriate safeguards to ensure the privacy, confidentiality and security of the Personal Data.

(e) Each Party shall provide written notice to the other Party of any unauthorized or improper use, access to, or disclosure of Personal Data obtained in connection with this Agreement (“**Security Breach**”), including any use, access or disclosure not expressly permitted under this Agreement, within three (3) Business Days of becoming aware of such Security Breach. Such notice shall include the timing and nature of the Security Breach, as well as a description of the Breach. Each Party acknowledges that it shall be responsible and liable for any Security Breach by it or its Affiliates. A Party shall not have any liability to the other Party or any other Person for any liability to the extent attributable to a Security Breach or other failure by its agents or other Third Parties under its control, provided that such Party shall use Commercially Reasonable Efforts to pass through to the other Party the benefit of any representations, warranties, and indemnities made by the agent or Third Party under its agreements with such Party and any other remedies such Party may have against such agents and Third Parties. Each Party shall take reasonable measures to remedy the Security Breach, provided that it shall also reasonably consider all reasonable measures recommended by the other Party.

(f) Where applicable data protection, privacy or security laws or regulations require additional agreements, breach remedies or mitigation, data safeguards or privacy protections as a result of Personal Data that is collected and maintained and transferred to the Patient Care Database, each Party will use Commercially Reasonable Efforts to ensure that all necessary agreements are implemented and in place, and that all breach remedies or mitigation, data safeguards or privacy protections are implemented and in place.

(g) These provisions will survive termination or expiration of this Agreement.

ARTICLE 4 COMPENSATION

4.1 Co-Promotion Fees. During the Term of this Agreement, OraSure shall pay, as compensation for AbbVie's Co-Promotion activities and obligations under this Agreement, a co-promotion fee (the "**Co-Promotion Fees**") as follows:

(a) The number of Details per year provided by the AbbVie Sales Force is expected to range from [***] as indicated below. Each Detail will be a secondary position detail (as defined in Section 1.38) at a cost of [***] per Detail, subject to Section 4.1(b). AbbVie will provide OraSure a report on the Details performed within ten (10) days of the end of each Calendar Quarter, and together with such report shall provide a written invoice to OraSure for the Co-Promotion Fee.

(b) The table below sets forth, on an annual basis, the minimum number of Details required from AbbVie's Sales Force and the maximum cost that OraSure shall be obligated to pay for such Details, regardless if the number of such Details performed exceeds the amounts set forth below during the applicable annual period.

	2014	2015	2016	2017	2018	2019
# Physicians			[***]			
Calls per MD	[***]	[***]	[***]	[***]	[***]	[***]
\$ Per Call			[***]			
Maximum \$	[***]	[***]	[***]	[***]	[***]	[***]

(c) If the target primary care physician, gastroenterologist, hepatologist and/or infectious disease specialist market for the Product materially changes at any time during the Term, at OraSure's request, the Parties agree to discuss in good faith potential adjustment to the level of Details to be performed per year and/or the Co-Promotion Fees.

4.2 Fees for Database Establishment, Ownership, Exclusivity and Other OraSure Services.

(a) *Database Establishment, Ownership and Exclusivity Fees.* Subject to the termination rights set forth herein, AbbVie shall pay OraSure the fees set forth in this Section 4.2(a) for the design and development of, and AbbVie's exclusive rights to, the Patient Care Database, as well as the Right of First Refusal and, subject to rights retained by OraSure under Section 2.2(a) during the Term, the Exclusivity granted to AbbVie hereunder (collectively referred to herein as the "**Database Establishment, Ownership and Exclusivity Fee**"):

[***] Portions of this page have been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Patient Care Database Ownership and Exclusivity Fee Payment Date	US\$ Amount
Within thirty (30) days following the Effective Date	Fifteen Million Dollars (\$15,000,000)
Within [***] days following [***]	[***]
Within [***] days following [***]	[***]
Within [***] days following [***]	[***]
Within [***] days following [***]	[***]
Within [***] days following [***]	[***]
Within [***] days following [***]	[***]
Within [***] days following [***]	[***]

Except as specifically provided below, the Database Establishment, Ownership and Exclusivity Fees shall be non-refundable, non-creditable and not subject to setoff. The maximum aggregate amount of the Database Establishment, Ownership and Exclusivity Fees payable by AbbVie to OraSure pursuant to this Agreement shall be Seventy Five Million Dollars (\$75,000,000) (the “**Aggregate Exclusivity Amount**”), unless otherwise agreed to by the Parties in connection with a renewal of this Agreement or material expansion of the Field. Notwithstanding the schedule of fee payments set forth above, the Aggregate Exclusivity Amount shall accrue and be earned ratably on a daily basis by OraSure during the period from the Effective Date through the end of the Term on December 31, 2019 (the “**Exclusivity Period**”). In the event this Agreement is terminated prior to December 31, 2019, either by OraSure for convenience pursuant to Section 8.5 or by AbbVie as a result of a material breach by OraSure pursuant to Section 8.2, then OraSure shall refund to AbbVie an amount (the “**Exclusivity Refund**”) equal to the excess, if any, of (i) the aggregate Database Establishment, Ownership and Exclusivity Fees received by OraSure hereunder on or prior to the effective date of termination (the “**Paid Exclusivity Fees**”), over (ii) the portion of the Accrued Exclusivity Amount accrued and earned through the effective date of termination (the “**Accrued Exclusivity Amount**”). For clarity, the Accrued Exclusivity Amount shall equal (A) the Aggregate Exclusivity Amount multiplied by (B) a fraction having (x) a numerator equal to the number of calendar days occurring from the Effective Date through the date of termination, and (y) a denominator equal to the total number of calendar days in the Exclusivity Period. To the extent that the Paid Exclusivity Fees are less than the Accrued Exclusivity Amount (the “**Exclusivity Shortfall**”), AbbVie shall be obligated to pay such Exclusivity Shortfall to OraSure. Payment of

[***] Portions of this page have been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

any Exclusivity Refund or Exclusivity Shortfall hereunder, as applicable, shall occur no later than thirty (30) days after the effective date of termination. For avoidance of doubt, no Exclusivity Refund or Exclusivity Shortfall shall be payable in respect of termination of this Agreement other than termination either by OraSure for convenience pursuant to Section 8.5 or by AbbVie as a result of a material breach by OraSure pursuant to Section 8.2. In the event this Agreement is terminated by AbbVie for convenience pursuant to Section 8.5, AbbVie will not be obligated to pay OraSure any Database Establishment, Ownership and Exclusivity Fees payable after the effective date of such termination and, subject to its compliance with Section 8.7(b) and fulfillment of its obligations under this Agreement, AbbVie shall obtain rights to the Patient Care Database and Intellectual Property Rights therein as specified in Section 8.7(d).

(b) *Fee for Maintenance Services*. AbbVie shall pay OraSure for each Calendar Year, within thirty (30) days of receipt of OraSure's invoice therefor, the following fees for services relating to data collection, input, aggregation, analytics and the ongoing operations and maintenance of the Patient Care Database based upon the aggregate number of new Patients testing HCV positive using the Product that are entered into the Patient Care Database during the applicable Calendar Year as verified by the information from the Patient Care Database (each a "**Maintenance Services Payment**"), and which aggregate diagnosis thresholds shall be reported by AbbVie to OraSure within twenty (20) days of the end of each Calendar Year. For the sake of clarity, any Patient testing HCV positive using the Product who has been included in the calculation of the Maintenance Services Payment during a prior Calendar Year shall be excluded from the calculation of the Maintenance Services Payment in any subsequent Calendar Year.

Tier	Patients Tested Positive with Product and Entered in Patient Care Database	US\$ Amount
1	***	Three Million Five Hundred Thousand Dollars (\$3,500,000)
2	***	***
3	***	***
4	***	***
5	***	***
6	***	***
7	***	***
8	***	***
9	***	***
10	***	***
11	***	***
12	***	***
13	***	***
14	***	***
15	***	***
16	***	***
17	***	***

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18	***	***
19	***	***
20		Fifty Five Million Five Hundred Thousand Dollars
	***	(\$55,500,000)

The Maintenance Services Payment shall be non-refundable, non-creditable and not subject to setoff, *provided, however*, in the event of an accounting error the Parties will true up any discrepancies related to the number of diagnoses subject to the chart above on or before the date that the next Maintenance Services Payment is due and owing. Moreover, the Parties acknowledge and agree that (i) aggregate services contracted for do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement, and (ii) the compensation to be paid over the term of each arrangement is set in advance, does not exceed fair market value for this arm's length transaction, and, is not determined in a manner that takes into account the volume or value of any referrals between the Parties. The Parties acknowledge and agree that the services to be furnished under this Agreement do not involve the counseling or promotion of a business arrangement or other activity that violates any applicable Federal or State law.

4.3 Invoicing and Payment. All payments required to be made under this Agreement shall be paid on or before the date specified for such payment in this Agreement, and if not so specified, within thirty (30) days of receipt of an invoice therefor.

4.4 Interest on Late Payments. If any payment due to either Party under this Agreement is not paid when due, then the receiving Party shall have the right to require that such paying Party pay interest thereon (before and after any judgment) at a rate equal to the lesser of: (a) one and one half percentage points (1.5%) above the prime rate as published by Citibank, N.A., New York, New York, or any successor thereto, at 12:01 a.m. on the first day of each Calendar Quarter in which such payments are overdue or (b) the maximum rate permitted by Applicable Law, such interest to run from the date on which payment of such sum became due until payment thereof in full together with such interest.

4.5 Audit.

(a) *Maintenance of Books and Records.* Each Party shall maintain complete and accurate books and records in sufficient detail, in accordance with the Accounting Standards and Applicable Law, to enable verification of the performance of such Party's obligations and the amounts required to be paid by such Party under this Agreement. Such records shall be maintained for a period of seven (7) years after the end of the Term or longer if required by Applicable Law.

(b) *Audit Procedure.* At the request of the other Party, each Party shall, and shall cause its Affiliates to, as applicable, permit an independent public accounting firm of

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nationally recognized standing designated by the other Party and reasonably acceptable to the audited Party, at reasonable times during normal business hours and upon reasonable notice, to audit the books and records of the audited Party to ensure the accuracy of all reports and payments made hereunder. Such examinations may not: (i) be conducted for any Calendar Quarter more than three (3) years after the end of such quarter; (ii) be conducted more than once in any twelve (12) month period (unless a previous audit during such twelve (12)-month period revealed an underpayment or other material issues with respect to such period); or (iii) be repeated for any Calendar Quarter. The accounting firm shall disclose only whether the reports and payments are correct or not, and the specific details concerning any discrepancies or noncompliance with this Agreement. No other information shall be shared. Except as provided below, the cost of this audit shall be borne by the auditing Party, unless the audit reveals a variance of more than five percent (5%) from the reported amounts, in which case the audited Party shall bear the cost of the audit. Unless disputed pursuant to Section 4.5(c) below, if such audit concludes: (y) additional amounts were owed by the audited Party, the audited Party shall pay the additional amounts, with interest from the date originally due as provided in Section 4.4; or (z) excess payments were made by the audited Party, the auditing Party shall reimburse such excess payments, in either case ((y) or (z)), within sixty (60) days after the date on which such audit is completed by the auditing Party.

(c) *Audit Dispute*. In the event of a dispute with respect to any audit under Section 4.5, the Parties shall work in good faith to resolve the disagreement. If the Parties are unable to reach a mutually acceptable resolution of any such dispute within thirty (30) days, the dispute shall be submitted for resolution to a certified public accounting firm jointly selected by each Party's certified public accountants or to such other Person as the Parties shall mutually agree (the "**Audit Arbitrator**"). The decision of the Audit Arbitrator shall be final and the costs of such arbitration as well as the initial audit shall be borne between the Parties in such manner as the Audit Arbitrator shall reasonably determine. Not later than thirty (30) days after such decision and in accordance with such decision, the audited Party shall pay the additional amounts, with interest from the date originally due as provided in Section 4.4 or the auditing Party shall reimburse the excess payments, as applicable. The Parties shall cause the Audit Arbitrator to enter into a reasonably acceptable confidentiality agreement with the audited Party obligating such firm to retain all such financial information in confidence pursuant to such confidentiality agreement.

4.6 Tax Withholding. If Applicable Law requires that taxes be withheld with respect to any payments by a Party to the other Party under this Agreement, the paying Party shall: (a) deduct those taxes from the remittable payment, (b) pay the taxes to the proper taxing authority, and (c) send evidence of the obligation together with proof of tax payment to the payee Party on a timely basis following that tax payment. Each Party agrees to cooperate with the other Party in claiming refunds or exemptions from such deductions or withholdings under any relevant agreement or treaty which is in effect. The Parties shall discuss applicable mechanisms for minimizing such taxes to the extent possible in compliance with Applicable Laws. In addition, the Parties shall cooperate in accordance with Applicable Laws to minimize indirect taxes (such as sales tax, consumption tax and other similar taxes) in connection with this Agreement.

4.7 Fair Market Value; Independent Appraisal. The Database Ownership and Exclusivity Fees, Database Maintenance Fees and other fees for OraSure Services paid to OraSure by AbbVie and the Co-Promotion Fees paid to AbbVie by OraSure have each been determined by the Parties to be consistent with the fair market value of the applicable items and services provided hereunder, without taking into account any source of referrals, or the volume or value of any business generated by OraSure or its Affiliates for AbbVie or its Affiliates, or by AbbVie or its Affiliates for OraSure or its Affiliates that is reimbursed under any governmental or commercial health care payment or insurance program. All of the fees set forth herein have been established as of the Effective Date through good-faith and arm's length bargaining between the Parties.

ARTICLE 5 REPRESENTATIONS AND WARRANTIES

5.1 Mutual Representations and Warranties. Each Party represents and warrants to the other, as of the Effective Date, as follows:

(a) *Organization.* It is a corporation duly organized, validly existing, and in good standing under the laws of the jurisdiction of its organization, and has all requisite power and authority, corporate or otherwise, to execute, deliver, and perform their respective obligations under this Agreement.

(b) *Authorization.* The execution and delivery of this Agreement and the performance by it of the transactions contemplated hereby have been duly authorized by all necessary corporate action, and do not violate: (a) such Party's charter documents, bylaws, or other organizational documents; (b) in any material respect, any agreement, instrument, or contractual obligation to which such Party is bound; (c) any requirement of any Applicable Law applicable to such Party; or (d) any order, writ, judgment, injunction, decree, determination, or award of any court or Regulatory Authority presently in effect applicable to such Party.

(c) *Binding Agreement.* This Agreement is a legal, valid, and binding obligation of such Party enforceable against it in accordance with its terms and conditions, subject to the effects of bankruptcy, insolvency, or other laws of general application affecting the enforcement of creditor rights, judicial principles affecting the availability of specific performance, and general principles of equity (whether enforceability is considered a proceeding at law or equity).

(d) *No Inconsistent Obligation.* It is not under any obligation, contractual or otherwise, to any Person that conflicts with or is inconsistent in any material respect with the terms of this Agreement, or that would impede the diligent and complete fulfillment of its obligations hereunder.

5.2 Additional Representations and Warranties of OraSure. OraSure further represents and warrants to AbbVie, as of the Effective Date, as follows:

(a) *Compliance with Applicable Law.* OraSure is in compliance with, and undertakes that in performance of its obligations and exercise of its rights under this Agreement, it shall continue to comply with all Applicable Laws, including anti-bribery and anti-corruption laws, the Patient Protection and Affordable Care Act of 2010, the Health Insurance Portability and Accountability Act of 1996 (as amended) ("**HIPAA**"), laws applicable to the use and

disclosure of personally identifiable information, rules governing healthcare programs and applicable FDA regulatory requirements, and Applicable Laws relating to OraSure's Co-Payment Assistance Program.

(b) *OraSure Intellectual Property*. OraSure and its Affiliates: (i) Control the OraSure Intellectual Property licensed or needed to grant the rights granted to AbbVie hereunder, that such rights to such OraSure Intellectual Property have been, to OraSure's knowledge, validly granted to OraSure and its Affiliates, and the granting of such rights to AbbVie and its Affiliates under this Agreement does not, to OraSure's knowledge, require the consent of a Third Party in accordance with the terms of this Agreement; and (ii) have not granted any right or license to any Third Party relating to the OraSure Intellectual Property and/or the Product that would conflict with the rights granted to AbbVie and its Affiliates under this Agreement.

(c) *Absence of Litigation*. (i) There are no claims, judgments or settlements against or owed by OraSure or its Affiliates or any pending or, to OraSure's knowledge, threatened claims or litigation relating to the Product or the Product Promotional Materials used by OraSure prior to the Effective Date; and (ii) there are no claims, judgments or settlements against or owed by OraSure or its Affiliates relating to the OraSure Intellectual Property.

(d) *Intellectual Property Infringement*. To OraSure's knowledge, there are no Third Party patents, patent applications or other Third Party Intellectual Property Rights that would be infringed by making, using, or selling the Product or any related Product Promotional Materials in the Field in the Territory.

(e) *Misappropriation*. To OraSure's knowledge, there is no infringement or misappropriation by a Third Party of the OraSure Intellectual Property that would have a material adverse effect on the Product, OraSure, or the ability of the Parties to perform under this Agreement.

(f) *Licenses and Permits*. OraSure (and any Third Party subcontractors used by OraSure) has obtained all necessary licenses, permits and certifications under Applicable Law to use, make, Co-Promote and otherwise commercialize the Product or provide Samples in the Field in Territory.

(g) *Product Promotional Materials and Training Materials*. All Product Promotional Materials and training materials used by OraSure in connection with the Product in the Field in the Territory comply, and all Product Promotional Materials and training materials to be created and developed by OraSure pursuant to this Agreement shall comply, with all Applicable Laws.

(h) *Performance Standards*. All activities and obligations performed under this Agreement by OraSure shall be performed: (i) in a professional and workmanlike manner; and (ii) by appropriately qualified individuals.

(i) *Debarment and Exclusion*. None of OraSure or its employees performing activities or services hereunder, nor to OraSure's knowledge, any agents or Third Party Providers of OraSure performing activities or services hereunder, are currently, or currently are the subject of a proceeding that could lead to OraSure or such employees, agents, or subcontractors

becoming, as applicable, a Debarred Entity or Debarred Individual, an Excluded Entity or Excluded Individual or a Convicted Entity or Convicted Individual, nor are they listed on the FDA's Disqualified and Restricted Lists. OraSure further covenants, represents and warrants that if, during the Term, OraSure, or any of its employees, agents or Third Party Providers performing activities or services hereunder, becomes or is the subject of a proceeding that could lead to that party becoming, as applicable, a Debarred Entity or Debarred Individual, an Excluded Entity or Excluded Individual or a Convicted Entity or Convicted Individual, or added to FDA's Disqualified and Restricted Lists, OraSure shall immediately notify AbbVie. The provision of this paragraph regarding notice of acts occurring during the Term shall survive termination or expiration of this Agreement. For purposes of this provision, the following definitions shall apply: (i) a **"Debarred Individual"** is an individual who has been debarred by the FDA pursuant to Title 21 of the United States Code ("USC") Section 335a(a) or (b) from providing services in any capacity to a person that has an approved or pending drug product application; (ii) a **"Debarred Entity"** is (A) a corporation, partnership or association that has been debarred by the FDA pursuant to Title 21 of USC Section 335a(a) or (b) from submitting or assisting in the submission of any drug application, or (B) an agent, subsidiary or affiliate of a Debarred Entity; (iii) an **"Excluded Individual"** or **"Excluded Entity"** is (A) an individual or entity, as applicable, who has been excluded, debarred, suspended or is otherwise ineligible to participate in federal health care programs such as Medicare or Medicaid by the Office of the Inspector General (OIG/HHS) of the U.S. Department of Health and Human Services; or (B) is an individual or entity, as applicable, who has been excluded, debarred, suspended or is otherwise ineligible to participate in federal procurement and non-procurement programs, including those produced by the U.S. General Services Administration (GSA); (iv) a **"Convicted Individual"** or **"Convicted Entity"** is an individual or entity, as applicable, who has been convicted of a criminal offense or has been subject to a civil penalty that falls within the ambit of Title 21 of USC Section 335a(a) or (b), Title 42 of USC Section 1320a – 7(a), or Title 42 of U.S.C. Section 1320a – 7(b)(1) – (3) but has not yet been excluded, debarred, suspended or otherwise declared ineligible; and (v) **"FDA's Disqualified/Restricted Lists"** are (A) the list of clinical investigators FDA has determined repeatedly or deliberately failed to comply with regulatory requirements for studies, or submitted false information to the study sponsor or the FDA, and as a result have been disqualified or "totally restricted" from receiving investigational drugs, biologics, or devices and is ineligible to conduct any clinical investigation that supports and application for research or marketing permit for products regulated by the FDA, and (B) the list of clinical investigators whom FDA has placed certain restrictions with respect to their conduct of clinical investigations.

5.3 Additional Representations and Warranties of AbbVie. AbbVie further represents and warrants to OraSure, as of the Effective Date as follows:

(a) *Compliance with Applicable Law.* AbbVie is in compliance with, and undertakes that in performance of its obligations and exercise of its rights under this Agreement, it shall continue to comply with, all Applicable Laws, including anti-bribery and anti-corruption laws, Patient Protection and Affordable Care Act of 2010, HIPAA, laws applicable to the use and disclosure of personally identifiable information, rules governing healthcare programs and applicable FDA regulatory requirements.

(b) *AbbVie Intellectual Property.* AbbVie and its Affiliates: (i) Control the Intellectual Property Rights licensed or otherwise granted by AbbVie to OraSure hereunder, that such rights to such Intellectual Property Rights have been, to AbbVie's knowledge, validly granted to AbbVie and its Affiliates, and the granting of such rights to OraSure and its Affiliates under this Agreement does not, to AbbVie's knowledge, require the consent of a Third Party in accordance with the terms of this Agreement; and (ii) have not granted any right or license to any Third Party relating to the Intellectual Property Rights licensed or otherwise granted by AbbVie to OraSure hereunder that would conflict with the rights granted to OraSure and its Affiliates under this Agreement.

(c) *Absence of Litigation.* (i) There are no claims, judgments or settlements against or owed by AbbVie or its Affiliates or any pending or, to AbbVie's knowledge, threatened claims or litigation relating to the Care Model or HCV therapeutics of AbbVie or its Affiliates; and (ii) there are no claims, judgments or settlements against or owed by AbbVie or its Affiliates relating to the AbbVie Intellectual Property.

(d) *Intellectual Property Infringement.* To AbbVie's knowledge, there are no Third Party patents, patent applications or other Third Party Intellectual Property Rights that would be infringed by establishing, deploying, offering or administering the Care Model.

(e) *Misappropriation.* To AbbVie's knowledge there is no infringement or misappropriation by a Third Party of any Intellectual Property Rights Controlled by AbbVie that would have a material adverse effect on the Care Model, AbbVie, or the ability of the Parties to perform under of this Agreement.

(f) *Licenses and Permits.* AbbVie (and any Third Party subcontractors used by AbbVie) has obtained all necessary licenses, permits and certifications under Applicable Law to Co-Promote the Product and to establish, deploy, administer and offer the Care Program to Patients.

(g) *Performance Standards.* All activities and obligations performed under this Agreement by AbbVie shall be performed: (i) in a professional and workmanlike manner; and (ii) by appropriately qualified individuals.

(h) *Care Model.* All materials relating to the Care Model and any HCV awareness programs conducted by or on behalf of AbbVie or its Affiliates comply and shall comply with all Applicable Laws.

(i) *Debarment and Exclusion.* None of AbbVie or its employees performing activities hereunder, nor to AbbVie's knowledge, any agents or Third Party Providers of AbbVie performing activities hereunder are currently, or currently are the subject of a proceeding that could lead to AbbVie or such employees, agents, or subcontractors becoming, as applicable, a Debarred Entity or Debarred Individual, an Excluded Entity or Excluded Individual or a Convicted Entity or Convicted Individual, nor are they listed on the FDA's Disqualified and Restricted Lists. AbbVie further covenants, represents and warrants that if, during the Term, AbbVie, or any of its employees, agents or Third Party Providers performing activities hereunder, becomes or is the subject of a proceeding that could lead to that party becoming, as

applicable, a Debarred Entity or Debarred Individual, an Excluded Entity or Excluded Individual or a Convicted Entity or Convicted Individual, or added to FDA's Disqualified and Restricted Lists, AbbVie shall immediately notify OraSure. The provision of this paragraph regarding notice of acts occurring during the Term shall survive termination or expiration of this Agreement.

5.4 Disclaimer of Warranties. EXCEPT AS EXPRESSLY STATED IN THIS ARTICLE 5, ALL OTHER WARRANTIES, CONDITIONS AND REPRESENTATIONS, EXPRESS OR IMPLIED, STATUTORY OR OTHERWISE, INCLUDING A WARRANTY AS TO THE QUALITY OR FITNESS FOR ANY PARTICULAR PURPOSE OF THE PRODUCT ARE HEREBY EXCLUDED.

ARTICLE 6 CONFIDENTIALITY

6.1 Confidentiality Obligations. At all times during the Term and for a period of ten (10) years following termination or expiration hereof in its entirety, each Party shall, and shall cause its Affiliates and its and their respective Representatives to, keep confidential and not publish or otherwise disclose to a Third Party and not use, directly or indirectly, for any purpose, any Confidential Information furnished or otherwise made known to it, directly or indirectly, by the other Party or its Affiliates, except to the extent such disclosure or use is expressly permitted by the terms of this Agreement. Notwithstanding the foregoing, to the extent the receiving Party can demonstrate by documentation or other competent proof, the confidentiality and non-use obligations under this Section 6.1 with respect to any Confidential Information shall not include any information that:

(a) has been published by a Third Party or otherwise is or hereafter becomes part of the public domain by public use, publication, general knowledge or the like through no wrongful act, fault or negligence on the part of the receiving Party;

(b) has been in the receiving Party's possession prior to disclosure by the disclosing Party without any obligation of confidentiality with respect to such information;

(c) is subsequently received by the receiving Party from a Third Party without restriction and without breach of any agreement between such Third Party and the disclosing Party;

(d) is generally made available to Third Parties by the disclosing Party without restriction on disclosure; or

(e) has been independently developed by or for the receiving Party without reference to, or use or disclosure of, the disclosing Party's Confidential Information.

Specific aspects or details of Confidential Information shall not be deemed to be within the public domain or in the possession of the receiving Party merely because the Confidential Information is embraced by more general information in the public domain or in the possession of the receiving Party. Further, any combination of Confidential Information shall not be considered in the public domain or in the possession of the receiving Party merely because

individual elements of such Confidential Information are in the public domain or in the possession of the receiving Party unless the combination and its principles are in the public domain or in the possession of the receiving Party.

6.2 Permitted Disclosures. Each Party may disclose Confidential Information to the extent that such disclosure is:

(a) in the reasonable opinion of the receiving Party's legal counsel, required to be disclosed pursuant to Applicable Law, regulation or a valid order of a court of competent jurisdiction or other supra-national, federal, national, regional, state, provincial and local governmental body of competent jurisdiction (including by reason of filing with securities regulators or rules of a securities exchange, but subject to Section 6.4); *provided*, that the receiving Party shall first have given prompt written notice (and to the extent reasonably possible, at least five (5) Business Days' notice) to the disclosing Party and given the disclosing Party a reasonable opportunity, if reasonably possible, to take whatever action it deems necessary to protect its Confidential Information (for example, quash such order or to obtain a protective order or seek confidential treatment requiring that the Confidential Information and documents that are the subject of such order be held in confidence by such court or governmental body or, if disclosed, be used only for the purposes for which the order was issued). In the event that no protective order or other remedy is obtained, or the disclosing Party waives compliance with the terms of this Agreement, the receiving Party shall furnish only that portion of Confidential Information which the receiving Party is advised by legal counsel is legally required to be disclosed;

(b) made by or on behalf of the receiving Party to the Regulatory Authorities as required in connection with any filing, application or request for Marketing Authorization, all in accordance with the terms of this Agreement; *provided*, that reasonable measures shall be taken to assure confidential treatment of such Confidential Information to the extent practicable and consistent with Applicable Law;

(c) made to its or its Affiliates' financial and legal advisors who have a need to know such disclosing Party's Confidential Information and are either under professional codes of conduct giving rise to expectations of confidentiality and non-use or under written agreements of confidentiality and non-use, in each case, at least as restrictive as those set forth in this Agreement; *provided*, that the receiving Party shall be responsible for any failure by such financial and legal advisors, to treat such Confidential Information as required under this Article 6;

(d) made by the receiving Party or its Affiliates to potential or actual investors or acquirers as may be necessary in connection with their evaluation of such potential or actual investment or acquisition; *provided*, that such Persons shall be subject to obligations of confidentiality and non-use with respect to such Confidential Information substantially similar to the obligations of confidentiality and non-use of the receiving Party pursuant to this Article 6; and

(e) made by the receiving Party to its advisors, consultants, vendors, Third Party Providers or other Third Parties as may be necessary in connection with the performance of its obligations or exercise of its rights as contemplated by this Agreement; provided, that such Persons shall be subject to obligations of confidentiality and non-use with respect to such Confidential Information substantially similar to the obligations of confidentiality and non-use of the receiving Party pursuant to this Article 6.

6.3 Use of Name. Except as expressly provided herein related to the co-branding of Product Promotional Materials and Product samples and as provided in Section 2.11, neither Party shall mention or otherwise use the name, logo, or Trademark of the other Party or any of its Affiliates (or any abbreviation or adaptation thereof) in any publication, press release, marketing and promotional material, or other form of publicity without the prior written approval of such other Party in each instance. The restrictions imposed by this Section 6.3 shall not prohibit either Party from making any disclosure identifying the other Party that, in the opinion of the disclosing Party's legal counsel, is required by Applicable Law; *provided*, that, subject to Section 6.4, such Party shall submit the proposed disclosure identifying the other Party in writing to the other Party as far in advance as reasonably practicable (and in no event less than five (5) Business Days prior to the anticipated date of disclosure) so as to provide a reasonable opportunity to comment thereon.

6.4 Public Announcements. The Parties have agreed upon the content of a press release which shall be issued substantially in the agreed upon form, the release of which the Parties shall coordinate in order to accomplish such release promptly upon execution of this Agreement. Neither Party shall issue any other public announcement, press release, or other public disclosure regarding this Agreement or its subject matter without the other Party's prior written consent, except for any such disclosure that is, in the opinion of the disclosing Party's counsel, required by Applicable Law or the rules of a stock exchange on which the securities of the disclosing Party are listed. Notwithstanding the foregoing, the Parties contemplate that additional press releases may be issued in connection with the continued promotion and commercialization of the Product within the Field, subject to the consent rights in this Section 6.4. In the event a Party is, in the opinion of its legal counsel, required by Applicable Law or the rules of a stock exchange on which its securities are listed to make such a public disclosure, such Party shall submit the proposed disclosure in writing to the other Party as far in advance as is reasonably practicable under the circumstances so as to provide a reasonable opportunity to comment thereon. Each Party acknowledges and agrees that the other Party may file a redacted copy of this Agreement to the U.S. Securities and Exchange Commission and if a Party does submit this Agreement to the U.S. Securities and Exchange Commission, such Party agrees to consult with the other Party with respect to the preparation and submission of, a confidential treatment request for this Agreement.

6.5 Return of Confidential Information. Upon the effective date of the termination of this Agreement for any reason, each Party shall, with respect to Confidential Information to which such Party does not retain rights under the surviving provisions of this Agreement: (a) as soon as reasonably practicable, destroy all copies of such Confidential Information in the possession of the other Party and confirm such destruction in writing to the requesting Party; or (b) as soon as reasonably practicable, deliver to the requesting Party, at the other Party's expense, all copies of such Confidential Information in the possession of the other Party; *provided*, that the other Party shall be permitted to retain one (1) copy of such Confidential Information for the sole purpose of performing any continuing obligations hereunder, as required

by Applicable Law, or for archival purposes. Notwithstanding the foregoing, such other Party also shall be permitted to retain such additional copies of or any computer records or files containing such Confidential Information that have been created solely by such Party's automatic archiving and back-up procedures, to the extent created and retained in a manner consistent with such other Party's standard archiving and back-up procedures, but not for any other use or purpose.

6.6 Survival. All Confidential Information shall continue to be subject to the terms of this Agreement for the period set forth in Section 6.1.

ARTICLE 7 INDEMNIFICATION; INSURANCE

7.1 Indemnification by OraSure. OraSure shall defend, indemnify and hold AbbVie, its Affiliates and their respective Representatives ("**AbbVie Indemnitees**") harmless from and against any liabilities, losses, damages, penalties, charges, costs, or expenses, including reasonable attorneys' fees and settlement payments (collectively, "**Losses**") that arise from any claim, lawsuit or other action by a Third Party ("**Third Party Claim**") against an AbbVie Indemnitee to the extent resulting from:

- (a) the Co-Promotion or the research, development, manufacture, commercialization, distribution, importation or use of the Product by OraSure or its Affiliates, or the Co-Payment Assistance Program;
- (b) the accuracy of the Product;
- (c) performance of the Product, including the reporting of Product results to physicians or Patients;
- (d) a breach by OraSure of its covenants or the material terms and conditions of this Agreement;
- (e) an actual or alleged infringement by the Product or any Product Promotional Materials of any Intellectual Property Right of a Third Party;
- (f) the infringement or other violation of any Third Party Trademarks with respect to the use by AbbVie of the OraSure Trademarks in accordance with the terms and conditions of this Agreement;
- (g) subject to Section 3.3(d), the performance of the OraSure Services by OraSure or its employees, agents or subcontractors;
- (h) an inaccuracy of any of OraSure's representations and warranties under this Agreement; or
- (i) the negligence, gross negligence or intentional misconduct of OraSure, its Affiliates or their respective employees, agents or Third Party Providers.

The foregoing obligations shall not apply in the case of Losses for which AbbVie, in whole or in part, has an obligation to indemnify OraSure pursuant to Section 7.2, as to which Losses each Party shall indemnify the other Party to the extent of their respective liability for the Losses.

7.2 Indemnification by AbbVie. AbbVie shall defend, indemnify and hold OraSure, its Affiliates and their respective Representatives (“**OraSure Indemnitees**”) harmless from and against any Losses that arise from any Third Party Claim against an OraSure Indemnatee resulting from:

(a) the Co-Promotion of the Product (including all Detailing Activities) by AbbVie or its Affiliates, or the Care Model;

(b) a breach by AbbVie of its covenants or the material terms and conditions of this Agreement;

(c) an actual or alleged infringement by the Care Model or any materials relating to the Care Model or any HCV awareness program conducted by or on behalf of AbbVie or its Affiliates of any Intellectual Property Right of a Third Party;

(d) the infringement or other violation of any Third Party Trademarks with respect to the use by OraSure of the AbbVie Trademarks in accordance with the terms and conditions of this Agreement;

(e) an inaccuracy of any of AbbVie’s representations and warranties under this Agreement;

(f) training by AbbVie or its Affiliates of AbbVie’s Sales Force in a manner inconsistent with the training or training materials provided to AbbVie by OraSure; or

(g) the negligence, gross negligence or intentional misconduct of AbbVie, its Affiliates or their respective employees, agents, subcontractors or Third Party Providers.

(h) The foregoing obligations shall not apply in the case of Losses for which OraSure, in whole or in part, has an obligation to indemnify AbbVie pursuant to Section 7.1, as to which Losses each Party shall indemnify the other Party to the extent of their respective liability for the Losses.

7.3 Notice of Claim. All indemnification claims in respect of a Party, its Affiliates, or their respective Representatives shall be made solely by such Party to this Agreement (the “**Indemnified Party**”). The Indemnified Party shall give the indemnifying Party prompt written notice (an “**Indemnification Claim Notice**”) of any Losses or discovery of fact upon which such Indemnified Party intends to base a request for indemnification under this Section 7.3, but in no event shall the indemnifying Party be liable for any Losses that result from any delay in providing such notice. Each Indemnification Claim Notice must contain a description of the claim and the nature and amount of such Loss (to the extent that the nature and amount of such Loss is known at such time). The Indemnified Party shall furnish promptly to the indemnifying Party copies of all papers and official documents received in respect of any Losses or any Third Party Claim.

7.4 Control of Defense.

(a) *In General.* The indemnifying Party (or its insurer) may assume the defense of any Third Party Claim by giving written notice to the Indemnified Party within thirty (30) days after the indemnifying Party's receipt of an Indemnification Claim Notice, provided that, (i) such Third Party Claim solely seeks monetary damages and (ii) the indemnifying Party expressly agrees in writing that as between the indemnifying Party and the Indemnified Party, the indemnifying Party shall be solely obligated to satisfy and discharge such Third Party Claim in full (the matters described in (i) and (ii), the "**Litigation Conditions**"); provided further that the Indemnified Party may, at any time, assume the defense of a Third Party Claim if at any time the Litigation Conditions are not satisfied with respect to such Third Party Claim. The assumption of the defense of a Third Party Claim by the indemnifying Party shall not be construed as an acknowledgment that the indemnifying Party is liable to indemnify the Indemnified Party in respect of the Third Party Claim, nor shall it constitute a waiver by the indemnifying Party of any defenses it may assert against the Indemnified Party's claim for indemnification. Upon assuming the defense of a Third Party Claim, the indemnifying Party may appoint as lead counsel in the defense of the Third Party Claim any legal counsel selected by the indemnifying Party which shall be reasonably acceptable to the Indemnified Party. In the event the indemnifying Party assumes the defense of a Third Party Claim, the Indemnified Party shall immediately deliver to the indemnifying Party all original notices and documents (including court papers) received by the Indemnified Party in connection with the Third Party Claim. Should the indemnifying Party assume the defense of a Third Party Claim, except as provided in Section 7.4(b), the indemnifying Party shall not be liable to the Indemnified Party for any legal expenses subsequently incurred by such Indemnified Party in connection with the analysis, defense or settlement of the Third Party Claim unless specifically requested in writing by the indemnifying Party. In the event that it is ultimately determined that the indemnifying Party is not obligated to indemnify, defend or hold harmless the Indemnified Party from and against the Third Party Claim, the Indemnified Party shall reimburse the indemnifying Party for any Losses incurred by the indemnifying Party in its defense of the Third Party Claim.

(b) *Right to Participate in Defense.* Without limiting Section 7.4(a), any Indemnified Party shall be entitled to participate in, but not control, the defense of such Third Party Claim and to employ counsel of its choice for such purpose; *provided*, that such employment shall be at the Indemnified Party's own expense unless: (i) the employment thereof, and the assumption by the indemnifying Party of such expense, has been specifically authorized by the indemnifying Party in writing; (ii) the indemnifying Party has failed to assume the defense and employ counsel in accordance with Section 7.4(a) or the Litigation Conditions are not satisfied (in which case the Indemnified Party shall control the defense); or (iii) the interests of the Indemnified Party and the indemnifying Party with respect to such Third Party Claim are sufficiently adverse to prohibit the representation by the same counsel of both Parties under Applicable Law, ethical rules or equitable principles.

(c) *Settlement.* With respect to any Losses relating solely to the payment of money damages in connection with a Third Party Claim that shall not result in the Indemnified Party's becoming subject to injunctive or other relief, and as to which the indemnifying Party shall have acknowledged in writing the obligation to indemnify the Indemnified Party hereunder, the indemnifying Party shall have the sole right to consent to the entry of any judgment, enter

into any settlement or otherwise dispose of such Loss, on such terms as the indemnifying Party, in its sole discretion, shall deem appropriate. With respect to all other Losses in connection with Third Party Claims, where the indemnifying Party has assumed the defense of the Third Party Claim in accordance with Section 7.4(a), the indemnifying Party shall have authority to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Loss; provided, that it obtains the prior written consent of the Indemnified Party (which consent shall not be unreasonably withheld, conditioned or delayed). If the indemnifying Party does not assume and conduct the defense of a Third Party Claim as provided above, the Indemnified Party may defend against such Third Party Claim. Regardless of whether the indemnifying Party chooses to defend or prosecute any Third Party Claim, no Indemnified Party shall admit any liability with respect to, or settle, compromise or dispose of, any Third Party Claim without the prior written consent of the indemnifying Party, which consent shall not be unreasonably withheld, conditioned or delayed. The indemnifying Party shall not be liable for any settlement, compromise or other disposition of a Loss by an Indemnified Party that is reached without the written consent of the indemnifying Party, which consent shall not be unreasonably withheld, conditioned or delayed.

(d) *Cooperation.* Regardless of whether the indemnifying Party chooses to defend or prosecute any Third Party Claim, the Indemnified Party shall, and shall cause each indemnitee to, cooperate in the defense or prosecution thereof and shall furnish such records, information and testimony, provide such witnesses and attend such conferences, discovery proceedings, hearings, trials and appeals as may be reasonably requested in connection therewith. Such cooperation shall include access during normal business hours afforded to the indemnifying Party to, and reasonable retention by the Indemnified Party of, records and information that are reasonably relevant to such Third Party Claim, and making Indemnified Parties and other employees and agents available on a mutually convenient basis to provide additional information and explanation of any material provided hereunder, and the indemnifying Party shall reimburse the Indemnified Party for all its reasonable out-of-pocket expenses in connection therewith.

(e) *Expenses.* Except as provided above, the reasonable and verifiable costs and expenses, including fees and disbursements of counsel, incurred by the Indemnified Party in connection with any Third Party Claim shall be reimbursed on a quarterly basis in arrears by the indemnifying Party, without prejudice to the indemnifying Party's right to contest the Indemnified Party's right to indemnification and subject to refund in the event the indemnifying Party is ultimately held not to be obligated to indemnify the Indemnified Party.

7.5 Special, Indirect, and Other Losses. EXCEPT (A) FOR WILLFUL MISCONDUCT, (B) FOR A PARTY'S BREACH OF ITS OBLIGATIONS UNDER ARTICLE 6 OR SECTION 2.2(b), AND (C) TO THE EXTENT ANY SUCH DAMAGES ARE REQUIRED TO BE PAID TO A THIRD PARTY AS PART OF A CLAIM FOR WHICH A PARTY PROVIDES INDEMNIFICATION UNDER THIS ARTICLE 7, NEITHER PARTY NOR ANY OF ITS AFFILIATES SHALL BE LIABLE FOR INDIRECT, INCIDENTAL, SPECIAL, EXEMPLARY, PUNITIVE OR CONSEQUENTIAL DAMAGES, INCLUDING LOSS OF PROFITS OR BUSINESS INTERRUPTION, HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY, WHETHER IN CONTRACT, TORT, NEGLIGENCE, BREACH OF STATUTORY DUTY OR OTHERWISE IN CONNECTION WITH OR ARISING IN ANY WAY OUT OF THE TERMS OF THIS AGREEMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY, EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGE.

7.6 Insurance. Both Parties shall obtain and carry in full force and effect the minimum insurance requirements set forth herein or be sufficiently self-insured. Such insurance: (a) shall be primary insurance with respect to each party's own participation under this Agreement; (b) shall be issued by a recognized insurer rated by A.M. Best "A-VII" (or its equivalent) or better, or an insurer pre-approved in writing by the other party; (c) shall list the other party as an additional named insured thereunder; and (d) shall require thirty (30) days' written notice to be given to the other party prior to any cancellation thereof.

(a) *Types and Minimum Limits.* The types of insurance, and minimum limits shall be: (i) Worker's Compensation with statutory limits in compliance with the Worker's Compensation laws of the state or states in which the Party has employees in the United States (excluding Puerto Rico); (ii) Employer's Liability coverage with a minimum limit of \$500,000 per occurrence; *provided*, that a Party has employees in the United States (excluding Puerto Rico); and (iii) General Liability Insurance with a minimum limit of \$10,000,000 per occurrence and \$10,000,000 in the aggregate. General Liability Insurance shall include, at minimum product liability insurance. Insurance limits may be provided in any combination of primary or excess liability insurance policies as long as the limit of insurance required under this contract is met.

(b) *Certificates of Insurance.* Upon request by either Party, Certificates of Insurance evidencing compliance with this Section 7.6 shall be provided. The insurance policies may be written under an occurrence or claims made form. For claims made policies both parties agree to either maintain coverage or purchase a claims reporting tail of at least three (3) years after the natural end or termination of this contract.

ARTICLE 8 TERM; TERMINATION

8.1 Term and Termination.

(a) *Term and Termination.* This Agreement shall commence on the Effective Date and shall continue in full force and effect until December 31, 2019, unless otherwise terminated pursuant to the terms and conditions set forth herein (the foregoing period plus any renewals is referred to as the "**Term**"). The Parties agree to commence good faith discussions regarding one or more two (2) year extensions of the Term no later than six (6) months prior to the expiration of the then current Term. Upon expiration of the Term, this Agreement shall terminate without any notice of termination being required, unless the Parties agree in writing to extend the Agreement for an additional period to be agreed upon in writing by the Parties.

(b) *Termination due to Insufficient Patient Care Database.* AbbVie may, subject to this Section 8.1(b), terminate this Agreement upon sixty (60) days written notice to OraSure if OraSure fails to input and store into the Patient Care Database in the second or any subsequent Calendar Year at least ******* additional new Patients testing HCV

******* Portions of this page have been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

positive using the Product during each applicable Calendar Year (the “**Annual Minimum Patient Care Database Threshold**”) of the Term, provided however, that if the failure to meet the Annual Minimum Patient Care Database Threshold for any Calendar Year results, in whole or in part, from AbbVie’s failure to meet its obligations under this Agreement, including its obligations to fully design, develop, implement and make available to Patients the Care Model in the Field in the Territory or AbbVie’s failure to comply with its Co-Promotion or Detailing obligations hereunder, then AbbVie shall have no right of termination in respect of the applicable Calendar Year pursuant to this Section 8.1(b). Notwithstanding the foregoing, if OraSure is using Commercially Reasonable Efforts to satisfy the Annual Minimum Patient Care Database Threshold and fails to meet such threshold and the proviso in the preceding sentence does not apply, then the Parties shall work in good faith during such sixty (60) day period to develop a mutually acceptable plan for OraSure to implement in connection with meeting the Annual Minimum Patient Care Database Threshold. If the Parties are unable to reach a mutually acceptable plan in writing upon the expiration of such sixty (60) day period, then this Agreement shall terminate effective upon AbbVie’s delivery of written notice to OraSure. This Section 8.1(b) sets forth AbbVie’s sole and exclusive remedy in the event of a failure to meet the Annual Minimum Patient Care Database Threshold for any Calendar Year.

8.2 Termination for Breach. If either Party (the “**Non-Breaching Party**”) believes that the other Party (the “**Breaching Party**”) has breached one (1) or more of its material obligations under this Agreement, then the Non-Breaching Party may deliver notice of such material breach to the Breaching Party (a “**Default Notice**”), which Default Notice shall describe such breach in reasonable detail and shall state the non-breaching Party’s intention to terminate this Agreement pursuant to this Section 8.2. The following shall be considered a non-exclusive list of material obligations by the respective Party under this Agreement (the failure of which shall be deemed a material breach by such Party): (i) solely with respect to OraSure, OraSure’s material failure to exercise Commercially Reasonable Efforts to design, develop, implement and administer the Patient Care Database throughout the Term in the Field in the Territory in accordance with Section 3.1(a); (ii) solely with respect to AbbVie, AbbVie’s material failure to develop, deploy, make available to Patients and maintain the Care Model during the Term in the Field in the Territory in accordance with Section 2.3(a) or AbbVie’s material failure to Detail the Product in accordance with Sections 2.3(a) and 4.1(b); and (iii) with respect to each Party (A) such Party’s material failure to exercise Commercially Reasonable Efforts to implement, within one (1) year after the Effective Date, a retail pharmacy initiative to co-promote the Product in accordance with terms that are mutually acceptable to the Parties and consistent with the Co-Promotion Plan and the Guiding Principles, *provided, however*, that such one (1) year period shall not apply to either Party to the extent such one (1) year period is exceeded due to a factor outside of such Party’s reasonable control, including any delay directly or indirectly caused by a Third Party retail pharmacy or the other Party or the other Party’s Affiliates or Third Party Providers; (B) such Party’s material failure to reasonably respond to and negotiate in good faith with the other Party in connection with executing and implementing a new Statement of Work proposed by the other Party as long as such proposed Statement of Work is contemplated by, and structured in a manner materially consistent with, this Agreement, the Co-Promotion Plan and the Guiding Principles; and (C) such Party’s failure to comply with its material obligations

contained in each Statement of Work, including, without limitation, the HTAA Statement of Work, or such Party's material failure to negotiate in good faith agreements with any Third Parties that are reasonably necessary for and material to such Party's ability to carry out its responsibilities pursuant to each Statement of Work. Nothing in this Section 8.2 shall be interpreted as limiting either Party's rights or claims with respect to asserting the other Party's breach of any other material obligation that it has pursuant to this Agreement.

(a) If the Breaching Party does not dispute that it has committed a breach of one (1) or more of its material obligations under this Agreement, then if the Breaching Party fails to cure such breach within thirty (30) days after receipt of the Default Notice, or if such compliance cannot be fully achieved within such thirty (30) day period and the Breaching Party has failed to commence compliance or has failed to use diligent efforts to achieve full compliance as soon thereafter as is reasonably possible (but in any event within sixty (60) days after receipt of the Default Notice), the Non-Breaching Party may terminate this Agreement upon written notice to the Breaching Party.

(b) If the Breaching Party disputes that it has committed a breach of one (1) or more of its material obligations under this Agreement, the Breaching Party may submit the dispute to dispute resolution pursuant to Section 9.4(c).

(c) During the pendency of any dispute under this Agreement initiated before the end of any applicable cure period under this Section 8.2, (i) this Agreement will remain in full force and effect, (ii) the provisions of this Agreement relating to termination for material breach will not be effective, (iii) the time periods for cure under Section 8.2 as to any termination notice given prior to the initiation of the arbitration proceeding will be tolled, and (iv) neither Party will issue a notice of termination pursuant to this Agreement based on the subject matter of the ADR (and no effect will be given to previously issued termination notices), until the ADR has confirmed the existence of the facts claimed by a Party to be the basis for the asserted material breach.

8.3 Termination for Insolvency. In the event that either Party: (a) files for protection under bankruptcy or insolvency laws; (b) makes a general assignment of a substantial portion of its assets for the benefit of creditors; (c) appoints or suffers appointment of a receiver or trustee over substantially all of its property that is not discharged within ninety (90) days after such filing; (d) proposes or is a party to any dissolution or liquidation related to its business; or (e) files a petition under any bankruptcy or insolvency act or has any such petition filed against that is not discharged within ninety (90) days of the filing thereof; then the other Party may terminate this Agreement in its entirety effective immediately upon written notice to such Party.

8.4 Termination Upon Change of Control. AbbVie will have the right to immediately terminate this Agreement by written notice to OraSure in the event of a Change of Control of OraSure involving an AbbVie Competitor. OraSure shall provide notice to AbbVie not less than sixty (60) days prior to its proposed Change of Control; *provided, however*, that if OraSure is advised by its legal counsel that it is precluded from providing AbbVie with this prior notice under Applicable Law or contractual restriction, then OraSure shall deliver such notice immediately following the earlier of: (i) such time as OraSure is able to notify AbbVie in compliance with Applicable Law or contractual restriction, and (ii) after consummation of the

Change of Control. The above notice shall contain the following information regarding the Person that will assume control of OraSure: (a) the name and legal composition of the Person; and (b) a general description of the Change of Control.

8.5 Termination for Convenience. Either Party will have the right to terminate this Agreement for convenience (i.e., without cause) with termination effective any time on or after December 31, 2016 by giving the other Party not less than six (6) months prior written notice. For the purposes of clarity, it is the understanding of the Parties that during the notice period described above, the rights and obligations of the Parties shall continue in full force and effect until the applicable date of termination of the Agreement.

8.6 Termination for Change of Laws. In the event that any law or regulation enacted, promulgated or amended after the date of this Agreement or any interpretation of law or regulation by a court or regulatory authority of competent jurisdiction after the date of this Agreement (collectively, “**Change of Laws**”) materially and adversely affects the validity or enforceability of this Agreement, or materially and adversely impacts upon the ability of either Party to perform its obligations under this Agreement (excluding payment and other financial considerations), then either Party may request renegotiation of the applicable terms of this Agreement to address the Change of Law by written notice to the other Party. If, in the reasonable, good faith opinion of either Party, the Parties are unable to in good faith negotiate an amendment to this Agreement that addresses issue caused by the Change of Law as described in the immediately preceding sentence and which reasonably and materially preserves the original reasonable expectations of the Parties to the extent possible in a manner consistent with the Change of Law, then either Party may terminate this Agreement upon thirty (30) days written notice to the other Party; provided however, that if the other Party objects to such termination then the matter shall be resolved in accordance with Section 9.4(c) herein.

8.7 Effects of Expiration or Termination.

(a) *Survival.* Termination or expiration of this Agreement for any reason shall be without prejudice to any rights that shall have accrued to the benefit of a Party prior to such termination or expiration. Such termination or expiration shall not relieve a Party from obligations that are expressly indicated to survive the termination or expiration of this Agreement. Without limiting the foregoing, Sections 2.2(a)(iii), 2.7(b)(iv), 2.12, 2.14, 3.3, 4.2(a) (to the extent related to an Exclusivity Refund or Exclusivity Shortfall), 4.4, 4.5, 7.1, 7.2, 7.3, 7.4, 7.5, and 8.7 and Articles 5, 6 and 9 of this Agreement shall survive the termination or expiration of this Agreement for any reason. Except for payments that have accrued prior to the termination or expiration of this Agreement or otherwise as expressly set forth in Section 8.7(b) relating to a termination for convenience by either Party or a termination by OraSure for breach, in the event of the termination of this Agreement, AbbVie shall not be obligated to pay OraSure for any amount of compensation set forth in Article 4 of this Agreement that relates to a time period after the effective date of termination of this Agreement, including, without limitation, any Database Establishment, Ownership and Exclusivity Fee that would otherwise have accrued after the effective date of termination of this Agreement.

(b) *Termination For Convenience or Termination by OraSure for Breach.* In the event either Party terminates this Agreement for convenience pursuant to Section 8.5, the terminating Party shall pay an early termination penalty in the amount of [***] (the “**Termination Fee**”) to the other Party, provided however, that in the event that (i) AbbVie has paid Forty Million and 00/100 Dollars comprised of the initial three installments of the Database Establishment, Ownership and Exclusivity Fee due through the second anniversary of the Effective Date pursuant to Section 4.2(a); and (ii) AbbVie has delivered its written notice to OraSure exercising its right to terminate for convenience pursuant to Section 8.5 at least six (6) months prior to December 31, 2016 with a termination effective date of December 31, 2016, then no Termination Fee shall be due from AbbVie. Moreover, as to the Maintenance Services Payments, in the event AbbVie terminates this Agreement pursuant to Section 8.5, or OraSure terminates this Agreement for breach pursuant to Section 8.2, AbbVie shall pay to OraSure the pro-rated Maintenance Services Payment set forth in Section 4.2(b) for the Calendar Year of termination based upon the annualized threshold that would have been achieved had the Calendar Year been completed. Such annualized threshold will be calculated utilizing the number of new Patients testing positive for HCV using the Product that have opted-in to the Patient Care Database during such Calendar Year through the effective date of termination and who are entered into the Patient Care Database consistent with the terms of this Agreement or whose Patient Information has been collected or authorized to be collected, but not previously entered into the Patient Care Database. For example, if this Agreement is terminated effective on September 30, 2017 and the actual number of Patients meeting the criteria set forth in the previous sentence achieved during the first nine (9) months of 2017 is [***], then those [***] new Patients would be annualized to [***], which is on pace for Tier 6 of the Maintenance Services Payment chart and a Service Payment of [***] would be due to OraSure [***] x 75%) because Tier 6 requires the payment of a [***] Maintenance Services Payment and the effective date of termination occurred seventy five percent (75%) through the 2017 Calendar Year.

(c) *Termination of Rights.* Upon the termination or expiration this Agreement for any reason, AbbVie shall immediately cease all of its promotional and marketing activities for the Product and both Parties shall discontinue any use of the other Party’s Trademarks and return to the other Party or destroy all sales materials, training materials and AbbVie-developed Product Promotional Materials for the Product. After any expiration or termination OraSure shall retain the right to use any sales training and Product Promotional Materials developed during the term of this Agreement, provided, however, that OraSure shall have no further right to use AbbVie’s name or any AbbVie Trademarks or logos in connection therewith.

(d) *Transition.* Additionally, notwithstanding the foregoing or anything in this Agreement to the contrary, upon the termination or expiration of this Agreement, but subject to AbbVie’s fulfillment of its obligations under this Agreement:

(i) OraSure shall, and shall cause its Affiliates, agents and Third Party Providers to, use their Commercially Reasonable Efforts to engage in an orderly transition of the data and information contained in the Patient Care Database to AbbVie or its designee(s). Such transitional services shall include, without limitation, continued input into the Patient Care Database, for a period of thirty (30) days after such expiration or termination, of any Patient Information collected or authorized to be collected, but not previously entered into the Patient Care Database.

[***] Portions of this page have been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

(ii) OraSure shall, and shall cause its Affiliates, agents and Third Party Providers to, transfer and assign to AbbVie, all of their rights (including Intellectual Property Rights) in and to the data and information regarding Patients contained in the Patient Care Database.

(iii) To the extent that OraSure owns and has the right to transfer such items to AbbVie, OraSure shall transfer and assign to AbbVie any records, forms, files, materials, passwords, accounts, databases, software, source code, object code, algorithms, analytic tools, documentation, procedures, manuals, policies and other items, in each case solely relating to the Patient Care Database, including any Intellectual Property Rights solely relating to the Patient Care Database.

ARTICLE 9 MISCELLANEOUS

9.1 Force Majeure. Neither Party shall be held liable or responsible to the other Party or be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement when such failure or delay is caused by or results from events beyond the reasonable control of the non-performing Party, including fires, floods, earthquakes, hurricanes, embargoes, shortages, epidemics, quarantines, war, acts of war (whether war be declared or not), terrorist acts, insurrections, riots, civil commotion, strikes, lockouts, or other labor disturbances (whether involving the workforce of the non-performing Party or of any other Person), acts of God or acts, omissions or delays in acting by any governmental authority (except to the extent such delay results from the breach by the non-performing Party or any of its Affiliates of any term or condition of this Agreement). The non-performing Party shall immediately notify the other Party of such force majeure within five (5) Business Days after such occurrence by giving written notice to the other Party stating the nature of the event, its anticipated duration, and any action being taken to avoid or minimize its effect. The suspension of performance shall be of no greater scope and no longer duration than is necessary and the non-performing Party shall use commercially reasonable efforts to remedy its inability to perform.

9.2 Assignment. Without the prior written consent of the other Party, neither Party shall sell, transfer, assign, delegate (except as permitted by Section 3.2), or otherwise dispose of, whether voluntarily, involuntarily, by operation of law or otherwise, this Agreement or any of its rights or duties hereunder to any Third Party; *provided, however*, that, except as otherwise specifically provided herein, either Party may make such an assignment without the other Party's consent to its Affiliate (for so long as it remains an Affiliate of such Party) or to a successor, whether in a merger, sale of stock, sale of assets or any other transaction, of the business to which this Agreement relates. Any attempted assignment or delegation in violation of this Section 9.2 shall be void and of no effect. All validly assigned and delegated rights and obligations of the Parties hereunder shall be binding upon and inure to the benefit of and be enforceable by and against the successors and permitted assigns of OraSure or AbbVie, as the case may be. The permitted assignee or transferee shall assume all obligations of its assignor or transferor under this Agreement, *provided, however*, that a Party assigning or transferring this Agreement or its rights or duties hereunder to an Affiliate shall remain fully liable for the performance of this Agreement by such Affiliate.

9.3 Severability. If any provision of this Agreement is held to be illegal, invalid, or unenforceable under any present or future law, and if the rights or obligations of either Party under this Agreement will not be materially and adversely affected thereby, (a) such provision shall be fully severable, (b) this Agreement shall be construed and enforced as if such illegal, invalid, or unenforceable provision had never comprised a part hereof, (c) the remaining provisions of this Agreement shall remain in full force and effect and shall not be affected by the illegal, invalid, or unenforceable provision or by its severance herefrom, and (d) in lieu of such illegal, invalid, or unenforceable provision, the Parties shall negotiate in good faith a valid, legal and enforceable substitute provision that most nearly reflects the original intent of the Parties. To the fullest extent permitted by Applicable Law, each Party hereby waives any provision of law that would render any provision hereof illegal, invalid, or unenforceable in any respect.

9.4 Governing Law, Jurisdiction and Service.

(a) *Governing Law.* This Agreement or the performance, enforcement, breach or termination hereof shall be interpreted, governed by and construed in accordance with the laws of the State of Delaware, United States, excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction.

(b) *Service.* Each Party further agrees that service of any process, summons, notice or document by registered mail to its address set forth in Section 9.5 shall be effective service of process for any action, suit, or proceeding brought against it under this Agreement in any such court.

(c) *Dispute Resolution.* If a dispute arises between the Parties in connection with or relating to this Agreement or any document or instrument delivered in connection herewith (a “**Dispute**”), it shall be resolved pursuant to this Section 9.4(c). The Parties shall discuss in good faith for a period of thirty (30) days any Dispute to obtain resolution of the issue. Any final decision mutually agreed to by the Parties shall be conclusive and binding on the Parties. If the Parties are not able to agree on the resolution of any such issue within thirty (30) days, either Party may, by written notice to the other Party, elect to initiate an alternative dispute resolution (“**ADR**”) proceeding pursuant to the procedures set forth in Schedule 9.4 for purposes of having the matter settled. Any ADR proceeding under this Agreement shall take place pursuant to the procedures set forth in Schedule 9.4. Notwithstanding the procedures set forth in Schedule 9.4, in the event of an actual or threatened breach hereunder, the aggrieved Party may seek equitable relief (including restraining orders, specific performance or other injunctive relief) in any court or other forum, without first submitting to any dispute resolution procedures hereunder.

9.5 Notices.

(a) *Notice Requirements.* Any notice, request, demand, waiver, consent, approval, or other communication permitted or required under this Agreement shall be in writing, shall refer specifically to this Agreement and shall be deemed given only if (i) delivered by hand, (ii) sent by facsimile (with transmission confirmed), electronic mail transmission (email), or (iii) by internationally recognized overnight delivery service that maintains records of

delivery, addressed to the Parties at their respective addresses specified in Section 9.5(b) or to such other address as the Party to whom notice is to be given may have provided to the other Party in accordance with this Section 9.5(a). Such notice shall be deemed to have been given as of the date delivered by hand or transmitted by facsimile (with transmission confirmed) or email or on the second Business Day (at the place of delivery) after deposit with an internationally recognized overnight delivery service. Any notice delivered by facsimile shall be confirmed by a hard copy delivered as soon as practicable thereafter. This Section 9.5(a) is not intended to govern the day-to-day business communications necessary between the Parties in performing their obligations under the terms of this Agreement.

(b) *Address for Notice.*

If to AbbVie, to:
AbbVie Bahamas Ltd.
c/o AbbVie Inc.
1 North Waukegan Road
North Chicago, IL 60064
Attention: VP Specialty Brands
Facsimile: 847-785-8534

with a copy (which shall not constitute notice) to:

AbbVie Inc.
1 North Waukegan Road
North Chicago, IL 60064
Attention: VP Business Legal
Facsimile: 847-935-9643

If to OraSure, to:

220 East First Street
Bethlehem, PA 18014
Attention: President & CEO
Facsimile: 610-882-2275

with a copy (which shall not constitute notice) to:

220 East First Street
Bethlehem, PA 18014
Attention: General Counsel
Facsimile: 610-882-2275

9.6 Entire Agreement; Amendments. This Agreement, together with the Exhibits and Schedules attached hereto, and the Nondisclosure Agreement among the Parties dated as of September 23, 2013, sets forth and constitutes the entire agreement and understanding between the Parties with respect to the subject matter hereof and all prior agreements, understandings, promises, and representations, whether written or oral, with respect thereto are superseded hereby. Each Party confirms that it is not relying on any representations or warranties of the

other Party except as specifically set forth in this Agreement. No amendment, modification, release, or discharge shall be binding upon the Parties unless in writing and duly executed by authorized Representatives of both Parties.

9.7 English Language. This Agreement shall be written and executed in, and all other communications under or in connection with this Agreement shall be in, the English language. Any translation into any other language shall not be an official version thereof, and in the event of any conflict in interpretation between the English version and such translation, the English version shall control.

9.8 Waiver and Non-Exclusion of Remedies. Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver shall be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. The waiver by either Party hereto of any right hereunder or of the failure to perform or of a breach by the other Party shall not be deemed a waiver of any other right hereunder or of any other breach or failure by such other Party whether of a similar nature or otherwise. The rights and remedies provided herein are cumulative and do not exclude any other right or remedy provided by Applicable Law or otherwise available except as expressly set forth herein.

9.9 No Benefit to Third Parties. Except as provided in Article 7, the covenants and agreements set forth in this Agreement are for the sole benefit of the Parties hereto and their successors and permitted assigns, and they shall not be construed as conferring any rights on any other Persons.

9.10 Further Assurance. Each Party shall duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including the filing of such assignments, agreements, documents, and instruments, as may be necessary or as the other Party may reasonably request in connection with this Agreement or to carry out more effectively the provisions and purposes hereof, or to better assure and confirm unto such other Party its rights and remedies under this Agreement.

9.11 Relationship of the Parties. It is expressly agreed that OraSure, on the one hand, and AbbVie, on the other hand, shall be independent contractors and that the relationship between the two (2) Parties shall not constitute a partnership, joint venture, or agency. Neither OraSure, on the one hand, nor AbbVie, on the other hand, shall have the authority to make any statements, representations, or commitments of any kind, or to take any action, which shall be binding on the other, without the prior written consent of the other Party to do so. All persons employed by a Party shall be employees of such Party and not of the other Party and all costs and obligations incurred by reason of any such employment shall be for the account and expense of such Party.

9.12 Performance by Affiliates. The Parties recognize that each may perform some or all of its obligations under this Agreement through Affiliates or may exercise some or all of its rights under this Agreement through Affiliates, *provided, however*, that each Party shall remain responsible and be guarantor of the performance by its Affiliates and shall cause its Affiliates to comply with the provisions of this Agreement in connection with such performance. In particular

and without limitation, all Affiliates of a Party that receive Confidential Information of the other Party pursuant to this Agreement shall be governed and bound by all obligations set forth in Article 6. Each Party will prohibit all of its Affiliates from taking any action that such Party is prohibited from taking under this Agreement as if such Affiliates were parties to this Agreement. The use of an Affiliate by a Party shall have no effect on the rights and obligations of such Party under this Agreement.

9.13 Counterparts; Facsimile or Electronic Execution. This Agreement may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one (1) and the same instrument. This Agreement may be executed by facsimile, .pdf or other electronically transmitted signatures and such signatures shall be deemed to bind each Party hereto as if they were original signatures.

9.14 References. Unless otherwise specified: (a) references in this Agreement to any Article, Section, Exhibit or Schedule shall mean references to such Article, Section, Exhibit or Schedule of this Agreement; (b) references in any Section to any clause are references to such clause of such Section; and (c) references to any agreement, instrument, or other document in this Agreement refer to such agreement, instrument, or other document as originally executed or, if subsequently amended, replaced, or supplemented from time to time, as so amended, replaced, or supplemented and in effect at the relevant time of reference thereto.

9.15 Schedules and Exhibits. In the event of any inconsistencies between this Agreement and any schedules, exhibits or other attachments hereto, the terms of this Agreement shall control.

9.16 Construction. Except where the context otherwise requires, wherever used, the singular shall include the plural, the plural the singular, the use of any gender shall be applicable to all genders and the word “or” is used in the inclusive sense (and/or). Whenever this Agreement refers to a number of days, unless otherwise specified, such number refers to calendar days. The captions of this Agreement are for convenience of reference only and in no way define, describe, extend, or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. The term “including,” “include,” or “includes” as used herein shall mean “including, but not limited to,” and shall not limit the generality of any description preceding such term. The language of this Agreement shall be deemed to be the language mutually chosen by the Parties and no rule of strict construction shall be applied against either Party hereto. Each Party represents that it has been represented by legal counsel in connection with this Agreement and acknowledges that it has participated in the drafting hereof. In interpreting and applying the terms and provisions of this Agreement, the Parties agree that no presumption will apply against the Party which drafted such terms and provisions.

[SIGNATURE PAGE FOLLOWS]

THIS MASTER PROGRAM SERVICES AND PRODUCT CO-PROMOTION AGREEMENT IS EXECUTED by the duly authorized representatives of the Parties as of the Effective Date.

ORASURE TECHNOLOGIES, INC.

By: _____
Name: _____
Title: _____

ABBVIE BAHAMAS LTD.

By: _____
Name: William J. Chase
Title: Director and President

EXHIBIT A

ABBVIE COMPETITORS

“**AbbVie Competitors**” means any Third Party that, at the relevant time, (a) is marketing and selling in the Territory [***] and which product directly and, as determined in AbbVie’s reasonable discretion, materially competes with [***] of AbbVie or any of its Affiliates in the Territory; (b) is identified as among [***] and is a material competitor of AbbVie and its Affiliates (on a consolidated basis) in any of the following fields: [***]; or (c) [***]. For purposes of this definition, (i) the “relevant time” means (A) with respect to Section 2.2(b)(i), the time during which the activities described in such Section occur, and (B) with respect to Section 8.4, the date on which a Change of Control of OraSure is consummated, and (ii) this definition shall be limited to clause (a) above with respect to Section 2.2(b)(i).

[***] Portions of this page have been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

EXHIBIT B

CO-PROMOTION PLAN

[To be agreed and attached within 60 days of the Effective Date]

EXHIBIT C

STATEMENT OF WORK TEMPLATE

See Attached

Exhibit C
Statement of Work
(Template)

Program #

Date: , 2014

Products Covered: OraQuick Rapid HCV Test

This Statement of Work is issued under the Master Program Services and Product Co-Promotion Agreement, dated as of June 10, 2014 (the “Agreement”), between OraSure Technologies, Inc. (“OraSure”) and AbbVie Bahamas Ltd. (“AbbVie”). This Statement of Work, as amended, modified, or supplemented, includes the terms and conditions of such Agreement, which are incorporated by this reference. A capitalized term not otherwise defined herein shall have the meaning ascribed to such term in the Agreement. To the extent that there is a conflict between this SOW and the Agreement, the Agreement shall supersede, control, and prevail.

Scope of Work

Per the Agreement, OraSure agrees to provide testing and AbbVie agrees to generate awareness and patient activation among **[Describe initiative or event]**. The program by which this partnership exists shall be called for any and all communications or programs related to **[Name other party(ies) to initiative/event]**.

Two agreements will be generated, one for OraSure and **[Name other party(ies) to initiative/event]** address of and another for AbbVie address of 1 North Waukegan Rd., North Chicago, IL 60064 and **[Name other party(ies) to initiative/event]** address of .

1. **Responsibilities**

Per the Agreement, OraSure shall be responsible for any and all services related to testing, including, but not limited to: [(i) public affairs activities, (ii) administration of the Co-Payment Assistance Program (via vendor) with (including copay payment, processing, transaction fees, and related materials), (iii) distribution of Product sampling, (iv) providing tests by direct sales, distribution through distributors and/or donations), (v) collaborating with in generating promotion among for the Product and generating Product testing/screening participation, (vi) community outreach activities, (vii) advisory boards, (viii) ongoing Product support, (ix) Product training, (x) CLIA training, (xi) distribution costs related to Product; (xii) establishing and maintaining the Patient Care Database; (xiii) obtaining or causing to be obtained and maintaining from each Patient enrolling and participating in the Patient Care Database the relevant Marketing Consent Form and HIPAA Authorization Form; (xiv) obtaining and maintaining the Marketing Authorization and any other applicable regulatory approvals reasonably necessary to market and sell the Product in the Field in the Territory to the

HCPs; and (xvii) distributing Patient Forms to HCPs.] **[Specific responsibilities to be determined for each initiative/event as contemplated by the Agreement and Guiding Principles]**

AbbVie shall be responsible for: [(i) developing and making the Care Model available to , (ii) introducing physicians and other HCPs to the Care Model, and (iii) creating and providing materials to that include: (a) promotional, disease state awareness and educational materials regarding HCV and the availability of rapid HCV testing in written or digital form for HCPs; (b) promotional, disease state awareness and educational materials regarding HCV and the availability of rapid HCV testing in written or digital form for consumers; (c) patient materials that allow patients to register for the Care Model; (d) exhibition/health fairs materials and booths; and (e) market research regarding .] **[Specific responsibilities to be determined for each initiative/event as contemplated by the Agreement and Guiding Principles]**

[Define other responsibilities].

In addition, all parties hereto agree to participate in the Coalition of Cure initiative including using likeness and endorsements in print, digital, social media, radio, television and any other medium deemed appropriate by all parties.

2. **List of Applicable Documents**

See Exhibit XX for the detailed budget broken out by related activities.

3. **Program Contacts**

AbbVie: Melissa Bassler, Senior Product Manager
OraSure: Deborah Katz, Marketing Director

4. **Estimated Program Schedule/Term of the Program**

The length of the Agreement will be 5 years (60 Months) from the date of execution.

5. **Sub-contractors**

[To be determined]

6. **Price and Payment**

AbbVie agrees to pay for the tactics outlined in Exhibit XX per the agreed payment schedule below. Budgets for years will be established annually per the agreed timelines by both parties.

OraSure agrees to pay as agreed to by OraSure and or as outlined in Exhibit XX.

Invoices under this Program Agreement and shall be sent to:

AbbVie, Inc.
1 North Waukegan Road
North Chicago, IL 60064
Attention: Melissa Bassler

(Identify all expenses or third party vendor charges that may be approved for reimbursement by AbbVie.)

7. **Payment Schedule.**

[To be determined]

8. **Change Management**

Program Modification. This Program may be modified only upon the written approval of both parties.

The scope change request process will be the vehicle for communicating change. Either party may initiate a change request in writing. Both parties must review the proposed change and either approve or reject such change in writing prior to proceeding with any change to this SOW. Only the following individuals are authorized to make and/or approve changes.

OraSure:

AbbVie:

Tony Zezzo, EVP, Marketing and Sales

Lutz Schlicht, Vice President US Hepatology

9. Reviewed for content, deliverables and expenses:

ABBVIE DIVISIONAL OWNER.

By: _____

Name: _____

Date: _____

10. **OUR AGREEMENT**

While the signatures of the AbbVie Division Owner and AbbVie Corporate Purchasing on this Statement of Work signify acceptance of the descriptions, charges and expenses, the legal commitment of funds from AbbVie for this project or program are only conveyed by the issuance of a Purchase Order. Signatures on this Statement of Work do not authorize the commencement of chargeable work towards this project or program. OraSure agrees to commence chargeable work only after a Purchase Order is issued for the project or program.

This Statement of Work and our existing Agreement form the basis for our agreement. Please indicate your acceptance by signing below.

[Other terms and/or modifications to this form shall be determined by agreement of the parties]

AGREED AND ACCEPTED:

ABBVIE BAHAMAS LTD.

By: _____

Printed Name: William J. Chase

Title: Director and President

Date: June 10, 2014

ORASURE TECHNOLOGIES, INC.

By: _____

Printed Name: _____

Title: _____

Date: June 10, 2014

**ABBVIE, INC.
CORPORATE PURCHASING**

By: _____

Printed Name: _____

Title: _____

Date: June 10, 2014

EXHIBIT C-1

HTAA STATEMENT OF WORK

See Attached

**Exhibit C-1 to Master Program and Product Co-Promotion Agreement
HTAA Statement of Work**

Program #

Effective Date: June 10, 2014

Products Covered: HCV

This Statement of Work (“SOW”), effective as of the Effective Date, is issued pursuant to the Master Program and Product Co-Promotion Services Agreement, dated of even date herewith (the “Agreement”), between OraSure Technologies, Inc. (“OraSure”) and AbbVie Bahamas Ltd. (“AbbVie”). This Statement of Work, as amended, modified, or supplemented, includes the terms and conditions of such Agreement, which are incorporated by this reference. A capitalized term not otherwise defined herein shall have the meaning ascribed to such term in the Agreement. To the extent that there is a conflict between this SOW and the Agreement, the Agreement shall supersede, control, and prevail.

Scope of Work

Pursuant to the Agreement, OraSure agrees to, among other matters, promote and supply the Product, establish and maintain the Patient Care Database and administer the Co-Payment Assistance Program for eligible Patients, and AbbVie agrees to educate patients about HCV and provide patients with access to the Care Model. To accomplish these objectives, OraSure and AbbVie will collaborate with the Healthy Trucking Association of America (HTAA) and MedMatRx (MMR). The collaboration between OraSure, AbbVie, HTAA and MMR shall be known as “Truckers Rolling Against Hep-C” for any and all communications or programs related to Truckers.

In order to enter into this multi-party collaboration, two separate services agreements will be executed: one (1) between OraSure and MMR/HTAA (“OraSure Services Agreement”), and one (1) between AbbVie and MMR/HTAA (“AbbVie Services Agreement”) (collectively, the “Services Agreements”).

11. Responsibilities

Per the Agreement, OraSure shall be responsible for any and all services related to testing, including, but not limited to: (i) public affairs activities, (ii) administration of the Co-Payment Assistance Program (through its vendor) for eligible Patients with MMR/HTAA (including copay payment, processing, transaction fees, and related materials), (iii) distribution of Product sampling, (iv) providing Product (including negotiating price for direct purchases by MMR/HTAA, distributing Product to clinics and providers through distributors and/or donations), (v) collaborating with MMR/HTAA in generating promotion among the HTAA membership base and extended network for the Product and generating Product testing/screening participation, (vi) community outreach activities, (vii) funding event staffing for tests at non-clinic initiatives (Healthwatch), health fairs and/or truck shows, (viii) advisory boards, (ix) ongoing Product support, (x) Product training, (xi) CLIA training, (xii) distribution costs related to Product; (xiii) establishing and maintaining the Patient Care Database; (xiv) obtaining or causing to be obtained and maintaining from each Patient enrolling and participating in the

Patient Care Database the relevant Marketing Consent Form and HIPAA Authorization Form; (xv) obtaining and maintaining the Marketing Authorization and any other applicable regulatory approvals reasonably necessary to market and sell the Product in the Field in the Territory to the HCPs; and (xvi) distributing Patient Forms to HCPs. In addition, OraSure agrees to evaluate, and if deemed appropriate, participate in or support one or more pharmacoeconomic studies related to Truckers and HCV.

AbbVie shall be responsible for: (i) developing and making the Care Model available to HTAA's membership base, clinics and extended network of providers, (ii) introducing physicians and other HCPs to the Care Model, and (iii) creating and providing materials to HTAA/MMR that include: (a) promotional, disease state awareness and educational materials regarding HCV and the availability of rapid testing in written or digital form for HCPs; (b) promotional, disease state awareness and educational materials regarding HCV and the availability of rapid testing in written or digital form for consumers; (c) patient materials that allow patients to register for the Care Model; (d) exhibition/health fairs materials and booths; and (e) market research regarding Truckers and HCV. In addition, AbbVie agrees to evaluate, and if deemed appropriate by the Health Economics and Outcomes Research department at AbbVie, conduct one or more pharmacoeconomic studies related to Truckers and HCV.

OraSure and AbbVie acknowledge that HTAA/MMR will be responsible for (i) creating awareness of HCV among Truckers, in particular HTAA's membership base, clinics and extended network; (ii) promoting and conducting non-clinical testing events at truck stops, truck industry events, employer/terminal sites, trucking schools, and/or CDL HUB sites; (iii) purchasing Product directly from OraSure as needed and facilitating access by OraSure to affiliated clinics and provider network for sale of Product by OraSure's distributors; assisting AbbVie in various community outreach activities among Truckers, in particular HTAA's membership base and extended network, with respect to the Care Model; (iii) participating in the "Coalition of Cure" initiative; (iv) providing guidance to AbbVie/OraSure on strategic approaches to the Transportation Industry, as requested by AbbVie/OraSure; and (v) assisting AbbVie/OraSure in facilitating the establishment of contacts with and an open channel of direct communications and dialogue with clinics, Truckers, Trucker fleets, Trucker training schools and work place sites where Truckers visit. This will be done through consumer, professional, provider, media and management programming, using materials provided by AbbVie/OraSure, and more fully set forth in the Services Agreements. In addition, HTAA/MMR will agree to provide data, information and/or consulting services required for AbbVie/OraSure to conduct a pharmacoeconomic study or studies.

In addition, all parties agree to participate in the Coalition of Cure initiative including using likeness and endorsements in print, digital, social media, radio, television and any other medium deemed appropriate by all parties.

All responsibilities and activities will be performed in compliance with all Applicable Laws, including anti-bribery and anti-corruption laws, the Patient Protection and Affordable Care Act of 2010, the Health Insurance Portability and Accountability Act of 1996 (as amended) ("HIPAA"), rules governing healthcare programs and applicable FDA regulatory requirements.

12. List of Applicable Documents

See Exhibit A to the AbbVie Services Agreement for the detailed budget and description of services to be performed by MMR/HTAA for AbbVie.
See Exhibit A to the OraSure Services Agreement for the detailed budget and description of services to be performed by MMR/HTAA for OraSure.

13. Program Contacts:

AbbVie: Melissa Bassler, Senior Product Manager
OraSure: Deborah Katz, Marketing Director

14. Estimated Program Schedule/Term of the Program

The term of each of the Services Agreements will begin on the Effective date and end on the earlier of December 31, 2019 or the termination of the Agreement. The Services Agreements may not be terminated without cause prior to December 31, 2016.

15. Sub-contractors:

Each of the Services Agreements will permit performance of activities by subcontractors, including, but not limited to, Healthwatch and Rolling Strong.

16. Price and Payment:

AbbVie agrees to pay MMR/HTAA [***] in exchange for the services set forth in Section 2.1 and Exhibit A of the AbbVie Services Agreement, which corresponds to services performed from the Effective Date of the AbbVie Services Agreement through December 31, 2015. A budget for 2016-2019 will be mutually agreed upon by AbbVie and HTAA/MMR based on timelines set forth in the AbbVie Services Agreement.

OraSure agrees to pay MMR/HTAA [***] in exchange for the services set forth in Section 2 and Exhibit A of the OraSure Services Agreement. At present, within the first [***] months, if not earlier, MMR/HTAA is expected to reach or exceed [***] Truckers screened for HCV through the various programs set forth in the OraSure Services Agreement. The number of truckers that enter the Care Model will be discussed and a goal will be set so that all parties are satisfied.

17. Change Management.

SOW Modification. This SOW may be modified only upon the written approval of both OraSure and AbbVie.

The scope change request process will be the vehicle for communicating change. Either party may initiate a change request in writing. Both parties must review the proposed change and either approve or reject such change in writing prior to proceeding with any change to this SOW. Only the following individuals are authorized to make and/or approve changes.

[***] Portions of this page have been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

OraSure:

AbbVie:

Tony Zezzo, EVP, Marketing and Sales
U.S. Hepatology

Lutz Schlicht, Vice President

18. Reviewed for content, deliverables and expenses:

ABBVIE DIVISIONAL OWNER.

By: _____

Name: _____

Date: _____

19. OUR AGREEMENT:

While the signatures of the AbbVie Division Owner and AbbVie Corporate Purchasing on this Statement of Work signify acceptance of the descriptions, charges and expenses, the legal commitment of funds from AbbVie for this project or program are only conveyed by the issuance of a Purchase Order. Signatures on this Statement of Work do not authorize the commencement of chargeable work towards this project or program. OraSure agrees to commence chargeable work only after a Purchase Order is issued for the project or program.

[Signatures appear on next page]

This Statement of Work and our existing Agreement form the basis for our agreement and has been executed and effective as of the Effective Date.

AGREED AND ACCEPTED:

ABBVIE BAHAMAS LTD.

By: _____

Printed Name: William J. Chase

Title: Director and President

Date: June 10, 2014

**ABBVIE, INC.
CORPORATE PURCHASING**

By: _____

Printed Name: _____

Title: _____

Date: June 10, 2014

**ORASURE TECHNOLOGIES, INC., a
Delaware corporation**

By: _____

Printed Name: _____

Title: _____

Date: June 10, 2014

EXHIBIT D

HIPAA AUTHORIZATION FORM

See attached

**HIPAA AUTHORIZATION FOR
USE AND DISCLOSURE OF HEALTH INFORMATION 1**

Signing this document authorizes your Provider (named below) to use and/or disclosure certain information about you, including certain demographic information, contact information, OraQuick HCV Rapid Antibody Test results and insurance information (collectively, “Health Information”). Please provide all information requested or this form cannot be used for its intended purpose.

PATIENT NAME: _____

PROVIDER NAME: _____ (“Provider”)

PROVIDER’S ADDRESS: _____

AUTHORIZATION FOR USE AND DISCLOSURE

A. Provider would like to make you aware of a patient support program provided by AbbVie to help newly diagnosed Hepatitis C patients at no additional charge (the “Care Program”). AbbVie has partnered with OraSure in connection with the development of a Patient Care Database as part of the Care Program. OraSure also offers a patient co-payment assistance program in connection with your purchase and use of the OraQuick HCV Rapid Antibody Test (the “Co-Payment Assistance Program”) and your participation in the Patient Care Database. **Patients who have commercial insurance or are uninsured are eligible for the Co-Payment Assistance Program while patients insured under any federal, state or local government funded health care program are not eligible to participate. Participation in the Co-Payment Assistance Program may also be limited or prohibited by law in certain States.**

B. I hereby authorize Provider to release the information described in Section C to:

OraSure Technologies, Inc.
220 East First Street
Bethlehem, PA 18015

and/or

AbbVie, Inc.
1 North Waukegan Road
North Chicago, IL 60064

C. I authorize Provider to disclose the following information about me in connection with my participation in the Care Program and the Co-Payment Assistance Program: my date of birth, gender, ethnicity and contact information, my OraQuick HCV Rapid Antibody Test results and my insurance information.

PURPOSE OF USE OR DISCLOSURE

I am requesting this disclosure so that I can participate in the Care Program, including the Patient Care Database and/or the Co-Payment Assistance Program if I am eligible to participate.

My participation in one or both programs will involve using and/or disclosing my Health Information for the purposes of such programs and may include further disclosure of my Health Information to other third parties that administer the programs on behalf of AbbVie and/or OraSure. I also understand that participation in the programs will involve the use of my Health Information for marketing purposes, for which a separate authorization form will be requested of me.

1 This form is designed to comply with HIPAA and may not comply with applicable state laws. A state law analysis should be conducted and revisions should be made to comply with state law prior to use.

EXPIRATION

This authorization expires on the earlier of (i) my Provider's receipt of my written revocation of this Authorization sent to the Provider's address set forth above, with copies sent to AbbVie and OraSure at the addresses set forth below; or (ii) [five (5) years]² from the date of my signature below.

PATIENT RIGHTS

I understand that I may refuse to sign this authorization, and my refusal will not affect my ability to obtain treatment, eligibility for benefits, or payment for health care services, except that OraSure and/or AbbVie will not be able to evaluate my eligibility for the Programs and I will therefore not have the right to participate in either the Care Program or the Co-Payment Assistance Program.

I understand that I may revoke this authorization at any time, but my revocation will not change any uses, disclosures, or other actions already taken with my Health Information. In order to revoke this authorization I must do so in writing and send it to my Provider at the address set forth above, with copies sent to AbbVie and OraSure at the addresses set forth below.

I acknowledge that I have been provided with a signed copy of this authorization.

I understand that Health Information disclosed pursuant to this authorization in some instances could be legally re-disclosed by the recipient without my knowledge and in such cases may no longer be protected by federal confidentiality law (HIPAA).

I understand that OraSure may benefit from the authorized use or disclosure of my Health Information.

I understand that my Provider may benefit from the authorized use or disclosure of my Health Information.

PATIENT SIGNATURE

Date: _____

Signature: _____

Print Name: _____

If not the patient, indicate relationship to patient:

ABBVIE'S ADDRESS

Attention: Privacy Officer
AbbVie, Inc.
1 North Waukegan Road
North Chicago, Illinois 60064

ORASURE'S ADDRESS

Attention: General Counsel
OraSure Technologies, Inc.
220 East First Street
Bethlehem, Pennsylvania 18015

² To be determined in accordance with applicable state law prior to use.

EXHIBIT E

MARKETING CONSENT FORM

See attached

Authorization to Enroll in the AbbVie Care Program and Patient Care Database

AbbVie and OraSure would like to make you aware of a patient support program provided by AbbVie to help newly diagnosed Hepatitis C patients understand and better manage their disease (the “Care Program”). The Care Program includes support services at no additional charge, such as access to HCV education and live support from AbbVie’s HCV patient educators. **Please carefully read all of the information below. If, after reading this information, you would like to enroll in the Care Program and the Patient Care Database, please sign the authorization.**

Patient Authorization

I authorize OraSure and AbbVie to use certain information about me; my date of birth, gender, ethnicity and contact information, my OraQuick HCV Rapid Antibody Test results and my insurance information (collectively “Private Information”). My Private Information may be provided directly by me or through my health care providers. My Private Information will be used only in connection with the Care Program, including AbbVie’s Patient Care Database and will only be used to:

- Allow AbbVie’s Patient Educators to contact me about issues related to Hepatitis C;
- Administer the Care Program, which may require AbbVie or OraSure to disclose my Private Information to third parties that AbbVie or OraSure hire to help administer the Care Program and the Patient Care Database;
- Contact me by mail, email, or phone with marketing information about AbbVie products or services that relate to Hepatitis C; or
- Contact me by mail, email, or phone about my participation in the Care Program.

OraSure and AbbVie will use appropriate safeguards to protect my Private Information and will not use or disclose my Private Information other than as described in this authorization without my permission. OraSure and AbbVie will not sell or transfer my Private Information to any third party for such third party’s use of any kind that does not relate to the Care Program or the Patient Care Database.

To be removed from the Care Program or the Patient Care Database or to request a copy of this form, please contact AbbVie Customer Service at 1-800-255-5162.

Patient Rights

I understand that this authorization is voluntary and any re-disclosure of my Private Information may not be protected by federal or state law.

I understand that I may decide not to sign this authorization, which will not affect my ability to obtain care from my Provider, including diagnosis or treatment, eligibility for benefits, or payment for health care services from health care providers, health plans, and health insurance. However, I understand that if I decide not to sign this form I will not be able to participate in the Care Program, Patient Care Database or the OraSure Patient Co-Payment Assistance Program.

I understand that being a member of the Care Program and Patient Care Database does NOT require me to purchase or use any AbbVie or OraSure product.

I understand that I have the right to revoke this authorization in writing at any time but that my revocation will not change any actions already taken in reliance on my authorization.

Expiration of This Authorization

This authorization will expire upon the earlier of (i) AbbVie’s receipt of my written revocation mailed to the address below; or (ii) [five (5) years]¹ from the date of my signature below.

Date: _____

Signature: _____

Print Name: _____

If not the patient, indicate relationship to patient:

ABBVIE’S ADDRESS

AbbVie, Inc.
1 North Waukegan Road
North Chicago, Illinois 60064
Attention: Privacy Officer

¹ To be determined in accordance with applicable state law prior to use.

EXHIBIT F

GUIDING PRINCIPLES

See attached

Responsibilities Related to Each of the Four “Pillars”¹

Pillar 1: Employer Group (HTAA is representative model)

OraSure Responsibilities:

- Sell and distribute OraQuick Rapid HCV Test to HTAA and its affiliate corporate organizations, mini-clinics, etc. (Direct sales to HTAA and through distributors to clinics and providers and/or donations as determined by the parties)
- Provide training and promotional materials pertaining to use of OraQuick Rapid HCV Test (including CLIA training)
- Provide program set up (via vendor) for patient enrollment in Patient Care Database at mini-clinics, truck shows, etc.
- Provide promotional materials for testing initiative to mini-clinics and Providers
- Provide patient Co-Payment Assistance Program for commercially insured patients, including Product training/education to mini-clinics/Providers for implementation and consideration of kiosk program
- Assist in the coordination and implementation of testing programs into the approximately [***] mini-clinics
- Provide a limited number of Product samples for training purposes as reasonably requested by HTAA and determined by OraSure
- HTAA management fees associated with program implementation per agreed budget with HTAA
- Provide funding to support event staffing by HTAA at non-clinic settings if requested by HTAA and negotiate and pay reasonable and fair market value management fees per agreed budget with HTAA
- Publicity for program successes
- Collaborate with AbbVie in development of Patient Forms and utilize and implement the Patient Forms

AbbVie Responsibilities:

- Provide promotional support and material pertaining to Program for HTAA corporate outreach initiatives
- Provide consumer education at health fairs , truck shows, training schools, terminals pertaining to disease state awareness, the Care Model and the availability of rapid HCV testing
- Train mini-clinic Providers and appropriate network physicians on disease state awareness, the Care Model and the availability of rapid HCV testing
- Co-promote the Product
- Purchase Providers list from HTAA
- Provide electronic education and leave behind promotional material as needed to Providers
- Advisory Board (1) for developing insights
- Provide media promotional spots/interviews (radio, iTruck TV, twitter messaging) – Consumer Campaigns

[***] Portions of this page have been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

¹ A capitalized term not otherwise defined herein shall have the meaning ascribed to such term in the Agreement.

- Deliver the Care Model
- Exhibition fees, booth & collateral for Trade Shows/Health Fairs
- Collaborate with OraSure on the development of Patient Forms

Pillar 2: Retail Pharmacy Clinic Initiative

OraSure Responsibilities:

- Sell and distribute OraQuick Rapid HCV Test product, targeting at least [***] retail clinics and pharmacies (e.g., CVS, Walgreens, Target) to facilitate birth cohort HCV antibody screening programs
- Provide training and promotional materials pertaining to use of OraQuick Rapid HCV Test (including CLIA training)
- Provide program set up (via vendor) for patient enrollment in the Patient Care Database at pharmacies and mini-clinics where permitted by retailer
- Provide promotional materials to introduce testing initiative to pharmacies and mini-clinics
- Provide patient co-payment assistance program for commercially insured patients, including training/education to pharmacies and mini-clinics for implementation where permitted by retailers
- Coordination and implementation of testing programs into the mini-clinics
- Provide management fees to retailers associated with patient enrollment per agreed upon budgets
- Publicity for program successes
- Collaborate with AbbVie in development of Patient Forms and utilize and implement the Patient Forms

AbbVie Responsibilities:

- Provide promotional support and material pertaining to Program
- Provide co-branded “get tested” campaigns aimed at rapid HCV testing for consumers (including social media, radio, etc.)
- Training on disease state awareness and Care Model to Providers associated with mini-clinics, including educational leave behinds
- Provide electronic education and leave behind promotional material pertaining to Care Model as needed to Providers
- Co-Promote the Product
- Delivery of Care Model
- Collaborate with OraSure on the development of Patient Forms
- EMR prompt to screen Baby Boomers (pilot)

Pillar 3: Specialty Physician Initiative

OraSure Responsibilities:

- Provide limited amount of Product Sample Kits for training purposes
- Provide product training and promotional materials pertaining to OraQuick Rapid HCV Test through OraSure’s distributors, MROs and other third party vendors.

[***] Portions of this page have been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

- Sell and distribute OraQuick Rapid HCV Test to appropriate gastroenterologist, hepatologist and infectious disease specialist offices to facilitate birth cohort HCV antibody screening programs
- Provide program set up at physician offices (via vendor) for patient enrollment in Patient Care Database
- Provide patient Co-Payment Assistance Program (via vendor) for commercially insured patients, including training/education to physician offices for implementation
- Provide publicity for program success stories
- Collaborate with AbbVie in development of Patient Forms and utilize and implement the Patient Forms

AbbVie Responsibilities:

- Develop a co-branded Disease State Awareness Campaign
- Develop all Provider-directed leave-behind promotional materials associated with Disease State Awareness and the Care Model
- Provide consumer promotional support and material pertaining to Program
- Develop Consumer Campaign (digital, social)
- Detail target physicians as described in Agreement (P1: DSA, P2: Testing)
- Enroll HCPs in sample program (reps incentivized on Product ordered and % of call plan targets who place an order)
- Install the Care Model (all program communications)
- Deliver The Care Model
- Collaborate with OraSure on the development of Patient Forms
- EMR prompt to screen Baby Boomers (pilot)

Pillar 4: Primary Care Physician Initiative

OraSure Responsibilities:

- Provide limited amount of Product Sample Kits for training purposes
- Provide product training and promotional materials pertaining to OraQuick Rapid HCV Test through OraSure's distributors, MROs and other third party vendors
- Sell and distribute OraQuick Rapid HCV Test product to primary care physician offices to facilitate birth cohort HCV antibody screening programs
- Provide program set up (via vendor) for patient enrollment at physician offices in Patient Care Database
- Provide patient Co-Payment Assistance Program (via vendor) for commercially insured patients, including training/education to physician offices for implementation
- Publicity for program success stories
- Collaborate with AbbVie in development of Patient Forms and utilize and implement the Patient Forms

AbbVie Responsibilities:

- Develop a co-branded Disease State Awareness Campaign
- Develop all Provider-directed leave-behind promotional materials associated with Disease State Awareness and The Care Model

-
- Consideration in AbbVie's discretion of establishing KOL speaker programs and Centers of Excellence speaker programs with referral networks
 - Provide consumer promotional support and material pertaining to Program
 - Enroll HCPs in sample program (reps incentivized on Product ordered and % of call plan targets who place an order)
 - Install the Care Model (all program communications)
 - Deliver the Care Model
 - Detail to appropriate physicians as described in the Agreement (P1: DSA, P2: Testing)
 - Collaborate with OraSure on the development of Patient Forms

EXHIBIT G

PATIENT CARE DATABASE REQUIREMENTS

To Be Attached After the Effective Date

TRADEMARKS

OraSure Trademarks

OraSure Technologies Inc.
OraSure
OraQuick
OraQuick HCV
TestHepC.com
844-TEST-HEP C

AbbVie Trademarks

AbbVie, Inc.
AbbVie
Nurse Connectors
ProCeed

SCHEDULE 9.4

DISPUTE RESOLUTION PROCEDURES

Any Dispute referred to ADR under this Agreement shall be resolved as follows:

1. To begin an ADR proceeding, a Party shall provide written notice to the other Party of the Dispute to be resolved by ADR. Within fourteen (14) days after its receipt of such notice, the other Party may, by written notice to the Party initiating the arbitration, add additional issues to be resolved within the same ADR.

2. Within twenty-one (21) days following the initiation of the ADR proceeding, the Parties shall select a mutually acceptable independent, impartial and conflicts-free neutral to preside in the resolution of all issues in this ADR proceeding. If the Parties are unable to agree on a mutually acceptable neutral within such period, each Party will select one (1) independent, impartial and conflicts-free neutral and those two (2) neutrals will select a third independent, impartial and conflicts-free neutral within ten (10) days thereafter (such neutral(s), the “**Neutral**”). None of the neutrals selected may be current or former employees, officers or directors of either Party or its Affiliates.

3. No earlier than twenty-eight (28) days or later than fifty-six (56) days after selection, the Neutral shall hold a hearing to resolve each of the issues identified by the Parties. The ADR proceeding shall take place at a location agreed upon by the Parties. If the Parties cannot agree, the Neutral shall designate a location other than the principal place of business of either Party or any of their Affiliates.

4. At least seven (7) days prior to the hearing, each Party shall submit the following to the other Party and the Neutral:

(a) a copy of all exhibits on which such Party intends to rely in any oral or written presentation to the Neutral;

(b) a list of any witnesses such Party intends to call at the hearing, and a short summary of the anticipated testimony of each witness;

(c) a proposed ruling on each issue to be resolved, together with a request for a specific damage award or other remedy for each issue. The proposed ruling shall not contain any recitation of the facts or any legal arguments, and the proposed remedy shall not include any punitive damages. The proposed ruling and the proposed remedy collectively shall not exceed one (1) page per issue.

(d) a brief in support of such Party’s proposed rulings and remedies; *provided*, that the brief shall not exceed twenty (20) pages. This page limitation shall apply regardless of the number of issues raised in the ADR proceeding.

5. Except as expressly set forth in subparagraphs 4(a) - 4(d), no discovery shall be required or permitted by any means, including depositions, interrogatories, requests for admissions, or production of documents.

The hearing shall be conducted on two (2) consecutive days and shall be governed by the following rules:

(a) Each Party shall be entitled to five (5) hours of hearing time to present its case. The Neutral shall determine whether each Party has had the five (5) hours to which it is entitled.

(b) Each Party shall be entitled, but not required, to make an opening statement, to present regular and rebuttal testimony, documents, or other evidence, to cross-examine witnesses, and to make a closing argument. Cross-examination of witnesses shall occur immediately after their direct testimony, and cross-examination time shall be charged against the Party conducting the cross-examination.

(c) The Party initiating the ADR shall begin the hearing and, if it chooses to make an opening statement, shall address therein not only issues it raised but also any issues raised by the responding Party. The responding Party, if it chooses to make an opening statement, also shall address all issues raised in the ADR. Thereafter, the presentation of regular and rebuttal testimony and documents, other evidence, and closing arguments shall proceed in the same sequence.

(d) Except when testifying, witnesses shall be excluded from the hearing until closing arguments.

(e) Settlement negotiations, including any statements made therein, shall not be admissible under any circumstances. Affidavits prepared for purposes of the ADR hearing also shall not be admissible. As to all other matters, the Neutral shall have sole discretion regarding the admissibility of any evidence.

6. Within seven (7) days following completion of the hearing, each Party may submit to the other Party and the Neutral a post-hearing brief in support of its proposed rulings and remedies; *provided*, that such brief shall not contain or discuss any new evidence and shall not exceed ten (10) pages. This page limitation shall apply regardless of the number of issues raised in the ADR proceeding.

7. The Neutral shall rule on each disputed issue within fourteen (14) days following completion of the hearing. Such ruling shall adopt in its entirety the proposed ruling and remedy of one (1) of the Parties on each disputed issue but may adopt one (1) Party's proposed rulings and remedies on some issues and the other Party's proposed rulings and remedies on other issues. The Neutral shall not issue any written opinion or otherwise explain the basis of the ruling.

8. The Neutral shall be paid a reasonable fee plus expenses. These fees and expenses, along with the reasonable legal fees and expenses of the prevailing Party (including all expert witness fees and expenses), the fees and expenses of a court reporter, and any expenses for a hearing room, shall be paid as follows:

(a) If the Neutral rules in favor of one (1) Party on all disputed issues in the ADR, the losing Party shall pay one hundred percent (100%) of such fees and expenses.

(b) If the Neutral rules in favor of one (1) Party on some issues and the other Party on other issues, the Neutral shall issue with the rulings a written determination as to how such fees and expenses shall be allocated between the Parties. The Neutral shall allocate fees and expenses in a way that bears a reasonable relationship to the outcome of the ADR, with the Party prevailing on more issues, or on issues of greater value or gravity, recovering a relatively larger share of its legal fees and expenses.

9. The rulings of the Neutral and the allocation of fees and expenses shall be binding, non-reviewable, and non-appealable, and may be entered as a final judgment in any court having jurisdiction.

10. Except as provided in paragraph 9 or as required by law, the existence of the Dispute, any settlement negotiations, the ADR proceeding, any submissions (including exhibits, testimony, proposed rulings, and briefs), and the rulings shall be deemed to be Confidential Information of both Parties. The Neutral shall have the authority to impose sanctions for unauthorized disclosure of Confidential Information.

11. All ADR proceedings shall be conducted in the English language.

12. Notwithstanding anything to the contrary in this Schedule 9.4, the Neutral shall have discretion to modify the procedures set forth herein (including with respect to discovery) upon good cause shown by a Party.

13. Each Party shall have the right to be represented by counsel in all aspects of any ADR proceeding.

AMENDMENT TO THE

ORASURE TECHNOLOGIES, INC. 2000 STOCK AWARD PLAN

On March 24, 2014, the Company's Board of Directors approved, and recommended for approval by stockholders, a 4,000,000 share increase in the number of shares authorized under the Company's Stock Award Plan (the "Award Plan"). In order to reflect this increase in authorized shares, Section 4.2.2 of the Award Plan was amended and restated, subject to stockholder approval at the Company's Annual Meeting of Stockholders on May 22, 2014 (the "2014 Annual Meeting"), to read as follows:

"4.2.2 Number of Shares; Limits.

(a) The maximum number of Shares for which Awards may be granted under the Plan on or after May 22, 2014, is 4,898,401 Shares, plus any Shares that become available as the result of the cancellation or expiration of any Award, subject to adjustment for changes in capitalization affecting the Corporation's Common Stock pursuant to Section 14.2 of the Plan. Any Shares granted on or after May 22, 2014 in connection with Options and Stock Appreciation Rights shall be counted against this limit on the basis of one Share for each Share subject to such Option or Stock Appreciation Right. Any Shares granted on or after May 22, 2014 in connection with Restricted Awards, Performance Awards or Other Stock-Based Awards shall be counted against this limit on the basis of one and a half Shares for every one Share granted in connection with such Awards.

(b) The maximum number of Shares that may be issued pursuant to paragraph (a) above on or after May 22, 2014 pursuant to Incentive Stock Options, is 4,898,401 Shares, subject to adjustment for changes in capitalization affecting the Corporation's Common Stock pursuant to Section 14.2 of the Plan.

The foregoing amendment to the Stock Award Plan was approved by stockholders at the 2014 Annual Meeting.

Certification

I, Douglas A. Michels, certify that:

1. I have reviewed this report on Form 10-Q of OraSure Technologies, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within the entity, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors:
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 6, 2014

/s/ Douglas A. Michels

Douglas A. Michels
 President and Chief Executive Officer
 (Principal Executive Officer)

Certification

I, Ronald H. Spair, certify that:

1. I have reviewed this report on Form 10-Q of OraSure Technologies, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within the entity, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors:
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 6, 2014

/s/ Ronald H. Spair

Ronald H. Spair
Chief Operating Officer and
Chief Financial Officer
(Principal Financial Officer)

**CERTIFICATION PURSUANT TO
18 U.S.C. §1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of OraSure Technologies, Inc. (the “Company”) on Form 10-Q for the quarter ended June 30, 2014 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I, Douglas A. Michels, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Douglas A. Michels

Douglas A. Michels
President and Chief Executive Officer

August 6, 2014

**CERTIFICATION PURSUANT TO
18 U.S.C. §1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of OraSure Technologies, Inc. (the "Company") on Form 10-Q for the quarter ended June 30, 2014 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Ronald H. Spair, Chief Operating Officer and Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Ronald H. Spair

Ronald H. Spair
Chief Operating Officer and
Chief Financial Officer

August 6, 2014