

**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 September 30, 2021.

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)

36-4370966

(IRS Employer Identification No.)

220 East First Street, Bethlehem, Pennsylvania

(Address of Principal Executive Offices)

18015

(Zip code)

Registrant's telephone number, including area code: (610) 882-1820

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.000001 par value per share	OSUR	The NASDAQ Stock Market LLC

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

Indicate by check mark whether the Registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit such files). Yes No

Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer Accelerated filer

Non-accelerated filer Smaller reporting company

Emerging growth company

If an emerging growth company, indicate by check mark if the Registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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

As of November 1, 2021, the registrant had 72,038,439 shares of common stock, \$0.000001 par value per share, outstanding.

PART I. FINANCIAL INFORMATION

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Item 1. FINANCIAL STATEMENTS

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

	September 30, 2021	December 31, 2020
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 134,962	\$ 160,802
Short-term investments	50,065	48,599
Accounts receivable, net of allowance for doubtful accounts of \$4,891 and \$3,654	40,075	38,835
Inventories	53,583	31,863
Prepaid expenses	8,103	3,860
Other current assets	2,439	4,934
Total current assets	<u>289,227</u>	<u>288,893</u>
Noncurrent Assets:		
Property, plant and equipment, net	77,586	51,860
Operating right-of-use assets, net	9,615	4,461
Finance right-of-use assets, net	4,629	1,312
Intangible assets, net	15,221	17,904
Goodwill	40,264	40,351
Long-term investments	17,271	47,718
Other noncurrent assets	1,944	1,973
Total noncurrent assets	<u>166,530</u>	<u>165,579</u>
TOTAL ASSETS	<u>\$ 455,757</u>	<u>\$ 454,472</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	\$ 23,778	\$ 17,407
Deferred revenue	3,488	4,811
Accrued expenses and other current liabilities	22,610	22,227
Finance lease liability	1,912	517
Operating lease liability	2,178	1,125
Acquisition-related contingent consideration obligation	201	402
Total current liabilities	<u>54,167</u>	<u>46,489</u>
Noncurrent Liabilities:		
Finance lease liability	2,834	895
Operating lease liability	7,740	3,591
Acquisition-related contingent consideration obligation	318	2,049
Other noncurrent liabilities	1,998	1,682
Deferred income taxes	880	1,195
Total noncurrent liabilities	<u>13,770</u>	<u>9,412</u>
TOTAL LIABILITIES	<u>67,937</u>	<u>55,901</u>
Commitments and contingencies (Note 11)		
STOCKHOLDERS' EQUITY		
Preferred stock, par value \$.000001, 25,000 shares authorized, none issued	—	—
Common stock, par value \$.000001, 120,000 shares authorized, 72,038 and 71,738 shares issued and outstanding	—	—
Additional paid-in capital	508,601	505,123
Accumulated other comprehensive loss	(10,721)	(9,097)
Accumulated deficit	(110,060)	(97,455)
Total stockholders' equity	<u>387,820</u>	<u>398,571</u>
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	<u>\$ 455,757</u>	<u>\$ 454,472</u>

See accompanying notes to the consolidated financial statements.

ORASURE TECHNOLOGIES, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

(in thousands, except per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
NET REVENUES:				
Products and services	\$ 53,229	\$ 46,749	\$ 165,549	\$ 105,972
Other	688	1,262	4,557	2,894
	<u>53,917</u>	<u>48,011</u>	<u>170,106</u>	<u>108,866</u>
COST OF PRODUCTS AND SERVICES SOLD	<u>32,449</u>	<u>17,722</u>	<u>79,639</u>	<u>45,182</u>
Gross profit	<u>21,468</u>	<u>30,289</u>	<u>90,467</u>	<u>63,684</u>
OPERATING EXPENSES:				
Research and development	8,596	8,007	25,270	20,575
Sales and marketing	13,886	7,849	33,836	25,339
General and administrative	12,499	10,108	33,680	30,442
Change in the estimated fair value of acquisition-related contingent consideration	(500)	(60)	(1,526)	390
	<u>34,481</u>	<u>25,904</u>	<u>91,260</u>	<u>76,746</u>
Operating income (loss)	<u>(13,013)</u>	<u>4,385</u>	<u>(793)</u>	<u>(13,062)</u>
OTHER INCOME	<u>100</u>	<u>314</u>	<u>429</u>	<u>1,960</u>
Income (loss) before income taxes	<u>(12,913)</u>	<u>4,699</u>	<u>(364)</u>	<u>(11,102)</u>
INCOME TAX EXPENSE	<u>2,102</u>	<u>3,659</u>	<u>12,241</u>	<u>5,680</u>
NET INCOME (LOSS)	<u>\$ (15,015)</u>	<u>\$ 1,040</u>	<u>\$ (12,605)</u>	<u>\$ (16,782)</u>
INCOME (LOSS) PER SHARE:				
BASIC	<u>\$ (0.21)</u>	<u>\$ 0.01</u>	<u>\$ (0.18)</u>	<u>\$ (0.25)</u>
DILUTED	<u>\$ (0.21)</u>	<u>\$ 0.01</u>	<u>\$ (0.18)</u>	<u>\$ (0.25)</u>
SHARES USED IN COMPUTING INCOME (LOSS) PER SHARE:				
BASIC	<u>72,023</u>	<u>71,537</u>	<u>71,962</u>	<u>66,088</u>
DILUTED	<u>72,023</u>	<u>72,662</u>	<u>71,962</u>	<u>66,088</u>

See accompanying notes to the consolidated financial statements.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
NET INCOME (LOSS)	\$ (15,015)	\$ 1,040	\$ (12,605)	\$ (16,782)
OTHER COMPREHENSIVE INCOME (LOSS)				
Currency translation adjustments	(4,117)	1,953	(1,362)	(3,542)
Unrealized gain (loss) on marketable securities	(161)	(266)	(262)	83
COMPREHENSIVE INCOME (LOSS)	\$ (19,293)	\$ 2,727	\$ (14,229)	\$ (20,241)

See accompanying notes to the consolidated financial statements.

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

	Nine Months Ended September 30,	
	2021	2020
OPERATING ACTIVITIES:		
Net loss	\$ (12,605)	\$ (16,782)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:		
Stock-based compensation	5,155	5,913
Depreciation and amortization	8,479	6,880
Other non-cash amortization	664	171
Provision for doubtful accounts	1,228	1,141
Unrealized foreign currency gain	(319)	(41)
Interest expense on finance leases	84	56
Deferred income taxes	(324)	(764)
Loss on sale of fixed assets	—	104
Change in the estimated fair value of acquisition-related contingent consideration	(1,526)	390
Payment of acquisition-related contingent consideration	(142)	(496)
Changes in assets and liabilities		
Accounts receivable	(2,102)	5,228
Inventories	(21,689)	(7,425)
Prepaid expenses and other assets	(1,942)	2,420
Accounts payable	2,790	3,269
Deferred revenue	(1,331)	1,664
Accrued expenses and other liabilities	982	468
Net cash (used in) provided by operating activities	<u>(22,598)</u>	<u>2,196</u>
INVESTING ACTIVITIES:		
Purchases of investments	(25,443)	(90,137)
Proceeds from maturities and redemptions of investments	53,745	102,616
Purchases of property and equipment	(27,508)	(11,234)
Proceeds from escrow associated with business acquisitions	—	126
Acquisition of businesses, net of cash acquired	—	(3,037)
Purchase price adjustment related to business acquisition	(18)	—
Purchase of patent and product rights	—	(2,250)
Net cash (used in) provided by investing activities	<u>776</u>	<u>(3,916)</u>
FINANCING ACTIVITIES:		
Cash payments for lease liabilities	(1,111)	(521)
Payment of acquisition-related contingent consideration	(264)	(3,004)
Issuance of common stock in connection with public offering, net	—	95,036
Proceeds from exercise of stock options	247	2,115
Repurchase of common stock	(1,924)	(2,076)
Net cash (used in) provided by financing activities	<u>(3,052)</u>	<u>91,550</u>
EFFECT OF FOREIGN EXCHANGE RATE CHANGES ON CASH	(966)	(2,686)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(25,840)	87,144
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	160,802	75,715
CASH AND CASH EQUIVALENTS, END OF PERIOD	<u>\$ 134,962</u>	<u>\$ 162,859</u>
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:		
Cash paid for income taxes	\$ 12,540	\$ 3,888
Non-cash investing and financing activities		
Accrued property and equipment purchases	\$ 4,382	\$ 2,093
Unrealized gain (loss) on marketable securities	\$ (262)	\$ 83

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

The overall goal of OraSure Technologies, Inc. (“OraSure” or “the Company”) is to empower the global community to improve health and wellness by providing access to accurate essential information. Our business consists of two segments: our “Diagnostics” segment, and our “Molecular Solutions” segment.

Our Diagnostics business primarily consists of the development, manufacture, marketing and sale of oral fluid diagnostic products and specimen collection devices using our proprietary technologies, as well as other diagnostic products including immunoassays and other *in vitro* diagnostic tests that are used on other specimen types. The Diagnostics business includes tests for diseases including HIV and Hepatitis C that are performed on a rapid basis at the point of care and tests that are processed in a laboratory. These products are sold in the United States and internationally to various clinical laboratories, hospitals, clinics, community-based organizations, and other public health organizations, distributors, government agencies, physicians’ offices, and commercial and industrial entities. Our HIV product is also sold in a consumer-friendly format in the over-the-counter (“OTC”) market in the U.S. and as a self-test to individuals in a number of other countries. Our Diagnostics business includes the operations of UrSure, Inc. (“UrSure”), which was acquired and merged into OraSure in 2020. This part of the Diagnostics business develops and commercializes products that measure adherence to HIV medications including pre-exposure prophylaxis or PrEP, the daily medication to prevent HIV, and anti-retroviral medications to suppress HIV. These products include laboratory-based tests that can measure levels of the medications in a patient’s urine or blood, as well as point-of-care products currently in development. In 2020, we began developing a rapid antigen self-test for COVID-19 and a COVID-19 antibody enzyme-linked immunosorbent assay (“ELISA”) for use in laboratory settings. In June 2021, we received three Emergency Use Authorizations (“EUA”) from the U.S. Food and Drug Administration (“FDA”) for our IntelliSwab™ COVID-19 Rapid Antigen Tests for non-prescription OTC, professional point-of-care and prescription use. We began recording revenues on the sales of our IntelliSwab™ COVID-19 Rapid Antigen Tests during the third quarter of 2021. Following discussions with the FDA and their de-prioritization of antibody testing in the U.S., we decided to no longer pursue EUAs for the ELISA test. We have, however, continued to offer the product for research use to labs and other parties interested in COVID antibody surveillance and research applications.

Our Molecular Solutions business is operated by our subsidiaries, DNA Genotek Inc. (“DNAG”), Diversigen, Inc. (“Diversigen”), and Novosanis NV (“Novosanis”). In our DNAG business, we manufacture and sell kits that are used to collect, stabilize, transport and store a biological sample of genetic material for molecular testing. Our products are used for academic research and commercial applications, including ancestry, disease risk management, lifestyle and animal testing. Three of our collection devices are used in connection with COVID-19 molecular testing. We also sell research-use-only collection products into the microbiome market. We offer our customers a suite of genomics and microbiome services that range from package customization and study design optimization to extraction, analysis and reporting services. The microbiome laboratory and bioinformatics services are provided by Diversigen, which includes the operations of CoreBiome, Inc. (“CoreBiome”), a subsidiary we acquired in early 2019. CoreBiome and Diversigen were merged together in 2020. Novosanis manufactures and sells the Colli-Pee® collection device for the volumetric collection of first-void urine for use in research, screening and diagnostics in the liquid biopsy and sexually transmitted infection markets. Our Molecular Solutions business serves customers in many countries worldwide, including many leading research universities and hospitals.

2. Summary of Significant Accounting Policies

Principles of Consolidation and Basis of Presentation. The accompanying interim unaudited consolidated financial statements include the accounts of OraSure and its wholly-owned subsidiaries, DNAG, Diversigen and Novosanis. 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 unaudited financial statements, 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, 2020. Results of operations for the three and nine months ended September 30, 2021 are not necessarily indicative of the results of operations expected for the full year.

Summary of Significant Accounting Policies. There have been no changes to the Company’s significant accounting policies described in our Annual Report on Form 10-K for the fiscal year ended December 31, 2020 that have had a material impact on the consolidated financial statements and related notes except as discussed herein.

Investments. We consider all investments in debt securities to be available-for-sale securities. These securities consist of guaranteed investment certificates and corporate bonds 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.

We record an allowance for credit loss for our available-for-sale securities when a decline in investment market value is due to credit-related factors. When evaluating an investment for impairment, we review factors such as the severity of the impairment, changes in underlying credit ratings, forecasted recovery, the Company's intent to sell or the likelihood that it would be required to sell the investment before its anticipated recovery in market value and the probability that the scheduled cash payments will continue to be made. As of September 30, 2021, we determined that the decline in the market value of our available-for-sale investment was not due to credit-related factors and as such no allowance for credit-loss was necessary.

The following is a summary of our available-for-sale securities as of September 30, 2021 and December 31, 2020:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
September 30, 2021				
Guaranteed investment certificates	\$ 33,122	\$ —	\$ —	\$ 33,122
Corporate bonds	34,824	—	(610)	34,214
Total available-for-sale securities	<u>\$ 67,946</u>	<u>\$ —</u>	<u>\$ (610)</u>	<u>\$ 67,336</u>
December 31, 2020				
Guaranteed investment certificates	\$ 25,132	\$ —	\$ —	\$ 25,132
Corporate bonds	71,533	135	(483)	71,185
Total available-for-sale securities	<u>\$ 96,665</u>	<u>\$ 135</u>	<u>\$ (483)</u>	<u>\$ 96,317</u>
At September 30, 2021, maturities of our available-for-sale securities were as follows:				
Less than one year	\$ 50,510	\$ —	\$ (445)	\$ 50,065
Greater than one year	<u>\$ 17,436</u>	<u>\$ —</u>	<u>\$ (165)</u>	<u>\$ 17,271</u>

Fair Value of Financial Instruments. As of September 30, 2021 and December 31, 2020, the carrying values of cash and cash equivalents, 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).

All of our available-for-sale debt securities are measured as Level 2 instruments as of September 30, 2021 and December 31, 2020. Our available-for-sale guaranteed investment certificates are measured as Level 1 instruments as of September 30, 2021 and December 31, 2020.

Included in cash and cash equivalents at September 30, 2021 and December 31, 2020, was \$23,862 and \$71,489 invested in government money market funds. These funds have investments in government securities and are measured as Level 1 instruments.

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 September 30, 2021 and December 31, 2020 was \$2,503 and \$2,565, 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 both current assets and noncurrent assets with the same amount included in accrued expenses and other noncurrent liabilities in the accompanying consolidated balance sheets.

Accounts Receivable. Accounts receivable have been reduced by an estimated allowance for amounts that may become uncollectible in the future. This estimated allowance is based primarily on management's evaluation of specific balances as they become past due, the financial condition of our customers and our historical experience related to write-offs.

Inventories. Inventories are stated at the lower of cost or net realizable value, with cost determined on a first-in, first-out basis, and include the cost of raw materials, labor and overhead. The majority of our inventories are subject to expiration dating, which can be extended in certain circumstances. We continually evaluate quantities on hand and the carrying value of our inventories to determine the need for reserves for excess and obsolete inventories, based on prior experience as well as estimated forecasts of product sales. We reserve for unidentified scrap or spoilage based on historical write-off rates. We also consider items identified through specific identification procedures in assessing the adequacy of our reserve. When factors indicate that impairment has occurred, either a reserve is established against the inventories' carrying value or the inventories are completely written off, as in the case of lapsing expiration dates. During the third quarter of 2021, we reserved \$1,750 of COVID-19 antibody inventory, which we do not believe we can sell as a result of the decision to no longer pursue EUAs for the ELISA test.

Property, Plant and Equipment. Property, plant 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, retired, or discarded, the related property amounts are relieved from the accounts, and any gain or loss is recorded in the consolidated statements of operations. Accumulated depreciation of property, plant and equipment as of September 30, 2021 and December 31, 2020 was \$58,755 and \$53,604, respectively.

Intangible Assets. Intangible assets consist of customer relationships, patents and product rights, acquired technology and tradenames. Patents and product rights consist of costs associated with the acquisition of patents, licenses, and product distribution rights. Intangible assets are amortized using the straight-line method over their estimated useful lives of five to fifteen years. Accumulated amortization of intangible assets as of September 30, 2021 and December 31, 2020 was \$29,554 and \$27,107, respectively. The decrease in intangibles from \$17,904 as of December 31, 2020 to \$15,221 as of September 30, 2021 was due to \$2,455 in amortization expense and foreign currency translation losses of \$228.

Goodwill. Goodwill represents the excess of the purchase price over the fair value of the net tangible and identifiable intangible assets acquired. Goodwill is not amortized but rather is tested annually for impairment or more frequently if we believe that indicators of impairment exist. Current generally accepted accounting principles ("GAAP") 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 carrying value of a reporting unit is greater than its fair value, then we would be required to recognize an impairment charge for the amount by which the carrying amount exceeds the reporting unit's fair value, provided the impairment charge does not exceed the total amount of goodwill allocated to the reporting unit.

The decrease in goodwill from \$40,351 as of December 31, 2020 to \$40,264 as of September 30, 2021 was a result of an adjustment of \$105 associated with foreign currency translation and a purchase price adjustment of \$18 related to a business acquisition.

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 a functional currency are included in our consolidated statements of income in the period in which the change occurs. Net foreign exchange gains resulting from foreign currency transactions that are included in other income in our consolidated statements of income were \$7 and \$70 for the three months ended September 30, 2021 and 2020, respectively. Net foreign exchange gains (losses) were \$(371) and \$563 for the nine months ended September 30, 2021 and 2020.

Accumulated Other Comprehensive Income (Loss). We classify items of other comprehensive income (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 consolidated balance sheets.

We have defined the Canadian dollar as the functional currency of our Canadian subsidiary, DNAG, and we have defined the Euro as the functional currency of our Belgian subsidiary, Novosanis. The results of operations for those subsidiaries are translated into U.S. dollars, which is the reporting currency of the Company. Accumulated other comprehensive loss at September 30, 2021 consisted of \$10,111 of currency translation adjustments and \$610 of net unrealized losses on marketable securities, which represents the fair market value adjustment for our

investment portfolio. Accumulated other comprehensive loss at December 31, 2020 consists of \$8,749 of currency translation adjustments and \$348 of net unrealized losses on marketable securities, which represents the fair market value adjustment for our investments portfolio.

Recent Accounting Pronouncements.

In March 2020, the FASB issued Accounting Standards Update (“ASU”) No. 2020-04, *Reference Rate Reform (Topic 848) Facilitation of the Effects of Reference Rate Reform on Financial Reporting*. The purpose of this update is to provide optional guidance for a limited time to ease the potential burden in accounting for (or recognizing the effects of) reference rate reform on financial reporting. The amendments provide optional expedients and exceptions for applying GAAP to contracts, hedging relationships, and other transactions affected by reference rate reform if certain criteria are met. The amendments in this update are elective and are effective upon issuance for all entities. Management is evaluating the impact of this ASU and does not expect this update to have a material impact on the Company’s Consolidated Financial Statements.

3. Business Combinations

UrSure

On July 22, 2020, the Company acquired all of the outstanding capital stock of UrSure, Inc. (“UrSure”), pursuant to the terms of a merger agreement. The initial aggregate purchase price of this transaction was \$3,000, adjusted for certain transaction costs, indebtedness, and holdback amounts, and was funded with cash on hand. A portion of the purchase price was deposited into an escrow account for a limited period after closing, pursuant to indemnification obligations under the merger agreement.

During the nine months ended September 30, 2020, we incurred acquisition related costs of \$393 including accounting, legal, and other professional fees, all of which were expensed and reported as a component of general and administrative expense in the consolidated statement of operations. No such costs were incurred for the nine months ended September 30, 2021.

Pursuant to our merger agreement, we were to pay up to an additional \$28,000 of contingent consideration over the three years following the acquisition date based on the achievement of certain performance criteria as defined under the agreements, including generating certain revenue dollars, and the achievement of certain clinical milestones associated with the development of certain new technology. The Company, with the assistance of an independent valuation specialist, determines the estimated fair value of the contingent consideration. The fair value is determined using a probability-weighted model based on our assessment of the likelihood that the benchmarks will be achieved. The probability-weighted payments were then discounted using a discount rate based on an internal rate of return analysis using the probability-weighted cash flows. The fair value measurement is based on significant inputs, including the likelihood of the achievement of clinical milestones and revenue forecasts, not observable in the market and thus represents a Level 3 measurement within the fair value hierarchy.

The following table represents the change in contingent consideration:

Balance as of December 31, 2020	\$	2,451
Payments made during the period		(406)
Change in fair value during the period		(1,526)
Balance as of September 30, 2021	\$	<u>519</u>

The change in fair value during the nine months ended September 30, 2021 is as a result of delays in achieving certain product development milestones and a decrease in associated revenue forecasts as a result of these delays.

Revenues from UrSure primarily consist of grant money received to fund the development of certain new technology. Effective as of July 22, 2020, the financial results of UrSure are included in our Diagnostics segment.

4. Inventories

	September 30, 2021	December 31, 2020
Raw materials	\$ 28,306	\$ 15,425
Work in process	2,653	2,572
Finished goods	22,624	13,866
	<u>\$ 53,583</u>	<u>\$ 31,863</u>

5. 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, unvested restricted stock or performance stock units, unless the impact is antidilutive. The number of incremental shares is calculated by assuming that outstanding stock options were exercised and unvested restricted shares and performance stock units were vested, and the proceeds from such exercises or vesting were used to acquire shares of common stock at the average market price during the reporting period. Basic and dilutive computations of net loss per share are the same in periods in which a net loss exists as the dilutive effects of excluded items would be anti-dilutive.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Net income (loss)	\$ (15,015)	\$ 1,040	\$ (12,605)	\$ (16,782)
Weighted-average shares of common stock outstanding:				
Basic	72,023	71,537	71,962	66,088
Dilutive effect of stock options, restricted stock, and performance stock units	—	1,125	—	—
Diluted	72,023	72,662	71,962	66,088
Earnings (loss) per share:				
Basic	\$ (0.21)	\$ 0.01	\$ (0.18)	\$ (0.25)
Diluted	\$ (0.21)	\$ 0.01	\$ (0.18)	\$ (0.25)

For the three months ended September 30, 2021, outstanding common stock options, unvested restricted stock, and unvested performance stock units representing 859 shares were excluded from the computation of diluted loss per share. For the three months ended September 30, 2020, outstanding common stock options, unvested restricted stock, and unvested performance stock units representing 136 shares were excluded from the computation of diluted earnings per share as their inclusion would have been anti-dilutive. For the nine months ended September 30, 2021 and 2020, outstanding common stock options, unvested restricted stock, and unvested performance stock units representing 847 and 917 shares, respectively, were excluded from the computation of diluted loss per share.

6. Revenues

Revenues by product line. The following table represents total net revenues by product line:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Infectious disease testing	\$ 12,932	\$ 13,224	\$ 39,664	\$ 36,625
Risk assessment testing	2,674	2,253	7,265	6,786
Genomics ⁽¹⁾	19,018	8,454	49,333	23,224
Microbiome ⁽¹⁾	1,693	1,530	5,888	3,869
COVID-19 ⁽¹⁾	13,930	18,867	54,147	27,918
Laboratory services	2,406	2,280	8,017	6,798
Other product and service revenues	576	141	1,235	752
Net product and services revenues	53,229	46,749	165,549	105,972
Royalty income	500	450	2,636	1,623
Other non-product revenues	188	812	1,921	1,271
Other revenues	688	1,262	4,557	2,894
Net revenues	\$ 53,917	\$ 48,011	\$ 170,106	\$ 108,866

⁽¹⁾ 2020 Genomics, Microbiome, and COVID-19 revenues were reclassified to reflect the correct classification of the product line sales. The reclassification increased (decreased) the product line revenues for the three months ended September 30, 2020 by \$(65), \$(298), and \$363, respectively and increased (decreased) the product line revenue for the nine months ended September 30, 2020 by \$(157), \$(390), and \$547, respectively.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
United States	\$ 42,969	\$ 38,594	\$ 139,669	\$ 82,125
Europe	2,411	2,789	10,288	8,663
Other regions	8,537	6,628	20,149	18,078
	<u>\$ 53,917</u>	<u>\$ 48,011</u>	<u>\$ 170,106</u>	<u>\$ 108,866</u>

Customer and Vendor Concentrations. At September 30, 2021, one customer accounted for 13% of our accounts receivable. Another customer accounted for 11% of our accounts receivable as of December 31, 2020. One customer accounted for 14% of net consolidated revenues for the three months ended September 30, 2021. Another customer accounted for 10% of net consolidated revenues for the nine months ended September 30, 2021. One customer accounted for 11% of net consolidated revenues for the three months ended September 30, 2020.

We currently purchase certain products and critical components of our products from sole-supply vendors. 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. Third-party suppliers also manufacture certain 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.

Deferred Revenue. We record deferred revenue when funds are received prior to the recognition of the associated revenue. Deferred revenue as of September 30, 2021 and December 31, 2020 includes customer prepayments of \$2,340 and \$3,216, respectively. Deferred revenue as of September 30, 2021 and December 31, 2020 also includes \$1,148 and \$1,595, respectively, associated with a long-term contract that has variable pricing based on volume. The average price over the life of the contract was determined and revenue is recognized at that average price.

7. Accrued Expenses and other current liabilities

	September 30, 2021	December 31, 2020
Payroll and related benefits	\$ 13,728	\$ 14,769
Professional fees	1,831	978
Sales tax payable	2,858	2,400
Other	4,193	4,080
	<u>\$ 22,610</u>	<u>\$ 22,227</u>

8. Leases

We determine whether an arrangement is a lease at inception. We have operating and finance leases for corporate offices, warehouse space and equipment (including vehicles). As of September 30, 2021, we are the lessee in all agreements. Our leases have remaining lease terms of 1 to 7 years, some of which include options to extend the leases based on agreed upon terms, and some of which include options to terminate the leases within 1 year.

As most of our leases do not provide an implicit rate, we use our incremental borrowing rate based on the information available at the lease commencement date in determining the present value of lease payments.

We have lease agreements that contain both lease and non-lease components (e.g., common-area maintenance). For these agreements, we account for lease components separate from non-lease components.

The components of lease expense are as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Operating Lease Cost	\$ 655	\$ 330	\$ 1,574	\$ 964
Finance Lease Cost				
Amortization of right-of use assets	571	150	910	476
Interest on lease liabilities	49	17	84	56
Total Finance Lease Cost	\$ 620	\$ 167	\$ 994	\$ 532

Supplemental cash flow information related to leases is as follows:

	Nine Months Ended September 30,	
	2021	2020
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	\$ 1,182	\$ 965
Operating cash flows from financing leases	84	56
Financing cash flows from financing leases	1,111	521
Non-cash activity:		
Right-of-use assets obtained in exchange for operating lease obligations	45	498
Right-of-use assets obtained in exchange for finance lease obligations	2,746	46

Supplemental balance sheet information related to leases is as follows:

	September 30, 2021	December 31, 2020
Operating Leases		
Right-of-use assets	\$ 9,615	\$ 4,461
Current lease liabilities	2,178	1,125
Non-current lease liabilities	7,740	3,591
Total operating lease liabilities	\$ 9,918	\$ 4,716

Finance Leases

Right-of-use assets	\$ 4,629	\$ 1,312
Current lease liabilities	1,912	517
Non-current lease liabilities	2,834	895
Total finance lease liabilities	\$ 4,746	\$ 1,412

Weighted Average Remaining Lease Term

Weighted-average remaining lease term—operating leases	5.42
Weighted-average remaining lease term—finance leases	2.49

Weighted Average Discount Rate

Weighted-average discount rate—operating leases	3.92%
Weighted-average discount rate—finance leases	3.45%

As of September 30, 2021, minimum lease payments by period are expected to be as follows:

	Finance	Operating
2021 (excluding the nine months ended September 30, 2021)	\$ 510	\$ 628
2022	2,040	2,493
2023	1,810	1,776
2024	582	1,808
2025	4	1,443
Thereafter	—	2,808
Total Minimum Lease Payments	4,946	10,956
Less: imputed interest	(200)	(1,038)
Present Value of Lease Liabilities	\$ 4,746	\$ 9,918

9. Stockholders' Equity

Reconciliation of the changes in stockholders' equity for the three and nine months ended September 30, 2021 and 2020

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total
	Shares	Amount				
Balance at December 31, 2020	71,738	\$ —	\$ 505,123	\$ (9,097)	\$ (97,455)	\$ 398,571
Common stock issued upon exercise of options	11	—	92	—	—	92
Vesting of restricted stock and performance stock units	318	—	—	—	—	—
Purchase and retirement of common shares	(111)	—	(1,730)	—	—	(1,730)
Stock-based compensation	—	—	1,464	—	—	1,464
Net income	—	—	—	—	3,774	3,774
Currency translation adjustments	—	—	—	1,352	—	1,352
Unrealized gain on marketable securities	—	—	—	21	—	21
Balance at March 31, 2021	71,956	\$ —	\$ 504,949	\$ (7,724)	\$ (93,681)	\$ 403,544
Common stock issued upon exercise of options	3	—	29	—	—	29
Vesting of restricted stock and performance stock units	64	—	—	—	—	—
Purchase and retirement of common shares	(15)	—	(147)	—	—	(147)
Stock-based compensation	—	—	1,473	—	—	1,473
Net loss	—	—	—	—	(1,364)	(1,364)
Currency translation adjustments	—	—	—	1,403	—	1,403
Unrealized loss on marketable securities	—	—	—	(122)	—	(122)
Balance at June 30, 2021	72,008	\$ —	\$ 506,304	\$ (6,443)	\$ (95,045)	\$ 404,816
Common stock issued upon exercise of options	18	—	126	—	—	126
Vesting of restricted stock and performance stock units	16	—	—	—	—	—
Purchase and retirement of common shares	(4)	—	(47)	—	—	(47)
Stock-based compensation	—	—	2,218	—	—	2,218
Net loss	—	—	—	—	(15,015)	(15,015)
Currency translation adjustments	—	—	—	(4,117)	—	(4,117)
Unrealized loss on marketable securities	—	—	—	(161)	—	(161)
Balance at September 30, 2021	72,038	\$ —	\$ 508,601	\$ (10,721)	\$ (110,060)	\$ 387,820

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total
	Shares	Amount				
Balance at December 31, 2019	61,731	\$ —	\$ 401,814	\$ (12,136)	\$ (82,533)	\$ 307,145

Common stock issued upon exercise of options	6	—	30	—	—	30
Vesting of restricted stock and performance stock units	486	—	—	—	—	—
Purchase and retirement of common shares	(197)	—	(1,408)	—	—	(1,408)
Stock-based compensation	—	—	1,376	—	—	1,376
Net loss	—	—	—	—	(7,328)	(7,328)
Currency translation adjustments	—	—	—	(9,221)	—	(9,221)
Unrealized loss on marketable securities	—	—	—	(442)	—	(442)
Balance at March 31, 2020	<u>62,026</u>	<u>\$ —</u>	<u>\$ 401,812</u>	<u>\$ (21,799)</u>	<u>\$ (89,861)</u>	<u>\$ 290,152</u>
Common stock issued upon exercise of options	71	—	530	—	—	530
Vesting of restricted stock and performance stock units	161	—	—	—	—	—
Purchase and retirement of common shares	(50)	—	(656)	—	—	(656)
Issuance of common stock in connection with public offering, net of commissions and expenses of \$6,200	9,200	—	95,036	—	—	95,036
Stock-based compensation	—	—	2,672	—	—	2,672
Net loss	—	—	—	—	(10,494)	(10,494)
Currency translation adjustments	—	—	—	3,726	—	3,726
Unrealized gain on marketable securities	—	—	—	791	—	791
Balance at June 30, 2020	<u>71,408</u>	<u>\$ —</u>	<u>\$ 499,394</u>	<u>\$ (17,282)</u>	<u>\$ (100,355)</u>	<u>\$ 381,757</u>
Common stock issued upon exercise of options	202	—	1,555	—	—	1,555
Vesting of restricted stock and performance stock units	2	—	—	—	—	—
Purchase and retirement of common shares	(1)	—	(12)	—	—	(12)
Stock-based compensation	—	—	1,865	—	—	1,865
Net income	—	—	—	—	1,040	1,040
Currency translation adjustments	—	—	—	1,953	—	1,953
Unrealized loss on marketable securities	—	—	—	(266)	—	(266)
Balance at September 30, 2020	<u>71,611</u>	<u>\$ —</u>	<u>\$ 502,802</u>	<u>\$ (15,595)</u>	<u>\$ (99,315)</u>	<u>\$ 387,892</u>

Stock-Based Awards

We grant stock-based awards under the OraSure Technologies, Inc. Stock Award Plan, as amended (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 account for stock-based compensation to employees and directors using the fair value method. 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. We recognize compensation expense related to performance-based restricted stock units based on assumptions as to what percentage of each performance target will be achieved. We evaluate these target assumptions on a quarterly basis and adjust compensation expense related to these awards, as appropriate. To satisfy the exercise of options, issuance of restricted stock, or redemption of performance-based restricted stock units, we issue new shares rather than shares purchased on the open market.

Total compensation cost related to stock options for the nine months ended September 30, 2021 and 2020 was \$793 and \$683, respectively.

Compensation cost of \$2,891 and \$3,329 related to restricted shares was recognized during the nine months ended September 30, 2021 and 2020, respectively.

We grant performance-based restricted stock units (“PSUs”) to certain executives. Vesting of these PSUs is dependent upon achievement of certain performance-based metrics during a one-year or three-year period from the date of grant. Assuming achievement of each performance-based metric, the executive must also generally remain employed for three years from the grant date. If the one-year target is achieved, the PSUs will then vest three years from grant date. If the three-year target is achieved, the corresponding PSUs will then vest three years from grant date. PSUs are converted into shares of our common stock once vested.

Compensation cost of \$1,471 and \$1,901 related to PSUs was recognized during the nine months ended September 30, 2021 and 2020, respectively.

Public Offering

On June 1, 2020, we entered into an underwriting agreement with J.P. Morgan Securities LLC, Citigroup Global Markets Inc. and Evercore Group LLC, as representatives of several underwriters, relating to the issuance and sale of 8,000 shares of our common stock. The price to the public in the offering was \$11.00 per share. Under the terms of the underwriting agreement, we also granted the underwriters an option, exercisable for 30 days, to purchase up to an additional 1,200 shares of common stock. On June 3, 2020, we announced the full exercise by the underwriters of their option to purchase these additional shares.

The offering was made pursuant to an effective registration statement on Form S-3 (File No. 333-228877) we had previously filed with the SEC, and a prospectus supplement thereunder. The net proceeds from the offering were approximately \$95,000 after deducting underwriting discounts and offering expenses paid by the Company.

Stock Repurchase Program

On August 5, 2008, our Board of Directors approved a share repurchase program pursuant to which we are permitted to acquire up to \$25,000 of our outstanding common shares. No shares were purchased and retired during the nine months ended September 30, 2021 and 2020.

10. Income Taxes

During the three and nine months ended September 30, 2021, we recorded income tax expense of \$2,102 and \$12,241, respectively, which primarily consisted of foreign tax expense. During the three and nine months ended September 30, 2020, we recorded income tax expense of \$3,659 and \$5,680, respectively, which also primarily consisted of a foreign tax expense.

Tax expense reflects taxes due to the taxing authorities and 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 September 30, 2021 and December 31, 2020 relate to the tax effects of the basis difference between the intangible assets acquired in our acquisitions for financial reporting and for tax purposes along with basis differences arising from accelerated tax depreciation of fixed assets.

In 2008, we established a full valuation allowance against our U.S. deferred tax asset. Management believes the full valuation allowance is still appropriate at both September 30, 2021 and December 31, 2020 since the facts and circumstances necessitating the allowance have not changed.

11. Commitments and Contingencies

Litigation

From time to time, we are involved in certain legal actions arising in the ordinary course of business. In management's opinion, the outcomes of such actions, either individually or in the aggregate, are not expected to have a material adverse effect on our future financial position or results of operations.

In March 2021, we filed a complaint against Spectrum Solutions, LLC ("Spectrum") in the United States District Court for the Southern District of California alleging that certain saliva collection devices manufactured and sold by Spectrum infringe a patent held by DNAG. Spectrum has filed an answer to the initial complaint, asserting that its device does not infringe our patent and that our patent is invalid. In August 2021, we amended our complaint to add a second patent to this litigation. Spectrum responded to our amended complaint and asserted counterclaims for inequitable conduct and antitrust violations with respect to one of the patents in the litigation. We believe Spectrum's counterclaims are without merit and we filed a motion to dismiss both claims in October 2021. We are seeking injunctive relief and damages in this matter.

Commitments

As of September 30, 2021, we have entered in several new contracts associated with the manufacture and supply of our COVID-19 antigen products and our molecular collection solutions products that include unconditional commitments to purchase certain materials through the latest of the first quarter of 2026 in the aggregate amount of \$126,499.

12. Business Segment Information

Our business consists of two segments: our “Diagnostics” business, which primarily consists of the development, manufacture, marketing and sale of oral fluid diagnostic products and specimen collection devices using our proprietary technologies, other diagnostic products including immunoassays and other in vitro diagnostic tests that are used on other specimen types. Our Diagnostics segment includes the financial results of UrSure. Our “Molecular Solutions” business consists of the development, manufacture, marketing and sale of specimen collection kits that are used to collect, stabilize, transport and store samples of genetic material for molecular testing. Our collection kits are also used for the collection of first-void urine for liquid biopsy in the prostate and bladder cancer markets; and in the sexually transmitted infection screening market. In addition, our Molecular Solutions business provides microbiome laboratory services that accelerate research and discovery for customers in the pharmaceutical, agricultural, and academic research markets. Financial results of Diversigen and Novosanis are included in our Molecular Solutions segment.

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. 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 and inter-segment expenses have been eliminated.

The following table summarizes operating segment information for the three and nine months ended September 30, 2021 and 2020, and asset information as of September 30, 2021 and December 31, 2020:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Net revenues:				
Diagnostics	\$ 23,511	\$ 16,314	\$ 57,368	\$ 44,533
Molecular Solutions	30,406	31,697	112,738	64,333
Total	<u>\$ 53,917</u>	<u>\$ 48,011</u>	<u>\$ 170,106</u>	<u>\$ 108,866</u>
Operating income (loss):				
Diagnostics	\$ (18,638)	\$ (9,951)	\$ (42,755)	\$ (31,116)
Molecular Solutions	5,625	14,336	41,962	18,054
Total	<u>\$ (13,013)</u>	<u>\$ 4,385</u>	<u>\$ (793)</u>	<u>\$ (13,062)</u>
Depreciation and amortization:				
Diagnostics	\$ 1,136	\$ 934	\$ 2,965	\$ 2,448
Molecular Solutions	2,199	1,517	5,514	4,432
Total	<u>\$ 3,335</u>	<u>\$ 2,451</u>	<u>\$ 8,479</u>	<u>\$ 6,880</u>
Capital expenditures:				
Diagnostics	\$ 3,647	\$ 2,186	\$ 19,797	\$ 5,634
Molecular Solutions	932	3,011	7,711	5,600
Total	<u>\$ 4,579</u>	<u>\$ 5,197</u>	<u>\$ 27,508</u>	<u>\$ 11,234</u>
			September 30, 2021	December 31, 2020
Total assets:				
Diagnostics			\$ 206,668	\$ 242,613
Molecular Solutions			249,089	211,859
Total			<u>\$ 455,757</u>	<u>\$ 454,472</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, losses, expenses, or other financial performance, future product performance or development, expected regulatory filings and approvals, planned business transactions, expected manufacturing performance, 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 words such as "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 of the Company to manufacture sufficient quantities of the Inteliswab™ COVID-19 rapid test and resolve manufacturing challenges and the expected time frame for doing so; ability to successfully manage and integrate acquisitions of other companies in a manner that complements or leverages our existing business, or otherwise expands or enhances our portfolio of products and our end-to-end service offerings, and the diversion of management's attention from our ongoing business and regular business responsibilities to effect such integration; the expected economic benefits of acquisitions (and increased returns for our stockholders), including that the anticipated synergies, revenue enhancement strategies and other benefits from the acquisitions may not be fully realized or may take longer to realize than expected and our actual integration costs may exceed our estimates; impact of increased or different risks arising from the acquisition of companies located in foreign countries; ability to market and sell products, whether through our internal, direct sales force or third parties; impact of significant customer concentration in the genomics business; failure of distributors or other customers to meet purchase forecasts, historic purchase levels or minimum purchase requirements for our products; 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 U.S. Food and Drug Administration ("FDA") or other regulators; the impact of the novel coronavirus ("COVID-19") pandemic on our business and our ability to successfully develop new products, validate the expanded use of existing collection products, receive necessary regulatory approvals and authorizations and commercialize such products for COVID-19 testing; 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; ability to meet increased demand for the Company's products; impact of replacing distributors; inventory levels at distributors and other customers; ability of the Company to achieve its financial and strategic objectives and continue to increase its revenues, including the ability to expand international sales; ability to identify, complete, integrate and realize the full benefits of future acquisitions; impact of competitors, competing products and technology changes; 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; market acceptance of oral fluid or urine testing, collection or other products; market acceptance and uptake of microbiome informatics, microbial genetics technology and related analytics services; changes in market acceptance of products based on product performance or other factors, including changes in testing guidelines, algorithms or other recommendations by the Centers for Disease Control and Prevention ("CDC") or other agencies; 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; impact of contracting with the U.S. government; impact of negative economic conditions; ability to maintain sustained profitability; ability to utilize net operating loss carry forwards or other deferred tax assets; volatility of the Company'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 that could affect our results 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, 2020, 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. Readers are cautioned not to place undue reliance on the forward-looking statements. The forward-looking statements are made as of the date of this Report, and we undertake no duty to update these statements.

Investors should also be aware that while we do, from time to time, communicate with securities analysts, it is against our policy to disclose any material non-public information or other confidential commercial information. Accordingly, stockholders should not assume that we agree with any statement or report issued by any analyst irrespective of the content of the statement or report. Furthermore, we have a policy against issuing or confirming financial forecasts or projections issued by others. Thus, to the extent that reports issued by securities analysts contain any projections, forecasts or opinions, such reports are not the responsibility of OraSure.

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 and Business Segments

The overall goal of our Company is to empower the global community to improve health and wellness by providing access to accurate essential information. Our business consists of two segments: our “Diagnostics” segment and our “Molecular Solutions” segment.

Our Diagnostics business primarily consists of the development, manufacture, marketing and sale of oral fluid diagnostic products and specimen collection devices using our proprietary technologies, as well as other diagnostic products including immunoassays and other *in vitro* diagnostic tests that are used on other specimen types. The Diagnostics business includes tests for diseases including HIV and Hepatitis C that are performed on a rapid basis at the point of care and tests that are processed in a laboratory. These products are sold in the United States and internationally to various clinical laboratories, hospitals, clinics, community-based organizations, and other public health organizations, distributors, government agencies, physicians’ offices, and commercial and industrial entities. Our HIV product is also sold in a consumer-friendly format in the OTC market in the U.S. and as a self-test to individuals in a number of other countries. Our Diagnostics business includes the operations of UrSure, which was acquired and merged into OraSure in 2020. This part of the Diagnostics business develops and commercializes products that measure adherence to HIV medications including pre-exposure prophylaxis or PrEP, the daily medication to prevent HIV, and anti-retroviral medications to suppress HIV. These products include laboratory-based tests that can measure levels of the medication in a patient’s urine or blood, as well as point-of-care products currently in development.

Our Molecular Solutions business is operated by our subsidiaries, DNAG, Diversigen and Novosanis. In this business, we manufacture and sell kits that are used to collect, stabilize, transport and store a biological sample of genetic material for molecular testing. Our products are used for academic research and commercial applications, including ancestry, disease risk management, lifestyle and animal testing. Included in the disease risk management area are pharmacogenomics testing, hereditary disease screening, prenatal or cancer screening, population health initiatives and other molecular testing using DNA or RNA for diagnosis of acute disease. We also sell research-use-only collection products into the microbiome market. We offer our customers a suite of genomics and microbiome services that range from package customization and study design optimization to extraction, analysis and reporting services. The microbiome laboratory and bioinformatics services are provided by Diversigen, which includes the operations of CoreBiome, a subsidiary we acquired in early 2019. CoreBiome and Diversigen were merged together in 2020. Novosanis manufactures and sells the Colli-Pee® collection device for the volumetric collection of first-void urine for use in research, screening and diagnostics in the liquid biopsy and sexually transmitted infection markets. Our Molecular Solutions business serves customers in many countries worldwide, including many leading research universities and hospitals.

Recent Developments

Impact of COVID-19

The COVID-19 pandemic continues to impact our business operations and it is not possible for us to predict the duration or magnitude of the outbreak’s effects on our business or results of operations. During 2020, traditional HIV and HCV testing programs and drug testing in the workplace market were reduced or terminated as a result of the various “stay-at-home” orders and social distancing guidelines issued by federal, state and local governments to contain the spread of the COVID-19 pandemic and we continued to see this impact our business in early 2021. However, during the second and third quarters of 2021, we saw a resumption of HIV and HCV testing in the U.S. as domestic sales of our non-COVID diagnostic products began returning to pre-pandemic levels. On the international front, professional HIV and HCV testing in Europe and Asia also started to pick up. However, more recently we have experienced reductions and stoppages of HIV self-testing in Southern and Eastern African countries due to the COVID-19 pandemic. In our Molecular Solutions segment, COVID-related disruption in clinical and research work, particularly in the academic market, had reduced demand for our products in 2020 and early 2021, but demand levels started to return to normal in the second and third quarters of 2021. Although the negative trends that materially impacted our results of operations during 2020 and early 2021 are starting to abate, it is impossible to predict if this improvement will continue and these negative trends may adversely impact certain parts of our business in future periods and for an indeterminate time period, depending on the duration and severity of the COVID-19 pandemic, the impact of COVID-19 variants and the scope and success of vaccination programs globally.

We also have experienced significant opportunities, and continue to believe there are potentially more significant opportunities, for increased revenues as a result of the COVID-19 pandemic. In 2020, we began selling our saliva collection devices for use in molecular COVID-19 testing. In the first nine months of 2021, we generated revenues of approximately \$46.2 million from sales of our molecular collection devices related to COVID-19 testing. In the U.S., public health customers purchased increased quantities of our OraQuick® In-Home HIV Test in order to permit continued HIV testing while allowing clients and patients to adhere to “stay-at-home” and social distancing requirements. In addition, we saw increased demand for our molecular collection products from customers who conduct both saliva and blood-based testing. As it became more difficult to collect blood in clinics or healthcare settings, these customers increasingly relied on the saliva collection alternative. However, demand for molecular COVID-19 testing during the second and third quarters of 2021 began to decline primarily due to the availability of vaccines. We believe this trend will continue in future periods.

In June 2021, we received three Emergency Use Authorizations (“EUAs”) from the U.S. Food and Drug Administration (“FDA”) for our IntelliSwab™ COVID-19 Rapid Tests for non-prescription OTC, professional point-of-care and prescription use. These lateral flow, rapid antigen

diagnostic tests are designed to detect active COVID-19 infection with a simple, easy-to-use workflow, using samples self-collected from the lower nostrils. After users swab their lower nostrils, the test stick is swirled in a pre-measured buffer solution. No instrumentation, batteries, smart phone or laboratory analysis is needed to read the result, which appears on the test stick a short time later. During the third quarter of 2021 and for nine-month period ending September 30, 2021, we recorded \$7.7 million of IntelliSwab™ sales.

Following discussions with the FDA and their de-prioritization of antibody testing in the U.S., we decided to no longer pursue EUAs for a COVID-19 antibody enzyme-linked immunosorbent assay ("ELISA") for use in laboratory settings. We are, however, continuing to offer this product for research use only to labs and other parties interested in COVID antibody surveillance and research applications.

DLA Procurement Contract

In September 2021, we entered into a contract with the Defense Logistics Agency ("DLA") for the procurement of our IntelliSwab™ COVID-19 Rapid Test for OTC use, which the DLA estimated to have a value of \$205 million. Under the terms of the contract, the Company will provide its IntelliSwab™ COVID-19 Rapid Test to up to 25,000 sites throughout the United States. The contract will run from October 2021 through September 2022.

BARDA 510(k) funding

In September 2021, we entered into an agreement with the Biomedical Advanced Research Development Authority ("BARDA"), which is part of the office of the Assistant Secretary for Preparedness and Response at the U.S. Department of Health and Human Services ("HHS"), pursuant to which BARDA will provide up to \$13.6 million in funding for us to obtain 510(k) clearance and Clinical Laboratory Improvement Amendments ("CLIA") waiver of our IntelliSwab™ COVID-19 rapid test from the U.S. Food and Drug Administration ("FDA").

DOD Manufacturing Capacity funding

In September 2021, we also entered into an agreement for \$109 million in funding from the U.S. Department of Defense (the "DOD"), in coordination with the Department of Health and Human Services, to build additional manufacturing capacity in the United States for our IntelliSwab™ COVID-19 rapid tests as part of the nation's pandemic preparedness plan. Under this agreement, the funding will be used to expand our production capacity by 100 million tests annually. Funding will be paid to the Company based on achievement of milestones through March 2024 for the design, acquisition, installation, qualification and acceptance of the manufacturing equipment, as set forth in the agreement. An existing Company location in Bethlehem, PA will be retrofitted to accommodate increased manufacturing and an additional new facility will be added in another U.S. location to be determined.

Current Consolidated Financial Results

During the nine months ended September 30, 2021, our consolidated net revenues increased 56% to \$170.1 million, compared to \$108.9 million for the nine months ended September 30, 2020. Net product and services revenues during the nine months ended September 30, 2021 increased 56% when compared to the same period of 2020, largely due to increased revenues across all products lines, other than our international HIV self-test. The biggest contributors to the increased revenues for the period were higher sales of our genomics products and our molecular sample collection kits for COVID-19 testing and the first time inclusion of sales of our IntelliSwab™ COVID-19 rapid tests. Other revenues for the nine months ended September 30, 2021 were \$4.6 million compared to \$2.9 million in the same period of 2020. This increase was largely due to increased research and development funding for the development of our COVID-19 tests and higher royalty income.

Our consolidated net loss for the nine months ended September 30, 2021 was \$12.6 million, or \$0.18 per share on a fully diluted basis, compared to a consolidated net loss of \$16.8 million, or \$0.25 per share on a fully diluted basis, for the nine months ended September 30, 2020. Results for the nine months ended September 30, 2021 included a \$1.5 million non-cash pre-tax benefit associated with the change in the fair value of acquisition-related contingent consideration which accounted for approximately \$0.02 per share. Results for the nine months ended September 30, 2020 included a \$390,000 non-cash pre-tax charge associated with the change in the fair value of acquisition-related contingent consideration and \$393,000 of acquisition related transaction costs associated with the UrSure acquisition, which together accounted for approximately \$0.01 per share.

Cash used in operating activities during the nine months ended September 30, 2021 was \$22.6 million. Cash provided by operating activities during the nine months ended September 30, 2020 was \$2.2 million. As of September 30, 2021, we had \$202.3 million in cash, cash equivalents, and available-for-sale securities, compared to \$257.1 million at December 31, 2020.

Results of Operations

Three months ended September 30, 2021 compared to September 30, 2020

CONSOLIDATED NET REVENUES

The table below shows a breakdown of total consolidated net revenues (dollars in thousands) generated by each of our business segments during the three months ended September 30, 2021 and 2020.

	Three Months Ended September 30,				
	Dollars		% Change	Percentage of Total Net Revenues	
	2021	2020		2021	2020
Diagnostics	\$ 23,281	\$ 15,540	50 %	43 %	32 %
Molecular Solutions	29,948	31,209	(4)	56	65
Net product and services revenues	53,229	46,749	14	99	97
Other	688	1,262	(45)	1	3
Net revenues	\$ 53,917	\$ 48,011	12 %	100 %	100 %

Consolidated net product and services revenues increased 14% to \$53.2 million for the three months ended September 30, 2021 from \$46.7 million for the three months ended September 30, 2020. The increase in revenues was largely driven by increased genomic product sales and the first time inclusion of sales of our InteliSwab™ COVID-19 rapid tests, partially offset by a decline in sales of our molecular sample collection kits for COVID-19 testing. Other revenues for the three months ended September 30, 2021 decreased 45% to \$688,000 from \$1.3 million for the three months ended September 30, 2020 due to expected lower research and development funding for the development of our COVID-19 tests and our HIV medication adherence tests.

Consolidated net revenues derived from products sold to customers outside of the United States were \$10.9 million and \$9.4 million, or 20% of total net revenues in each period, for the three months ended September 30, 2021 and 2020, 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 consolidated net revenues.

Net Revenues by Segment

Diagnostics Segment

The table below shows a breakdown of total net revenues (dollars in thousands) generated by our Diagnostics segment during the three months ended September 30, 2021 and 2020.

Market	Three Months Ended September 30,				
	Dollars		% Change	Percentage of Total Net Revenues	
	2021	2020		2021	2020
Infectious disease testing	\$ 12,932	\$ 13,224	(2) %	55 %	81 %
COVID-19	7,675	63	NM	33	NM
Risk assessment testing	2,674	2,253	19	11	14
Net product revenues	23,281	15,540	50	99	95
Other	230	774	(70)	1	5
Net revenues	\$ 23,511	\$ 16,314	44 %	100 %	100 %

NM - not meaningful

Infectious Disease Testing Market

Sales to the infectious disease testing market decreased 2% to \$12.9 million for the three months ended September 30, 2021 from \$13.2 million for the three months ended September 30, 2020. This decrease resulted from lower world-wide OraQuick® HIV and international OraQuick® HCV product sales, partially offset by higher domestic OraQuick® HCV product sales.

The table below shows a breakdown of our total net OraQuick® HIV and HCV product revenues (dollars in thousands) during the three months ended September 30, 2021 and 2020.

Market	Three Months Ended September 30,		
	2021	2020	% Change
Domestic HIV	\$ 3,440	\$ 3,909	(12) %
International HIV	6,582	6,865	(4)
Net HIV revenues	10,022	10,774	(7)
Domestic HCV	1,827	1,186	54
International HCV	888	1,033	(14)
Net HCV revenues	2,715	2,219	22
Net OraQuick® revenues	\$ 12,737	\$ 12,993	(2) %

Domestic OraQuick® HIV sales decreased 12% to \$3.4 million for the three months ended September 30, 2021 from \$3.9 million for the three months ended September 30, 2020, primarily as a result of the timing of orders placed for our OraQuick® In-Home test.

International sales of our OraQuick® HIV tests decreased 4% to \$6.6 million for the three months ended September 30, 2021 from \$6.9 million for the three months ended September 30, 2020. This decline in revenues was primarily due to lower subsidies for the international sale of our HIV Self-Test under the charitable support agreement with the Gates Foundation. The Gates agreement and subsidy provided thereunder expired on June 30, 2021.

Domestic OraQuick® HCV sales increased 54% to \$1.8 million for the three months ended September 30, 2021 from \$1.2 million for the three months ended September 30, 2020, due to the re-opening of testing programs previously closed as a result of the COVID-19 pandemic and as resources used for COVID-19 testing and vaccinations were redirected back to HCV testing.

International OraQuick® HCV sales decreased 14% to \$888,000 for the three months ended September 30, 2021 from \$1.0 million for the three months ended September 30, 2020 due to customer ordering patterns.

COVID-19 Testing Market

During the three months ended September 30, 2021, COVID-19 revenues were \$7.7 million, driven by the first time sales of our InteliSwab™ COVID-19 rapid test which were limited by manufacturing constraints in the quarter.

Risk Assessment Market

Sales to the risk assessment market increased 19% to \$2.7 million for the three months ended September 30, 2021 compared to \$2.3 million for the three months ended September 30, 2020 due to hiring increases driven by the economic recovery from the COVID-19 pandemic.

Other Revenues

Other revenues for the three months ended September 30, 2021 decreased to \$230,000 from \$774,000 for the three months ended September 30, 2020, due to lower research and development funding for the development of our COVID-19 tests and our HIV medication adherence tests.

Molecular Solutions Segment

The table below shows a breakdown of our total net revenues (dollars in thousands) during the three months ended September 30, 2021 and 2020.

Market	Three Months Ended September 30,		
	2021	2020	% Change
Genomics	\$ 19,018	\$ 8,454	125 %
Microbiome	1,693	1,530	11
COVID-19	6,255	18,804	(67)
Laboratory services	2,406	2,280	6
Other product and service revenues	576	141	309
Net molecular product and services revenues	\$ 29,948	\$ 31,209	(4)
Other	458	488	(6)
Net molecular product and services revenues	\$ 30,406	\$ 31,697	(4) %

Sales of our genomics products increased 125% to \$19.0 million for the three months ended September 30, 2021 compared to \$8.5 million for the three months ended September 30, 2020, as this product line experienced a strong rebound from the impact of the COVID-19 pandemic in the prior period and benefited from ordering patterns of our larger customers.

Microbiome kit sales increased 11% to \$1.7 million for the three months ended September 30, 2021 compared to \$1.5 million for the three months ended September 30, 2020, due to customer ordering patterns.

Sales of our molecular sample collection kits for COVID-19 testing decreased 67% to \$6.3 million for the three months ended September 30, 2021 compared to \$18.8 million during the comparable period in 2020 due to lower COVID-19 PCR testing demand and the impact of the wider availability of vaccines.

Laboratory services revenues increased 6% to \$2.4 million for the three months ended September 30, 2021 compared to \$2.3 million for the three months ended September 30, 2020 due to customers resuming activities delayed by the COVID-19 pandemic.

Other product and service revenues increased 309% to \$576,000 for the three months ended September 30, 2021 compared to \$141,000 for the three months ended September 30, 2020 due to increased sales of our Colli-Pee® collection device.

Other revenues for the three months ended September 30, 2021 decreased 6% to \$458,000 from \$488,000 the three months ended September 30, 2020, largely as a result of lower royalty income received under a litigation settlement agreement.

CONSOLIDATED OPERATING RESULTS

Consolidated gross profit percentage was 40% for the three months ended September 30, 2021 compared to 63% for the three months ended September 30, 2020. The decrease in gross profit percentage was primarily due to a less favorable product mix, increased scrap expense, lower absorption of labor, and lower subsidies for the international sale of our HIV Self-Test under the charitable support agreement with the Gates Foundation.

Consolidated operating loss for the three months ended September 30, 2021 was \$13.0 million, a \$17.4 million decrease from the \$4.4 million operating income reported for the three months ended September 30, 2020. Results for the three months ended September 30, 2021 were negatively impacted by the lower gross profit percentage and an increase in operating expenses.

OPERATING INCOME (LOSS) BY SEGMENT

We evaluate performance of our operating segments based on revenue and operating income. Reportable segments have no inter-segment revenue and inter-segment expenses are eliminated in consolidation, including the fees associated with an intercompany service agreement between Diagnostics and Molecular Solutions.

Diagnostics Segment

The gross profit percentage for the Diagnostics segment was 16% for the three months ended September 30, 2021 compared to 44% for the three months ended September 30, 2020. This decrease is due to an increase in scrap costs associated with the production of our IntelliSwab™ test, and the recording of a reserve for COVID-19 antibody inventory, lower absorption of labor costs as we have increased headcount in anticipation of higher production demands, and lower subsidies for the international sale of our HIV Self-Test under the charitable support agreement with the Gates Foundation.

Research and development expenses increased 3% to \$5.9 million for the three months ended September 30, 2021 compared to \$5.7 million for the three months ended September 30, 2020 largely due to higher staffing costs and increased spend to investigate IntelliSwab™ manufacturing issues, partially offset by a decline in COVID-19 lab supply costs associated with reduced product development activities from the prior year period. Sales and marketing expenses increased 83% to \$9.0 million for three months ended September 30, 2021 from \$4.9 million for the three months ended September 30, 2020 due to an increase in advertising spend associated with the introduction of our IntelliSwab™ test into the market, higher commissions associated with the revenue increase, and increased consulting expense associated with business strategy planning. General and administrative expenses increased 24% to \$8.0 million for the three months ended September 30, 2021 from \$6.5 million for the three months ended September 30, 2020 largely due to increased business development consulting spend, increased staffing costs associated with increased headcount and higher recruiting expenses. We are anticipating higher operating expenses in the fourth quarter of 2021 as several of our on-going IntelliSwab™ post marketing clinical studies will lead to higher research and development expenses. In addition, we expect higher sales and marketing and general and administrative costs as we prepare for significant commercial ramp up of our IntelliSwab™ business in 2022.

All of the above contributed to the Diagnostics segment's operating loss of \$18.6 million for the three months ended September 30, 2021, which included non-cash charges of \$1.1 million for depreciation and amortization and \$1.9 million for stock-based compensation. The Diagnostics

segment operating loss also included a non-cash pre-tax benefit of \$500,000 associated with the change in the fair value of acquisition-related contingent consideration.

Molecular Solutions Segment

The gross profit percentage for the Molecular Solutions segment was 58% for the three months ended September 30, 2021 compared to 73% for the three months ended September 30, 2020. This decrease was due to a less favorable product mix associated with the higher sales of lower gross profit percentage product and an increase in costs at our third party contract manufacturers resulting from the capacity expansion at those vendors.

Research and development expenses increased 17% to \$2.7 million for the three months ended September 30, 2021 from \$2.3 million for the three months ended September 30, 2020 due to higher staffing costs. Sales and marketing expenses increased 67% to \$4.9 million for the three months ended September 30, 2021 from \$2.9 million for the three months ended September 30, 2020 due to increased consulting expense associated with business strategy planning, an increase in our reserve for uncollectible accounts, and higher staffing costs. General and administrative expenses increased 23% to \$4.4 million for the three months ended September 30, 2021 from \$3.6 million for the three months ended September 30, 2020 due to increased legal fees and staffing costs.

All of the above contributed to the Molecular Solutions segment's operating income of \$5.6 million for the three months ended September 30, 2021, which included \$2.2 million for depreciation and amortization and \$301,000 for stock-based compensation.

CONSOLIDATED INCOME TAXES

We continue to believe the full valuation allowance established against our total U.S. deferred tax asset is appropriate as the facts and circumstances necessitating the allowance have not changed. For the three months ended September 30, 2021, we recorded a U.S. state tax benefit of \$102,000 compared to a \$629,000 state income tax benefit for the three months ended September 30, 2020. For the three months ended September 30, 2021, we recorded foreign tax expense of \$2.2 million compared to foreign tax expense of \$4.3 million for the three months ended September 30, 2020. The overall decrease in tax expense is largely a result of the decrease in income before taxes generated by our Canadian subsidiary.

Nine months ended September 30, 2021 compared to September 30, 2020

CONSOLIDATED NET REVENUES

The table below shows a breakdown of total consolidated net revenues (dollars in thousands) generated by each of our business segments for the nine months ended September 30, 2021 and 2020.

	Nine Months Ended September 30,				
	Dollars		% Change	Percentage of Total Net Revenues	
	2021	2020		2021	2020
Diagnostics	\$ 54,867	\$ 43,473	26 %	32 %	40 %
Molecular Solutions	110,682	62,499	77	65	57
Net product and services revenues	165,549	105,972	56	97	97
Other	4,557	2,894	57	3	3
Net revenues	<u>\$ 170,106</u>	<u>\$ 108,866</u>	56 %	<u>100 %</u>	<u>100 %</u>

Consolidated net product and services revenues increased 56% to \$165.5 million for the nine months ended September 30, 2021 from \$106.0 million for the comparable period of 2020, largely due to increased revenues across all products lines, other than our international HIV self-test. The biggest contributors to the increased revenues for the period were higher sales of our genomics products and our molecular sample collection kits for COVID-19 testing and the first time inclusion of sales of our InteliSwab™ COVID-19 rapid tests. Other revenues for the nine months ended September 30, 2021 increased 57% to \$4.6 million from \$2.9 million for the nine months ended September 30, 2020. This increase was largely due to increased research and development funding for the development of our COVID-19 tests and higher royalty income.

Consolidated net revenues derived from products sold to customers outside of the United States were \$30.4 million and \$26.7 million, or 18% and 25% of total net revenues, in the first nine months of 2021 and 2020, 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 consolidated net revenues.

Net Revenues by Segment

Diagnostics Segment

The table below shows a breakdown of total net revenues (dollars in thousands) generated by our Diagnostics segment during the nine months ended September 30, 2021 and 2020.

Market	Nine Months Ended September 30,				
	Dollars		% Change	Percentage of Total Net Revenues	
	2021	2020		2021	2020
Infectious disease testing	\$ 39,664	\$ 36,625	8 %	69 %	82 %
COVID-19	7,938	63	NM	14	NM
Risk assessment testing	7,265	6,786	7	13	15
Net product revenues	54,867	43,474	26	96	97
Other	2,501	1,060	136	4	3
Net revenues	\$ 57,368	\$ 44,534	29 %	100 %	100 %

NM - not meaningful

Infectious Disease Testing Market

Sales to the infectious disease testing market increased 8% to \$39.7 million for the nine months ended September 30, 2021 from \$36.6 million for the nine months ended September 30, 2020. This increase resulted from higher domestic sales of our OraQuick® HIV and HCV products and higher international OraQuick® HVC product sales, partially offset by lower sales of our international OraQuick® HIV Self-Tests.

The table below shows a breakdown of our total net OraQuick® HIV and HCV product revenues (dollars in thousands) during the nine months ended September 30, 2021 and 2020.

Market	Nine Months Ended September 30,		
	2021	2020	% Change
Domestic HIV	\$ 12,490	\$ 11,323	10 %
International HIV	17,255	17,697	(2)
Net HIV revenues	29,745	29,020	2
Domestic HCV	5,580	3,437	62
International HCV	3,802	2,772	37
Net HCV revenues	9,382	6,209	51
Net OraQuick® revenues	\$ 39,127	\$ 35,229	11 %

Domestic OraQuick® HIV sales increased 10% to \$12.5 million for the nine months ended September 30, 2021 from \$11.3 million for the nine months ended September 30, 2020. This increase was primarily the result of higher sales of our OraQuick® In-Home HIV test used in a Centers for Disease Control and Prevention ("CDC") initiative to drive increased in-home HIV testing.

International sales of our OraQuick® HIV tests decreased 2% to \$17.3 million for the nine months ended September 30, 2021 from \$17.7 million for the nine months ended September 30, 2020 largely due to pricing associated with the expiration of the Gates Foundation subsidy for certain international tests.

Domestic OraQuick® HCV sales increased 62% to \$5.6 million for the nine months ended September 30, 2021 from \$3.4 million for the nine months ended September 30, 2020 due to the re-opening of testing programs previously closed as a result of the COVID-19 pandemic and as resources used for COVID-19 testing and vaccinations were redirected back to HCV testing.

International OraQuick® HCV sales increased 37% to \$3.8 million for the nine months ended September 30, 2021 from \$2.8 million for the nine months ended September 30, 2020 as sales into certain international markets continued to return to pre-pandemic levels.

COVID-19 Testing Market

During the nine months ended September 30, 2021, COVID-19 revenues were \$7.9 million, driven by the first time sales of our InteliSwab™ COVID-19 rapid antigen test which began in the third quarter of 2021.

Risk Assessment Market

Sales to the risk assessment market increased 7% to \$7.3 million for the nine months ended September 30, 2021 compared to \$6.8 million for the nine months ended September 30, 2020 due to hiring increases driven by the economic recovery from the COVID-19 pandemic.

Other Revenues

Other revenues for the nine months ended September 30, 2021 increased to \$2.5 million from \$1.1 million for the nine months ended September 30, 2020, largely due higher research and development funding for our COVID-19 tests and the inclusion of royalty income under the terms of a new licensing agreement related to our proprietary buffer solution used for the preservation and stabilization of oral fluid specimens.

Molecular Solutions Segment

The table below shows a breakdown of our total net revenues (dollars in thousands) during the nine months ended September 30, 2021 and 2020.

Market	Nine Months Ended September 30,		
	2021	2020	% Change
Genomics	\$ 49,333	\$ 23,224	112 %
Microbiome	5,888	3,869	52
COVID-19	46,209	27,855	66
Laboratory services	8,017	6,798	18
Other product revenues	1,235	752	64
Net molecular product and services revenues	\$ 110,682	\$ 62,498	77
Other	2,056	1,834	12
Net molecular product and services revenues	\$ 112,738	\$ 64,332	75 %

Sales of our genomics products increased 112% to \$49.3 million for the nine months ended September 30, 2021 compared to \$23.2 million for the nine months ended September 30, 2020 as we continued to see our customers' businesses recover from the COVID-19 pandemic and strong organic growth from customers in the commercial animal markets.

Microbiome kit sales increased 52% to \$5.9 million for the nine months ended September 30, 2021 compared to \$3.9 million for the nine months ended September 30, 2020 due to a recovery in the market from the COVID-19 pandemic.

Sales of our molecular sample collection kits for COVID-19 testing increased 66% to \$46.2 million for the nine months ended September 30, 2021 compared to \$27.9 million during the comparable period in 2020 due to increased demand as the COVID-19 pandemic began late in the first quarter of 2020 and testing ramped up in the second and third quarters of 2020 and continued into the first half of 2021 contributing to the revenue growth for the nine month period.

Laboratory services revenues increased 18% to \$8.0 million for the nine months ended September 30, 2021 compared to \$6.8 million for the nine months ended September 30, 2020, due to customers resuming activities delayed by the COVID-19 pandemic.

Other product and service revenues increased 64% to \$1.2 million for the nine months ended September 30, 2021 compared to \$752,000 for the nine months ended September 30, 2020 due to increased sales of our Colli-Pee® collection device.

Other revenues for the nine months ended September 30, 2021 increased 12% to \$2.1 million from \$1.8 million for the nine months ended September 30, 2020 largely as a result of higher royalty income received under a litigation settlement agreement.

CONSOLIDATED OPERATING RESULTS

Consolidated gross profit percentage was 53% for the nine months ended September 30, 2021 compared to 59% for the nine months ended September 30, 2020. Gross profit percentage for the nine months ended September 30, 2021 declined as a result of increased scrap expense, lower absorption of labor costs, and lower subsidies under the charitable support agreement with the Gates Foundation, partially offset by an improved product mix associated with an increase in higher gross profit percentage product sales.

Consolidated operating loss for the nine months ended September 30, 2021 was \$793,000 a \$12.3 million improvement from the \$13.1 million operating loss reported for the nine months ended September 30, 2020. Results for the nine months ended September 30, 2021 were positively

impacted by the increased revenues and the inclusion of an \$1.5 million non-cash benefit related to the fair value change in acquisition-related contingent consideration partially offset by the lower gross profit percentage and increased operating expenses.

OPERATING INCOME (LOSS) BY SEGMENT

We evaluate performance of our operating segments based on revenue and operating income. Reportable segments have no inter-segment revenue and inter-segment expenses are eliminated in consolidation, including the fees associated with an intercompany service agreement between Diagnostics and Molecular Solutions.

Diagnostics Segment

The gross profit percentage for the Diagnostics segment was 29% for the nine months ended September 30, 2021 compared to 43% for the nine months ended September 30, 2020. This decrease was due to an increase in scrap costs associated with the production of our IntelliSwab™ test and the recording of a reserve for COVID-19 antibody inventory, and lower absorption of labor costs as we have increased headcount in anticipation of higher production demands.

Research and development expenses increased 29% to \$17.4 million for the nine months ended September 30, 2021 from \$13.5 million for the nine months ended September 30, 2020, largely due to higher staffing costs and increased COVID-19 product development expenses. Sales and marketing expenses increased 35% to \$21.7 million for the nine months ended September 30, 2021 from \$16.1 million for the nine months ended September 30, 2020, due to higher market research and advertising spending associated with the introduction of our IntelliSwab™ test into the market, higher commissions directly related to the increase in revenues and increased consulting costs associated with business strategy planning. General and administrative expenses increased 4% to \$21.6 million for the nine months ended September 30, 2021 from \$20.7 million for the nine months ended September 30, 2020 due to higher staffing costs associated with increased headcount, and higher business development consulting costs, partially offset by lower legal fees, a lower allocation of building costs as administrative space was repurposed for manufacturing, and increased intercompany service fees allocated to the Molecular Solutions segment.

All of the above contributed to the Diagnostics segment's operating loss of \$42.8 million for the nine months ended September 30, 2021, which included non-cash charges of \$3.0 million for depreciation and amortization and \$4.7 million for stock-based compensation. The Diagnostics segment operating loss also included a non-cash pre-tax benefit of \$1.5 million associated with the change in the fair value of acquisition-related contingent consideration.

Molecular Solutions Segment

The gross profit percentage for the Molecular Solutions segment was 66% for the nine months ended September 30, 2021 compared to 69% for the nine months ended September 30, 2020. This decrease is due a less favorable product mix associated with increased sales of lower gross profit percentage product and increased costs at our third party contract manufacturers.

Research and development expenses increased 11% to \$7.9 million for the nine months ended September 30, 2021 from \$7.1 million for the nine months ended September 30, 2020 due to increased staffing and consulting costs. Sales and marketing expenses increased 31% to \$12.1 million for the nine months ended September 30, 2021 from \$9.2 million for the nine months ended September 30, 2020 due to higher staffing costs, increased consulting costs associated with business strategy planning, and an increase in our reserve for uncollectible accounts. General and administrative expenses increased 24% to \$12.1 million for the nine months ended September 30, 2021 from \$9.7 million for the nine months ended September 30, 2020 due to increased intercompany service fees allocated from the Diagnostics segment, estimated penalties incurred on delinquent sales tax filings that were not recognized in the prior year period, higher staffing costs, and increased legal fees.

All of the above contributed to the Molecular Solutions segment's operating income of \$42.0 million for the nine months ended September 30, 2021, which included \$5.5 million for depreciation and amortization and \$496,000 for stock-based compensation.

CONSOLIDATED INCOME TAXES

We continue to believe the full valuation allowance established against our total U.S. deferred tax asset is appropriate as the facts and circumstances necessitating the allowance have not changed. For the nine months ended September 30, 2021, we recorded U.S. state tax expense of \$13,000 compared to \$612,000 of state income tax benefit for the nine months ended September 30, 2020. For the nine months ended September 30, 2021, we recorded foreign tax expense of \$12.2 million compared to foreign tax expense of \$6.3 million for the nine months ended September 30, 2020. The overall increase in tax expense is largely a result of the increase in income before taxes generated by our Canadian subsidiary.

Liquidity and Capital Resources

	September 30, 2021	December 31, 2020
	(In thousands)	
Cash and cash equivalents	\$ 134,962	\$ 160,802
Available for sale securities	67,336	96,317
Working capital	235,060	242,404

Our cash and cash equivalents and available-for-sale securities decreased to \$202.3 million at September 30, 2021 from \$257.1 million at December 31, 2020. Our working capital decreased to \$235.1 million at September 30, 2021 from \$242.4 million at December 31, 2020.

During the nine months ended September 30, 2021, net cash used in operating activities was \$22.6 million. Our net loss of \$12.6 million included non-cash charges for depreciation and amortization expense of \$8.5 million, stock-based compensation expense of \$5.2 million, a provision for doubtful accounts of \$1.2 million, and other non-cash expense of \$105,000. Operating activities also included a benefit for the change in the estimated fair value of acquisition-related contingent consideration of \$1.5 million and a \$142,000 contingent consideration payment representing the excess of the total contingent consideration payment made during the nine months ended September 30, 2021 over the fair value of the liability estimated at the time of acquisition. Sources of cash generated from our working capital accounts included a \$2.8 million increase in accounts payable due to the timing of invoices received and payments made and an increase in accrued expenses and other liabilities of \$982,000 associated with increased accruals for professional fees and higher sales tax payable. Offsetting these sources of cash were an increase in inventory of \$21.7 million to meet anticipated demand to support COVID-19 testing programs, an increase in accounts receivable of \$2.1 million due to orders placed late in the quarter, an increase in prepaid expenses and other assets of \$1.9 million due to prepayments made on a manufacturing contract and a decrease in deferred revenue of \$1.3 million due to the recognition of revenue from customer prepayments.

Net cash provided by investing activities was \$776,000 for the nine months ended September 30, 2021, which reflects proceeds from the maturities and redemptions of investments of \$53.8 million offset by \$27.5 million used to acquire property and equipment largely to increase our manufacturing capacity and \$25.5 million used to purchase investments.

Net cash used in financing activities was \$3.1 million for the nine months ended September 30, 2021, which reflects \$1.9 million used for the repurchase of common stock to satisfy withholding taxes related to the vesting of restricted shares awarded to our employees, payments of lease liabilities of \$1.1 million and \$264,000 used for payment of our contingent consideration obligation, partially offset by proceeds from stock option exercises of \$247,000.

We expect current balances of cash and cash equivalents and available-for-sale securities to be sufficient to fund our current and foreseeable operating and capital needs. 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 including continued investment to expand our capacity to manufacture products for COVID-19 testing, changes in existing and potential relationships with business partners, the timing and cost of obtaining regulatory approvals, the timing and cost of future stock purchases, 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. In addition, \$129.2 million or 64% of our \$202.3 million in cash, cash equivalents and available-for-sale securities belongs to our Canadian subsidiary. Repatriation of such cash into the United States exceeding certain levels could have adverse tax consequences.

A summary of our obligations to make future payments under contracts existing at December 31, 2020 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, 2020. As of September 30, 2021, except as described in note 11 within the notes to the consolidated financial statements, there were no significant changes to this information.

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 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 bad debts, customer sales returns, inventories, intangible assets, income taxes, revenue recognition, performance-based compensation, contingencies and litigation. 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 Annual Report on Form 10-K for the year ended December 31, 2020 filed with the SEC. During the first nine months of 2021, there were no material changes to 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 September 30, 2021, we did not have any foreign currency exchange contracts or purchase currency options to hedge local currency cash flows. Sales denominated in foreign currencies comprised 5.2% of our total revenues for the nine months ended September 30, 2021. We do have foreign currency exchange risk related to our operating subsidiaries in Canada and in Belgium. The principal foreign currencies in which we conduct business are the Canadian dollar and the Euro. Fluctuations in the exchange rate between the U.S. dollar and these foreign currencies could affect year-to-year comparability of operating results and cash flows. Our foreign subsidiaries had net assets, subject to translation, of \$194.2 million in U.S. Dollars, which are included in the Company's consolidated balance sheet as of September 30, 2021. A 10% unfavorable change in the Canadian-to-U.S. dollar and Euro-to-U.S. dollar exchange rates would have decreased our comprehensive income by approximately \$16.8 million in the nine months ended September 30, 2021.

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 September 30, 2021. Based on that evaluation, the Company's management, including such officers, concluded that the Company's disclosure controls and procedures were effective as of September 30, 2021 to provide reasonable assurance that material information required to be disclosed by the Company in the reports that it files or submits 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 Securities and Exchange Commission.

(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 September 30, 2021 that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. LEGAL PROCEEDINGS

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, individually or in the aggregate, to have a material adverse effect on our future financial position or results of operations.

Spectrum Patent Litigation

In March 2021, we filed a complaint against Spectrum Solutions, LLC ("Spectrum") in the United States District Court for the Southern District of California alleging that certain saliva collection devices manufactured and sold by Spectrum infringe a patent held by DNAG. Spectrum has filed an answer to the initial complaint, asserting that its device does not infringe our patent and that our patent is invalid. In August 2021, we amended our complaint to add a second patent to this litigation. Spectrum responded to our amended complaint and asserted counterclaims for inequitable conduct and antitrust violations with respect to one of the patents in the litigation. We believe Spectrum's counterclaims are without merit and we filed a motion to dismiss both claims in October 2021. We are seeking injunctive relief and damages in this matter.

Item 1A. RISK FACTORS

The risk factors set forth in this report update should be read together with the risk factors discussed in Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2020.

Our U.S. Government Contracts Require Compliance With Numerous Laws and Increases Our Risk and Liability.

From time to time, we receive funding from the U.S. government and we sell some of our products to the federal government. Historically, we have sold a number of our products to the government under contracts with the General Services Administration and the Veterans

Administration. During the third quarter of 2021, we entered into a contract with the Defense Logistics Agency ("DLA") for the procurement of our IntelliSwab™ COVID-19 Rapid Test for over-the-counter use, with an estimated value of \$205 million. During the same quarter, we entered into a contract with the Biomedical Advanced Research Development Authority to provide us with up to \$13.6 million in funding to obtain FDA 510(k) clearance and Clinical Laboratory Improvement Amendments ("CLIA") waiver for our IntelliSwab™ COVID-19 Rapid Test. In September 2021, we entered into a contract with the U.S. Department of Defense, in coordination with the Department of Health and Human Services, for \$109 million in funding to build additional manufacturing capacity in the United States for our IntelliSwab™ COVID-19 Rapid Test.

As a result of our U.S. government funding and product sales to the U.S. government, we must comply with laws and regulations relating to the award, administration and performance of U.S. government contracts. U.S. government contracts typically contain a number of extraordinary provisions that would not typically be found in commercial contracts and which may create a disadvantage and additional risks to us as compared to competitors that do not rely on government contracts. For example, the government has the right to terminate one or more of these contracts at its convenience even if we have not defaulted in any of our obligations.

As a U.S. government contractor, we are subject to increased risks of investigation, criminal prosecution and other legal actions and liabilities to which purely private sector companies are not. The results of any such actions could adversely impact our business and have an adverse effect on our consolidated financial performance. The U.S. government recently announced that federal contractors who are party to a broad range of contracts with the government must require their employees to be vaccinated against the COVID-19 virus and comply with current masking and social distancing safety procedures. If we become subject to these requirements, we could experience a loss of personnel and difficulty in recruiting new employees, each of which could adversely affect our business.

A violation of specific laws and regulations could result in the imposition of fines and penalties or the termination of our contracts, as well as suspension or debarment. The suspension or debarment in any particular case may be limited to the facility, contract or subsidiary involved in the violation or could be applied to our entire enterprise in certain severe circumstances. Even a narrow scope suspension or debarment could result in negative publicity that could adversely affect our ability to renew contracts and to secure new contracts, both with the U.S. government and private customers, which could materially and adversely affect our business and results of operations. Fines and penalties could be imposed for failing to follow procurement integrity and bidding rules, employing improper billing practices or otherwise failing to follow rules relating to billing on cost-plus contracts, receiving or paying kickbacks, or filing false claims, among other potential violations. In addition, we could suffer serious reputational harm and the value of our common stock could be negatively affected if allegations of impropriety related to such contracts are made against us.

Our Inability to Manufacture Products in Accordance With Applicable Specifications, Performance Standards or Quality Requirements Could Adversely Affect Our Business.

The materials and processes used to manufacture our products must meet detailed specifications, performance standards and quality requirements to ensure our products will perform in accordance with their label claims, our customers' expectations and applicable regulatory requirements. As a result, our products and the materials used in their manufacture or assembly undergo regular inspections and quality testing. Factors such as defective materials or processes, mechanical failures, human errors, environmental conditions, changes in materials or production methods, and other events or conditions could cause our products or the materials used to produce or assemble our products to fail inspections and quality testing or otherwise not perform in accordance with our label claims or the expectations of our customers.

Any failure or delay in our ability to meet the applicable specifications, performance standards, quality requirements or customer expectations could adversely affect our ability to manufacture and sell our products or comply with regulatory requirements. These events could, in turn, adversely affect our revenues and results of operations.

In June 2021, we received FDA Emergency Use Authorization for our IntelliSwab™ COVID-19 Rapid Test. Although there has been significant demand for this product, we have experienced difficulties manufacturing our test in accordance with applicable specifications. We believe these difficulties are the result of variability in certain incoming raw materials used in the product and certain processing steps. As a result, we have not been able to meet the demand for our product and sales of our IntelliSwab™ COVID-19 Rapid Test have been negatively impacted. If we are not able to resolve the manufacturing difficulties in a timely manner, or at all, our revenues and results of operations may not meet expectations and could be adversely affected.

Our Business Results Depend on our Ability to Manage Disruptions in our Domestic and Global Supply Chains and Distribution Channels.

Our ability to meet our customers needs and achieve our financial objectives depends on our ability to maintain key manufacturing, supply and distribution arrangements. The loss or disruption of such manufacturing and supply arrangements could, in the future, interrupt our ability to obtain necessary raw materials and manufacture our products. Such disruptions could result from labor disputes, financial liquidity, natural disasters, extreme weather conditions, public health emergencies and pandemics, supply constraints and general economic and political conditions that could limit the ability of our suppliers to timely provide us with raw materials and components and distribute our products in a timely manner

in accordance with applicable quality requirements. Disruptions in the global supply chain could also delay or preclude the ability of our distributors to sell and deliver our products to customers. Recently, the global supply chain has experienced significant disruptions caused by the COVID-19 pandemic, resulting in shortages of labor and equipment. These conditions, if not mitigated or remedied in a timely manner, could delay or preclude delivery of raw materials needed to manufacture our products or delivery of our products to customers, particularly in international markets. This in turn could have an adverse impact on our business, financial condition, results of operations or cash flows.

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

Period	Total number of shares purchased	Average price paid per Share	Total number of shares purchased as part of publicly announced plans or programs	Maximum number (or approximate dollar value) of shares that may yet be repurchased under the plans or programs ^(1, 2)
July 1, 2021 - July 31, 2021	594 ⁽³⁾	\$ 10.40	—	11,984,720
August 1, 2021 - August 31, 2021	3,673 ⁽³⁾	11.15	—	11,984,720
September 1, 2021 - September 30, 2021	—	—	—	11,984,720
	4,267		—	

- (1) On August 5, 2008, our Board of Directors approved a share repurchase program pursuant to which we are permitted to acquire up to \$25.0 million of outstanding shares. This share repurchase program may be discontinued at any time.
- (2) This column represents the amount that remains available under the \$25.0 million repurchase plan, as of the period indicated. We have made no commitment to purchase any shares under this plan.
- (3) Pursuant to the OraSure Technologies, Inc. Stock Award Plan, and in connection with the vesting of restricted and performance shares, these shares were retired to satisfy minimum tax withholdings.

Item 3. DEFAULTS UPON SENIOR SECURITIES

None

Item 4. MINE SAFETY DISCLOSURES

Not applicable

Item 5. OTHER INFORMATION

None

Item 6. EXHIBITS

Exhibit Number	Exhibit
10.1**	<u>Change of Control Severance Letter of Michele Miller, Vice President, Finance and Controller.</u>
10.2*	<u>\$109 million Capital Funding Agreement With the U.S. Department of Defense, in coordination with the Department of Health and Human Services.</u>
10.3**	<u>Description of OraSure Technologies, Inc. 2021 Incentive Plan is incorporated by reference to Item 5.02 to the Company's Current Report on Form 8-k filed August 13, 2021.</u>
10.4**	<u>Description of Long Term Incentive Policy and 2021 Award Performance Measures is incorporated by reference to Item 5.02 to the Company's Current Report on Form 8-k filed August 13, 2021.</u>
31.1*	<u>Certification of Stephen S. Tang required by Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended.</u>
31.2*	<u>Certification of Scott Gleason required by Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended.</u>
32.1*	<u>Certification of Stephen S. Tang 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.</u>
32.2*	<u>Certification of Scott Gleason a 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.</u>
101.INS	Inline XBRL Instance Document – the Instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Labels Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
Exhibit 104	Cover Page from the Company's Quarterly Report on Form 10-Q for the Quarter Ended June 30, 2021 has been formatted in Inline XBRL

*Filed herewith

** Management contract or compensatory plan or arrangement.

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/ Scott Gleason

Scott Gleason
Interim Chief Financial Officer
(Principal Financial Officer)

Date: November 4, 2021

/s/Michele M. Miller

Michele M. Miller
Vice President, Finance and Controller
(Principal Accounting Officer)

Date: November 4, 2021



August 25, 2021

Ms. Michele M. Miller
Vice President, Finance and Controller

Re: Severance Benefit

Dear Michele:

As a valued employee of OraSure Technologies, Inc. (the “Company”), the Company would like to provide you with certain compensation in the event that your employment is terminated by the Company without Cause (as defined below) or by you for Good Reason (as defined below), in either case, during the one year period following the date of a Change of Control (as defined below) (a “Covered Termination”). Specifically, in the event of a Covered Termination, and subject to your execution and non-revocation of a release of claims and covenant not to sue in form and substance reasonably satisfactory to the Company (the “Release”) such that the Release is effective and irrevocable within 60 days after the date of a Covered Termination, the Company will provide you an amount equal to one (1) year of your base salary at the rate in effect immediately prior to your termination of employment, or if you terminate your employment for Good Reason as the result of a reduction in your base salary, at the rate in effect immediately prior to such reduction (the “Severance Payment”).

The Severance Payment will be paid in substantially equal installments during the one (1) year period commencing on your termination date in accordance with the Company’s normal payroll practices as in effect at the time, provided that the first payment shall be made on the first payroll date after the effective date of the Release and shall include a catch-up for any payments that would have been made had the Release been effective on your termination date. Notwithstanding the foregoing, to the extent required by Section 409A of the Internal Revenue Code of 1986, as amended (the “Code”), if the 60 day Release period overlaps two calendar years, then any portion of the Severance Payment that otherwise would have been made in the first calendar year instead shall be withheld and paid on the first payroll date in the second calendar year with all remaining payments to be made as if no such delay had occurred.

For purposes of this Agreement, the terms “Cause,” “Change of Control” and “Good Reason” have the following meanings:

1. “Cause” shall mean your (i) willful and continued failure to substantially perform your duties to the Company consistent with your job title; (ii) engaging in gross misconduct or gross negligence materially injurious to the Company; (iii) commission of any act in direct competition with or materially detrimental to the best interests of the Company; (iv) conviction of, or plea of guilty or no contest to, a felony; or (v) engaging in willful and

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serious misconduct that would reasonably be expected to harm the reputation of the Company or any of its affiliates or which would reasonably be expected to lead to unwanted or unfavorable publicity to the Company or its affiliates; provided, however, that the Company provides you with written notice of the event alleged to constitute Cause within 60 days after the Company first becomes aware of the occurrence thereof and you fail to cure such event (if capable of cure) within 30 days after your receipt of such written notice. Such written notice to you must describe the alleged events constituting Cause in reasonable detail.

2. “Change of Control” means a change of control of a nature that would be required to be reported in response to Item 6(e) of Schedule 14A of Regulation 14A pursuant to the U.S. Securities Exchange Act of 1934 (the “Exchange Act”); provided, however, that a change of control shall only be deemed to have occurred at such time as (i) any person, or more than one person acting as a group within the meaning of Section 409A of the Code and the regulations issued thereunder, acquires ownership of stock of the Company that, together with stock held by such person or group, constitutes more than fifty percent (50%) of the total fair market value or total voting power of the stock of the Company; (ii) any person, or more than one person acting as a group within the meaning of Code Section 409A and the regulations issued thereunder, acquires (or has acquired during the twelve (12) month period ending on the date of the most recent acquisition) ownership of stock of the Company possessing thirty percent (30%) or more of the total voting power of the Company’s stock; (iii) a majority of the members of the Board of Directors of the Company is replaced during any twelve (12) month period by directors whose appointment or election is not endorsed by a majority of the members of the Board of Directors before the date of the appointment or election; or (iv) a person, or more than one person acting as a group within the meaning of Code Section 409A and the regulations issued thereunder, acquires (or has acquired during the 12-month period ending on the date of the most recent acquisition) assets from the Company that have a total gross fair market value equal to or more than 40 percent of the total gross fair market value of all the assets of the Company immediately before such acquisition or acquisitions.
3. “Good Reason” means any of the following actions that are taken without your prior written consent: (i) a material diminution in your base compensation or authority, duties or responsibilities; (ii) a material change in your reporting obligation from the Chief Financial Officer of the Company to another employee of the Company; or (iii) a relocation of your principal worksite that increases your one-way commute by more than 30 miles. Notwithstanding the foregoing, Good Reason shall not be deemed to exist unless (x) you give the Company written notice within thirty (30) days after you first have knowledge of the occurrence of the event which you believe constitutes the basis for Good Reason, specifying the particular act or failure to act which you believe constitutes the basis for Good Reason, (y) the Company fails to cure such act or failure to act within thirty (30) days after receipt of such notice and (z) you terminate your employment within thirty (30) days after the end of the period specified in clause (y).

This Agreement shall be governed by and construed in accordance with the laws of the Commonwealth of Pennsylvania, applied without reference to principles of conflicts of law.

Any legal proceeding arising out of or relating to this Agreement shall be instituted in the United States District Court for the Eastern District of Pennsylvania, or if such court does not have jurisdiction or will not accept jurisdiction, in any court of general jurisdiction in the county in Pennsylvania in which the Company maintains its principal place of business, and you and the Company hereby consent to the personal and exclusive jurisdiction of such court and hereby waive any objection that you or the Company may have to personal jurisdiction, venue, and any claim or defense of inconvenient forum.

This Agreement may not be amended or modified otherwise than by a written agreement executed by you (or your legal representative) and the Company (or its successor).

The terms and provisions of this Agreement are intended to be separate and divisible provisions and if, for any reason, any one or more of them is held to be invalid or unenforceable, neither the validity nor the enforceability of any other provision of this Agreement shall thereby be affected.

This Agreement may be executed in counterparts and delivered by facsimile transmission or electronic transmission in "portable document format," each of which shall be an original and which taken together shall constitute one and the same document.

The Company may assign its rights and/or delegate its obligations under this Agreement to any successor of the Company, whether by operation of law, agreement or otherwise (including, without limitation, any person or entity who acquires all or a substantial portion of the business of the Company and its subsidiaries (whether direct or indirect and whether structured as a stock sale, asset sale, merger, recapitalization, consolidation or other transaction)) and, in connection with any such delegation of its obligations hereunder (but only so long as such assignee or delegee has consented in writing to be bound by the obligations hereunder) shall be released from such obligations hereunder. This Agreement may not be assigned by you. Except as otherwise provided herein, this Agreement shall bind and inure to the benefit of and be enforceable by you, the Company, your legal representatives and the Company's successors and permitted assigns.

If you agree to the terms of this Agreement, please sign below and return your signed copy of this Agreement to me.

OraSure Technologies, Inc.

Acknowledged and Agreed:

By: /s/ Stephen S. Tang

/s/ Michele M. Miller

Stephen S. Tang
President and Chief Executive Officer

Michele M. Miller

0001

Noun: EQUIPMENT LINE EXPANSION
Exhibit: AA
NSN: N – Not Applicable

Descriptive Data:

1. This CLIN encompasses the expansion of OraSure's current equipment line for the industrial production expansion initiative to establish additional domestic production capacity to increase testing for COVID -19. OraSure shall be responsible for the procurement, set up, and integration of all equipment/material required to meet the production capacity in accordance with Section J, Attachment 1 - Statement of Work (SOW) and OraSure's proposal including all subsequent updates. OraSure shall support Government verification of all CLINS/SubCLINS and production capabilities as outlined in this contract

Equipment Order Group 1

0001AA

1 [***]
 [***]

Noun: EQUIPMENT ORDER GROUP 1
ACRN: AA
PR/MIPR: F2BDBD1259A101 [***]
PSC: 6640
NSN: N – Not Applicable
Contract type: J – FIRM FIXED PRICE
Inspection: DESTINATION
Acceptance: DESTINATION
FOB: DESTINATION

Descriptive Data:

1. The contractor shall provide all purchase requests and confirmation documentation to account for all equipment acquisitions in accordance with Section J, Attachment 1 - Statement of Work (SOW) and OraSure's proposal including all subsequent updates. OraSure shall support Government verification of all CLINS/SubCLINS and production capabilities as outlined in this contract. Group 1 Equipment includes [***]
2. Ordering of Group 1 equipment (as defined in the SOW) as evidenced by a procurement document.
3. This is a Firm Fixed Price CLIN.
4. Deliverable due NLT [***].

ITEM	SUPPLIES OR SERVICES	Qty	Purch Unit	Unit Price	Total Item Amount
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Equipment Order Group 2

0001AB		1		[**]	[**]
		[**]		[**]	[**]

Noun: EQUIPMENT ORDER GROUP 2
ACRN: AA
PR/MIPR: F2BDBD1259A101
PSC: 6640
NSN: N – Not Applicable
Contract type: J – FIRM FIXED PRICE
Inspection: DESTINATION
Acceptance: DESTINATION
FOB: DESTINATION
Descriptive Data:

1. The contractor shall provide all purchase requests and confirmation documentation to account for all equipment acquisitions in accordance with Section J, Attachment 1 - Statement of Work (SOW) and OraSure's proposal including all subsequent updates. OraSure shall support Government verification of all CLINS/SubCLINS and production capabilities as outlined in this contract. Group 2 Equipment includes [**].
2. Ordering of Group 2 equipment (as defined in the SOW) as evidenced by a procurement document.
3. This is a Firm Fixed Price (FFP) CLIN.
4. The deliverable is due NLT [**].

ITEM	SUPPLIES OR SERVICES	Qty	Purch Unit	Unit Price	Total Item Amount
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Equipment Order Group 3

0001AC		1		[**]	[**]
		[**]		[**]	[**]

Noun: EQUIPMENT ORDER GROUP 3
ACRN: AA
PR/MIPR: F2BDBD1259A101
PSC: 6640
NSN: N – Not Applicable
Contract type: J – FIRM FIXED PRICE
Inspection: DESTINATION
Acceptance: DESTINATION
FOB: DESTINATION

Descriptive Data:

- The contractor shall provide all purchase requests and confirmation documentation to account for all equipment acquisitions in accordance with Section J, Attachment 1 - Statement of Work (SOW) and OraSure's proposal including all subsequent updates. OraSure shall support Government verification of all CLINS/SubCLINS and production capabilities as outlined in this contract. Group 3 Equipment includes [**]
- Ordering of Group 3 equipment (as defined in the SOW) as evidenced by a procurement document.
- This is a Firm Fixed Price (FFP) CLIN
- Deliverable due NLT [**].

ITEM	SUPPLIES OR SERVICES	Qty	Purch Unit	Unit Price	Total Item Amount
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Equipment Group 1 – Design Review/Material Order

0001AD		1		[**]	[**]
		[**]		[**]	[**]

Noun: EQUIPMENT GROUP 1 – DESIGN REVIEW/MATERIAL ORDER
ACRN: AA
PR/MIPR: F2BDBD1259A101 [**]
PSC: 6640
NSN: N – Not Applicable
Contract type: J – FIRM FIXED PRICE
Inspection: DESTINATION
Acceptance: DESTINATION
FOB: DESTINATION

Descriptive Data:

1. The contractor shall provide all confirmation documentation to account for equipment design review/material orders in accordance with Section J, Attachment 1 - Statement of Work (SOW) and OraSure's proposal including all subsequent updates. OraSure shall support Government verification of all CLINS/SubCLINS and production capabilities as outlined in this contract.
2. Design finalized and signed off. Vendor will invoice for design acceptance and material order.
3. This is a Firm Fixed Price (FFP) CLIN.
4. Deliverable due NLT [**].

ITEM	SUPPLIES OR SERVICES	Qty	Purch Unit	Unit Price	Total Item Amount
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Equipment Group 2 – Design Review/Material Order

0001AE		1		[**]	[**]
		[**]			[**]

Noun: EQUIPMENT GROUP 2 – DESIGN REVIEW/MATERIAL ORDER
ACRN: AA
PR/MIPR: F2BDBD1259A101 [**]
PSC: 6640
NSN: N – Not Applicable
Contract type: J – FIRM FIXED PRICE
Inspection: DESTINATION
Acceptance: DESTINATION
FOB: DESTINATION

Descriptive Data:

- The contractor shall provide all confirmation documentation to account for equipment design review/material orders in accordance with Section J, Attachment 1 - Statement of Work (SOW) and OraSure's proposal including all subsequent updates. OraSure shall support Government verification of all CLINS/SubCLINS and production capabilities as outlined in this contract.
- Design finalized and signed off. Vendor will invoice for design acceptance and material order.
- This is a Firm Fixed Price (FFP) CLIN.
- Deliverable due NLT [**].

ITEM	SUPPLIES OR SERVICES	Qty	Purch Unit	Unit Price	Total Item Amount
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Equipment Group 3 – Design Review/Material Order

0001AF		1		[**]	[**]
		[**]		[**]	[**]

Noun: EQUIPMENT GROUP 3 – DESIGN REVIEW/MATERIAL ORDER
ACRN: AA
PR/MIPR: F2BDBD1259A101 [**]
PSC: 6640
NSN: N – Not Applicable
Contract type: J – FIRM FIXED PRICE
Inspection: DESTINATION
Acceptance: DESTINATION
FOB: DESTINATION

Descriptive Data:

1. The contractor shall provide all confirmation documentation to account for equipment design review/material orders in accordance with Section J, Attachment 1 - Statement of Work (SOW) and OraSure's proposal including all subsequent updates. OraSure shall support Government verification of all CLINS/SubCLINS and production capabilities as outlined in this contract.
2. Vendor will invoice for material order.
3. This is a Firm Fixed Price (FFP) CLIN.
4. Deliverable due NLT [**].

ITEM	SUPPLIES OR SERVICES	Qty	Purch Unit	Unit Price	Total Item Amount
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Equipment Group 1 – Factory Acceptance Test

0001AG		1		[**]	[**]
		[**]		[**]	[**]

Noun: EQUIPMENT GROUP 1 – FACTORY ACCEPTANCE TEST
ACRN: AA
PR/MIPR: F2BDBD1259A101
PSC: 6640
NSN: N – Not Applicable
Contract type: J – FIRM FIXED PRICE
Inspection: DESTINATION
Acceptance: DESTINATION
FOB: DESTINATION

Descriptive Data:

1. The contractor shall provide all confirmation documentation to account for First Article Test approval in accordance with Section J, Attachment 1 - Statement of Work (SOW) and OraSure's proposal including all subsequent updates. OraSure shall support Government verification of all CLINS/SubCLINS and production capabilities as outlined in this contract.

2. Report documenting [**]

3. This is a Firm Fixed Price (FFP) CLIN.

4. Deliverable due NLT [**].

ITEM	SUPPLIES OR SERVICES	Qty	Purch Unit	Unit Price	Total Item Amount
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Equipment Group 2 – Factory Acceptance Test

0001AH		1		[**]	[**]
		[**]		[**]	[**]

Noun: EQUIPMENT GROUP 2 – FACTORY ACCEPTANCE TEST
ACRN: AA
PR/MIPR: F2BDBD1259A101
PSC: 6640
NSN: N – Not Applicable
Contract type: J – FIRM FIXED PRICE
Inspection: DESTINATION
Acceptance: DESTINATION
FOB: DESTINATION

Descriptive Data:

1. The contractor shall provide all confirmation documentation to account for First Article Test approval in accordance with Section J, Attachment 1 - Statement of Work (SOW) and OraSure's proposal including all subsequent updates. OraSure shall support Government verification of all CLINS/SubCLINS and production capabilities as outlined in this contract.
2. Report documenting [**].
3. This is a Firm Fixed Price (FFP) CLIN.
4. Deliverable due NLT [**].

ITEM	SUPPLIES OR SERVICES	Qty	Purch Unit	Unit Price	Total Item Amount
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Equipment Group 3 – Factory Acceptance Test

0001AJ		1		[***]	[***]
		[***]		[***]	[***]

Noun: EQUIPMENT GROUP 3 – FACTORY ACCEPTANCE TEST
ACRN AA
PR/MIPR: F2BDBD1259A101
PSC: 6640
NSN: N – Not Applicable
Contract type: J – FIRM FIXED PRICE
Inspection: DESTINATION
Acceptance: DESTINATION
FOB: DESTINATION

Descriptive Data:

1. The contractor shall provide all confirmation documentation to account for First Article Test approval in accordance with Section J, Attachment 1 - Statement of Work (SOW) and OraSure's proposal including all subsequent updates. OraSure shall support Government verification of all CLINS/SubCLINS and production capabilities as outlined in this contract.

2. Report documenting [***].

3. This is a Firm Fixed Price (FFP) CLIN.

4. Deliverable due NLT [***].

Equipment Group 1 – Site Acceptance Test

0001AK		1		[***]	[***]
		[***]		[***]	[***]

Noun: EQUIPMENT GROUP 1 – SITE ACCEPTANCE TEST
ACRN AA
PR/MIPR: F2BDBD1259A101
PSC: 6640
NSN: N – Not Applicable
Contract type: J – FIRM FIXED PRICE
Inspection: DESTINATION
Acceptance: DESTINATION
FOB: DESTINATION

Descriptive Data:

1. The contractor shall provide all acceptance documentation (Site Acceptance Tests) for equipment qualification and acceptance. OraSure shall ensure all equipment is in place and operational prior to Government Inspection and Acceptance. Validation shall be completed by DCMA at the contractor's facility.

2. Report documenting [***].

3. This is a Firm Fixed Price (FFP) CLIN.

4. Deliverable due NLT [***].

ITEM	SUPPLIES OR SERVICES	Qty	Purch Unit	Unit Price	Total Item Amount
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Equipment Group 2 – Site Acceptance Test

0001AL		1		[***]	[***]
		[***]		[***]	[***]

Noun: EQUIPMENT GROUP 2 – SITE ACCEPTANCE TEST
ACRN AA
PR/MIPR: F2BDBD1259A101
PSC: 6640
NSN: N – Not Applicable
Contract type: J – FIRM FIXED PRICE
Inspection: DESTINATION
Acceptance: DESTINATION
FOB: DESTINATION

Descriptive Data:

- The contractor shall provide all acceptance documentation (Site Acceptance Tests) for equipment qualification and acceptance. OraSure shall ensure all equipment is in place and operational prior to Government Inspection and Acceptance. Validation shall be completed by DCMA at the contractor's facility.
- Report documenting [***].
- This is a Firm Fixed Price (FFP) CLIN.
- Deliverable due NLT [***].

Equipment Group 3 – Site Acceptance Test

0001AM		1		[***]	[***]
		[***]		[***]	[***]

Noun: EQUIPMENT GROUP 3 – SITE ACCEPTANCE TEST
ACRN AA
PR/MIPR: F2BDBD1259A101
PSC: 6640
NSN: N – Not Applicable
Contract type: J – FIRM FIXED PRICE
Inspection: DESTINATION
Acceptance: DESTINATION
FOB: DESTINATION

Descriptive Data:

- The contractor shall provide all acceptance documentation (Site Acceptance Tests) for equipment qualification and acceptance. OraSure shall ensure all equipment is in place and operational prior to Government Inspection and Acceptance. Validation shall be completed by DCMA at the contractor's facility.
- Report documenting [***].
- This is a Firm Fixed Price (FFP) CLIN.
- Deliverable due NLT 31 [***].

ITEM	SUPPLIES OR SERVICES	Qty	Purch Unit	Unit Price	Total Item Amount
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Equipment Expansion Engineering/Program Management

0001AN		1		[***]	
		[***]		[***]	

Noun: EQUIPMENT EXPANSION ENGINEERING/PROGRAM MANAGEMENT
ACRN: AA
PR/MIPR: F2BDBD1259A101 [***]
PSC: 6640
NSN: N – Not Applicable
Contract type: J – FIRM FIXED PRICE
Inspection: DESTINATION
Acceptance: DESTINATION
FOB: DESTINATION

Descriptive Data:

1. This CLIN encompasses the necessary Project/Engineering management required to support the expansion of OraSure's current equipment line for the industrial production expansion initiative to establish additional domestic production capacity to increase testing for COVID -19. OraSure shall be responsible for the procurement, set up, and integration of all equipment/material required to meet the production capacity in accordance with Section J, Attachment 1 - Statement of Work (SOW) and OraSure's proposal including all subsequent updates. OraSure shall support Government verification of all CLINS/SubCLINS and production capabilities as outlined in this contract. Contractor May bill on a monthly basis [***]
2. Submission of Bi-Monthly reports as identified in the Statement of Work.
3. This is a Firm Fixed Price (FFP) CLIN.

0002					
	<i>Noun:</i>	[***]			
	<i>NSN:</i>	N – Not Applicable			

ITEM	SUPPLIES OR SERVICES	Qty Purch Unit	Unit Price Total Item Amount
0002AA		1	[***]
		[***]	[***]
	<i>Noun:</i> [***]		
	<i>ACRN</i> AA		
	<i>PR/MIPR:</i> F2BDBD1259A101		[***]
	<i>PSC:</i> 6640		
	<i>NSN:</i> N – Not Applicable		
	<i>Contract type:</i> J – FIRM FIXED PRICE		
	<i>Inspection:</i> DESTINATION		
	<i>Acceptance:</i> DESTINATION		
	<i>FOB:</i> DESTINATION		
	<i>Descriptive Data:</i>		
	1. The contractor shall provide all purchase requests and confirmation documentation to account for all molding equipment acquisitions in accordance with Section J, Attachment 1 - Statement of Work (SOW) and OraSure's proposal including all subsequent updates. OraSure shall support Government verification of all CLINS/SubCLINS and production capabilities as outlined in this contract. Molding Equipment includes [***].		
	2. Ordering of [***] Equipment (as defined in the SOW) as evidenced by a procurement document.		
	3. This is a Firm Fixed Price (FFP) CLIN.		
	4. Deliverable due [***].		

0002AB		1	[***]
		[***]	[***]
	<i>Noun:</i> FRIST ARTICLE INSPECTION & APPROVAL		
	<i>ACRN</i> AA		
	<i>PR/MIPR:</i> F2BDBD1259A101		[***]
	<i>PSC:</i> 6640		
	<i>NSN:</i> N – Not Applicable		
	<i>Contract type:</i> J – FIRM FIXED PRICE		
	<i>Inspection:</i> DESTINATION		
	<i>Acceptance:</i> DESTINATION		
	<i>FOB:</i> DESTINATION		
	<i>Descriptive Data:</i>		
	1. The contractor shall provide all confirmation documentation to account for Molding design review/material orders in accordance with Section J, Attachment 1 - Statement of Work (SOW) and OraSure's proposal including all subsequent updates. OraSure shall support Government verification of all CLINS/SubCLINS and production capabilities as outlined in this contract.		
	2. Ordering of Design Review/Material (as defined in the SOW) as evidenced by a procurement document.		
	3. This is a Firm Fixed Price (FFP) CLIN.		
	4. Deliverable due [***].		

ITEM	SUPPLIES OR SERVICES	Qty Purch Unit	Unit Price Total Item Amount
0002AC	<i>Noun:</i> COMPLETION OF [***] <i>ACRN:</i> AA <i>PR/MIPR:</i> F2BDBD1259A101 <i>PSC:</i> 6640 <i>NSN:</i> N – Not Applicable <i>Contract type:</i> J – FIRM FIXED PRICE <i>Inspection:</i> DESTINATION <i>Acceptance:</i> DESTINATION <i>FOB:</i> DESTINATION <i>Descriptive Data:</i>	1 [***]	[***] [***]
	<p>1. The contractor shall provide all acceptance documentation for [***] equipment qualification and acceptance. OraSure shall ensure all equipment is in place and operational prior to Government Inspection and Acceptance. Validation shall be completed by DCMA at the contractor's facility.</p> <p>2. Progress Report describing completion of [***] including photos of equipment and summary of completion qualification / Validation completed by DCMA at the contractor's facility</p> <p>3. This is a Firm Fixed Price (FFP) CLIN.</p> <p>4. Deliverable due NLT [***].</p>		

0003

Noun: ORASURE FACILITY EXPANSION
NSN: N – Not Applicable

Descriptive Data:

This CLIN is *established* to provide for an expansion to the existing [***] manufacturing facility and renovation for the OraSure production expansion to establish additional domestic production capacity to increase testing for COVID-19. This site includes the necessary rooms for raw materials storage, [***] packaging, to QC lot release testing, and finished goods storage. This CLIN includes all requirements for procuring, setting up, and integrating all equipment/material required meet the production capacity set forth in Section J, Attachment 1 - Statement of Work (SOW) and OraSure's proposal and all subsequent updates. OraSure shall support Government verification of all CLINS/SubCLINS and production capabilities as outlined in this contract.

ITEM	SUPPLIES OR SERVICES	Qty Purch Unit	Unit Price Total Item Amount
0003AA	<i>Noun:</i> [***]SIGNING OF CONTRACT/MASTER VALIDATION LIST <i>ACRN</i> AA <i>PR/MIPR:</i> F2BDBD1259A101 <i>PSC:</i> 6640 <i>NSN:</i> N – Not Applicable <i>Contract type:</i> J – FIRM FIXED PRICE <i>Inspection:</i> DESTINATION <i>Acceptance:</i> DESTINATION <i>FOB:</i> DESTINATION	1 [***]	[***] [***]

Descriptive Data:

1. The contractor shall provide the OraSure Master Validation List. This will include a master list of validation activities to be performed that can be referenced in subsequent progress reports to confirm percent completion. All reports/plans shall be submitted in accordance with Section J, Attachment 1 - Statement of Work (SOW) and OraSure's proposal and all subsequent updates. OraSure shall support Government verification of all CLINS/SubCLINS and production capabilities as outlined in this contract.
2. Report evidencing signed contract / Receipt of Master Validation List
3. This is a Firm Fixed Price (FFP) CLIN.
4. Deliverable due NLT [***].

ITEM	SUPPLIES OR SERVICES	Qty Purch Unit	Unit Price Total Item Amount
0003AB	<p><i>Noun:</i> [***] – PROGRESS REPORT #1 (25% COMPLETION)</p> <p><i>ACRN:</i> AA</p> <p><i>PR/MIPR:</i> F2BDBD1259A101</p> <p><i>PSC:</i> 6640</p> <p><i>NSN:</i> N – Not Applicable</p> <p><i>Contract type:</i> J – FIRM FIXED PRICE</p> <p><i>Inspection:</i> DESTINATION</p> <p><i>Acceptance:</i> DESTINATION</p> <p><i>FOB:</i> DESTINATION</p>	1 [***]	[***] [***]

Descriptive Data:

1. The contractor shall provide a progress report describing [***] overall project completion as defined by the Master Validation Plan, which may include completion of written protocols, execution of those written protocols, and report defining the results of those protocols. All reports/plans shall be submitted in accordance with Section J, Attachment 1 - Statement of Work (SOW) and OraSure's proposal and all subsequent updates. OraSure shall support Government verification of all CLINS/SubCLINS and production capabilities as outlined in this contract.
2. Report evidencing construction project status, updated construction project lead time, and confirmation documentation related to identified long lead time construction items.
3. This is a Firm Fixed Price (FFP) CLIN.
4. The deliverable is due NLT [***].

ITEM	SUPPLIES OR SERVICES	Qty Purch Unit	Unit Price Total Item Amount
0003AC		1	[***]
		[***]	[***]
	<i>Noun:</i> [***] – PROGRESS REPORT #2 (50% COMPLETION)		
	<i>ACRN</i> AA		
	<i>PR/MIPR:</i> F2BDBD1259A101		[***]
	<i>PSC:</i> 6640		
	<i>NSN:</i> N – Not Applicable		
	<i>Contract type:</i> J – FIRM FIXED PRICE		
	<i>Inspection:</i> DESTINATION		
	<i>Acceptance:</i> DESTINATION		
	<i>FOB:</i> DESTINATION		

Descriptive Data:

1. The contractor shall provide a progress report describing [***] overall project completion as defined by the Master Validation Plan, which may include completion of written protocols, execution of those written protocols, and report defining the results of those protocols. All reports/plans shall be submitted in accordance with Section J, Attachment 1 - Statement of Work (SOW) and OraSure's proposal and all subsequent updates. OraSure shall support Government verification of all CLINS/SubCLINS and production capabilities as outlined in this contract.

2. Report evidencing construction project status, updated construction project lead time, and confirmation documentation related to identified long lead time construction items.

3. This is a Firm Fixed Price (FFP) CLIN.

4. Deliverable due NLT [***].

ITEM	SUPPLIES OR SERVICES	Qty Purch Unit	Unit Price Total Item Amount
0003AD		1	[***]
		[***]	[***]
	<i>Noun:</i> [***] – PROGRESS REPORT #3 (75% COMPLETION)		
	<i>ACRN</i> AA		
	<i>PR/MIPR:</i> F2BDBD1259A101		[***]
	<i>PSC:</i> 6640		
	<i>NSN:</i> N – Not Applicable		
	<i>Contract type:</i> J – FIRM FIXED PRICE		
	<i>Inspection:</i> DESTINATION		
	<i>Acceptance:</i> DESTINATION		
	<i>FOB:</i> DESTINATION		

Descriptive Data:

1. The contractor shall provide a progress report describing [***] overall project completion as defined by the Master Validation Plan, which may include completion of written protocols, execution of those written protocols, and report defining the results of those protocols. All reports/plans shall be submitted in accordance with Section J, Attachment 1 - Statement of Work (SOW) and OraSure's proposal and all subsequent updates. OraSure shall support Government verification of all CLINS/SubCLINS and production capabilities as outlined in this contract.

2. Report evidencing construction project status, updated construction project lead time, and confirmation documentation related to identified long lead time construction items.

3. This is a Firm Fixed Price (FFP) CLIN.

4. Deliverable due [***].

ITEM	SUPPLIES OR SERVICES	Qty Purch Unit	Unit Price Total Item Amount	
0003AE		1	[***]	
		[***]	[***]	
	<i>Noun:</i>	[***] – COMMISSIONING OF [***]		
	<i>ACRN</i>	AA		
	<i>PR/MIPR:</i>	F2BDBD1259A101	[***]	
	<i>PSC:</i>	6640		
	<i>NSN:</i>	N – Not Applicable		
	<i>Contract type:</i>	J – FIRM FIXED PRICE		
	<i>Inspection:</i>	DESTINATION		
	<i>Acceptance:</i>	DESTINATION		
	<i>FOB:</i>	DESTINATION		
	<i>Descriptive Data:</i>			
		1. The contractor shall provide a final progress report demonstrating project and Master Validation Plan completion. All reports/plans shall be submitted in accordance with Section J, Attachment 1 - Statement of Work (SOW) and OraSure's proposal and all subsequent updates. OraSure shall support Government verification of all CLINS/SubCLINS and production capabilities as outlined in this contract. Validation shall be completed by DCMA at the contractor's facility.		
		2. Report evidencing [***] and qualification / Validation completed by DCMA at the contractor's facility .		
		3. This is a Firm Fixed Price (FFP) CLIN.		
	4. Deliverable due NLT [***].			

0003AF		1	[***]	
		[***]	[***]	
	<i>Noun:</i>	[***]		
	<i>ACRN</i>	AA		
	<i>PR/MIPR:</i>	F2BDBD1259A101	[***]	
	<i>PSC:</i>	6640		
	<i>NSN:</i>	N – Not Applicable		
	<i>Contract type:</i>	J – FIRM FIXED PRICE		
	<i>Inspection:</i>	DESTINATION		
	<i>Acceptance:</i>	DESTINATION		
	<i>FOB:</i>	DESTINATION		
	<i>Descriptive Data:</i>			
		1. The contractor shall provide proof of the fully executed [***] in accordance with in Section J, Attachment 1 - Statement of Work (SOW) and OraSure's proposal and all subsequent updates. OraSure shall support Government verification of all CLINS/SubCLINS and production capabilities as outlined in this contract.		
		2. Report evidencing fully executed [***].		
		3. This is a Firm Fixed Price (FFP) CLIN.		
	4. Deliverable due NLT [***].			

ITEM	SUPPLIES OR SERVICES	Qty Purch Unit	Unit Price Total Item Amount
0003AG	<i>Noun:</i> [***] FACILITY – PROGRESS REPORT #1 ([***] COMPLETION) <i>ACRN</i> AA <i>PR/MIPR:</i> F2BDBD1259A101 <i>PSC:</i> 6640 <i>NSN:</i> N – Not Applicable <i>Contract type:</i> J – FIRM FIXED PRICE <i>Inspection:</i> DESTINATION <i>Acceptance:</i> DESTINATION <i>FOB:</i> DESTINATION <i>Descriptive Data:</i>	1 [***]	[***] [***] [***]
<p>1. The contractor shall provide a report evidencing construction design, permit submission and contracting of general contractor, and a construction project plan. All documentation shall be in accordance with Section J, Attachment 1 - Statement of Work (SOW) and OraSure's proposal and all subsequent updates. OraSure shall support Government verification of all CLINS/SubCLINS and production capabilities as outlined in this contract.</p> <p>2. Report evidencing construction project status, updated construction project lead time, and confirmation documentation related to identified long lead time construction items</p> <p>3. This is a Firm Fixed Price (FFP) CLIN.</p> <p>4. Deliverable due NLT [***].</p>			

ITEM	SUPPLIES OR SERVICES	Qty Purch Unit	Unit Price Total Item Amount
0003AH	<p><i>Noun:</i> [***] – PROGRESS REPORT #2 ([***] COMPLETION)</p> <p><i>ACRN:</i> AA</p> <p><i>PR/MIPR:</i> F2BDBD1259A101</p> <p><i>PSC:</i> 6640</p> <p><i>NSN:</i> N – Not Applicable</p> <p><i>Contract type:</i> J – FIRM FIXED PRICE</p> <p><i>Inspection:</i> DESTINATION</p> <p><i>Acceptance:</i> DESTINATION</p> <p><i>FOB:</i> DESTINATION</p>	1 [***]	[***] [***]

Descriptive Data:

1. The contractor shall provide a progress report describing [***] of overall project completion as defined by the construction project plan/master validation plan. All reports/plans shall be submitted in accordance with Section J, Attachment 1 - Statement of Work (SOW) and OraSure's proposal and all subsequent updates. OraSure shall support Government verification of all CLINS/SubCLINS and production capabilities as outlined in this contract.
2. Report evidencing construction project status, updated construction project lead time, and confirmation documentation related to identified long lead time construction items.
3. This is a Firm Fixed Price (FFP) CLIN.
4. Deliverable due NLT [***].

ITEM	SUPPLIES OR SERVICES	Qty Purch Unit	Unit Price Total Item Amount
0003AJ	<p><i>Noun:</i> [***] – PROGRESS REPORT #3 ([***] COMPLETION)</p> <p><i>ACRN:</i> AA</p> <p><i>PR/MIPR:</i> F2BDBD1259A101</p> <p><i>PSC:</i> 6640</p> <p><i>NSN:</i> N – Not Applicable</p> <p><i>Contract type:</i> J – FIRM FIXED PRICE</p> <p><i>Inspection:</i> DESTINATION</p> <p><i>Acceptance:</i> DESTINATION</p> <p><i>FOB:</i> DESTINATION</p> <p><i>Descriptive Data:</i></p> <p>1. The contractor shall provide a progress report describing [***] of overall project completion as defined by the construction project plan/master validation plan. All reports/plans shall be submitted in accordance with Section J, Attachment 1 - Statement of Work (SOW) and OraSure's proposal and all subsequent updates. OraSure shall support Government verification of all CLINS/SubCLINS and production capabilities as outlined in this contract.</p> <p>2. Report evidencing construction project status, updated construction project lead time, and confirmation documentation related to identified long lead time construction items</p> <p>3. this is a Firm Fixed Price (FFP) CLIN.</p> <p>4. Deliverable due NLT [***].</p>	<p>1</p> <p>[***]</p>	<p>[***]</p> <p>[***]</p> <p>[***]</p>

ITEM	SUPPLIES OR SERVICES	Qty Purch Unit	Unit Price Total Item Amount
0003AK		1	[***]
		[***]	[***]
	<i>Noun:</i> [***] – COMMISSIONING OF [***] CERTIFIED AND BLDG. OCCUPANCY		
	<i>ACRN:</i> AA		
	<i>PR/MIPR:</i> F2BDBD1259A101		[***]
	<i>PSC:</i> 6640		
	<i>NSN:</i> N – Not Applicable		
	<i>Contract type:</i> J – FIRM FIXED PRICE		
	<i>Inspection:</i> DESTINATION		
	<i>Acceptance:</i> DESTINATION		
	<i>FOB:</i> DESTINATION		
	<i>Descriptive Data:</i>		
	1. The contractor shall provide a final progress report demonstrating project and Master Validation Plan completion. All reports/plans shall be submitted in accordance with Section J, Attachment 1 - Statement of Work (SOW) and OraSure's proposal and all subsequent updates. OraSure shall support Government verification of all CLINS/SubCLINS and production capabilities as outlined in this contract. Validation shall be completed by DCMA at the contractor's facility.		
	2. Report evidencing completion of new building construction and qualification. Report will evidence [***] completion of construction activities including the Certificate of occupancy or equivalent/ Validation completed by DCMA at the contractor's facility.		
	3. This is a Firm Fixed Price (FFP) CLIN.		
	4. Deliverable is due NLT [***].		
0004			
	<i>Noun:</i> INCREASE PRODUCTION CAPACITY		
	<i>NSN:</i> N – Not Applicable		

ITEM	SUPPLIES OR SERVICES	Qty Purch Unit	Unit Price Total Item Amount
0004AA	<i>Noun:</i> [***] TEST/MONTH <i>ACRN:</i> AA <i>PR/MIPR:</i> F2BDBD1259A101 <i>PSC:</i> 6640 <i>NSN:</i> N – Not Applicable <i>Contract type:</i> J – FIRM FIXED PRICE <i>Inspection:</i> DESTINATION <i>Acceptance:</i> DESTINATION <i>FOB:</i> DESTINATION	1 [***]	[***] [***]

Descriptive Data:

1. In order for this CLIN to be considered complete the contractor must verify production capacity to produce [***] test per month. All reports/plans shall be submitted in accordance with Section J, Attachment 1 - Statement of Work (SOW) and OraSure's proposal and all subsequent updates. OraSure shall support Government verification of all CLINS/SubCLINS and production capabilities as outlined in this contract. Validation shall be completed by DCMA at the contractor's facility.
2. Completion of approved equipment validation reports for the equipment required to produce a minimum of [***] tests per month.
3. This is a Firm Fixed Price (FFP) CLIN.
4. Deliverable is due NLT [***].

ITEM	SUPPLIES OR SERVICES	Qty Purch Unit	Unit Price Total Item Amount
0004AB	<i>Noun:</i> [***] TEST/MONTH <i>ACRN:</i> AA <i>PR/MIPR:</i> F2BDBD1259A101 <i>PSC:</i> 6640 <i>NSN:</i> N – Not Applicable <i>Contract type:</i> J – FIRM FIXED PRICE <i>Inspection:</i> DESTINATION <i>Acceptance:</i> DESTINATION <i>FOB:</i> DESTINATION	1 [***]	[***] [***] [***]

Descriptive Data:

1. In order for this CLIN to be considered complete the contractor must verify production capacity to produce [***] test per month. All reports/plans shall be submitted in accordance with Section J, Attachment 1 - Statement of Work (SOW) and OraSure's proposal and all subsequent updates. OraSure shall support Government verification of all CLINS/SubCLINS and production capabilities as outlined in this contract. Validation shall be completed by DCMA at the contractor's facility.
2. Completion of approved equipment validation reports for the equipment required to produce a minimum of [***] tests per month.
3. This is a Firm Fixed Price (FFP) CLIN.
4. Deliverable is due NLT [***].

ITEM	SUPPLIES OR SERVICES	Qty Purch Unit	Unit Price Total Item Amount
0004AC	<i>Noun:</i> [***] TESTS/MONTH <i>ACRN:</i> AA <i>PR/MIPR:</i> F2BDBD1259A101 <i>PSC:</i> 6640 <i>NSN:</i> N – Not Applicable <i>Contract type:</i> J – FIRM FIXED PRICE <i>Inspection:</i> DESTINATION <i>Acceptance:</i> DESTINATION <i>FOB:</i> DESTINATION	1 [***]	[***] [***]

Descriptive Data:

1. In order for this CLIN to be considered complete the contractor must verify production capacity to produce [***] test per month. All reports/plans shall be submitted in accordance with Section J, Attachment 1 - Statement of Work and OraSure's proposal and all subsequent updates. OraSure shall support Government verification of all CLINS/SubCLINS and production capabilities as outlined in this contract. Validation shall be completed by DCMA at the contractor's facility.
2. Completion of approved equipment validation reports for the equipment required to produce a minimum of [***] tests per month. DCMA will observe the manufacturing process and verify the final production numbers of [***] tests per month.
3. This is a Firm Fixed Price (FFP) CLIN.
4. Deliverable is due NLT [***]

ITEM	SUPPLIES SCHEDULE DATA	QTY	SHIP TO	MARK FOR	TRANS PRI	DATE
0001AA	<i>Noun:</i> <i>ACRN:</i>	1	U	EQUIPMENT ORDER GROUP 1 AA		[***]
0001AB	<i>Noun:</i> <i>ACRN:</i>	1	U	EQUIPMENT ORDER GROUP 2 AA		[***]
0001AC	<i>Noun:</i> <i>ACRN:</i>	1	U	EQUIPMENT ORDER GROUP 3 AA		[***]
0001AD	<i>Noun:</i> <i>ACRN:</i>	1	U	EQUIPMENT GROUP 1 – DESIGN REVIEW/MATERIAL ORDER AA		[***]
0001AE	<i>Noun:</i> <i>ACRN:</i>	1	U	EQUIPMENT GROUP 2 – DESIGN REVIEW/MATERIAL ORDER AA		[***]
0001AF	<i>Noun:</i> <i>ACRN:</i>	1	U	EQUIPMENT GROUP 3 – DESIGN REVIEW/MATERIAL ORDER AA		[***]
0001AG	<i>Noun:</i> <i>ACRN:</i>	1	U	EQUIPMENT GROUP 1 – [***] AA		[***]
0001AH	<i>Noun:</i> <i>ACRN:</i>	1	U	EQUIPMENT GROUP 2 – [***] AA		[***]
0001AJ	<i>Noun:</i> <i>ACRN:</i>	1	U	EQUIPMENT GROUP 3 – [***] AA		[***]
0001AK	<i>Noun:</i> <i>ACRN:</i>	1	U	EQUIPMENT GROUP 1 – [***] AA		[***]
0001AL	<i>Noun:</i> <i>ACRN:</i>	1	U	EQUIPMENT GROUP 2 – [***] AA		[***]
0001AM	<i>Noun:</i> <i>ACRN:</i>	1	U	EQUIPMENT GROUP 3 – [***] AA		[***]
0001AN	<i>Noun:</i> <i>ACRN:</i>	1	U	EQUIPMENT EXPANSION ENGINEERING/PROGRAM MANAGEMENT AA		ASREQ
0002AA	<i>Noun:</i> <i>ACRN:</i>	1	U	[***] EQUIPMENT ORDER AA		[***]
0002AB	<i>Noun:</i> <i>ACRN:</i>	1	U	FIRST ARTICLE INSPECTION & APPROVAL AA		[***]
0002AC	<i>Noun:</i> <i>ACRN:</i>	1	U	COMPLETION OF [***] LINE EXPANSION AA		[***]
0003AA	<i>Noun:</i> <i>ACRN:</i>	1	U	[***] – SIGNING OF CONTRACT/MASTER VALIDATION LIST AA		[***]

ITEM	SUPPLIES SCHEDULE DATA	QTY	SHIP TO	MARK FOR	TRANS PRI	DATE
0003AB	<i>Noun:</i> <i>ACRN:</i>	1	U	[**] – PROGRESS REPORT #1 ([**] COMPLETION)		[**]
0003AC	<i>Noun:</i> <i>ACRN:</i>	1	U	[**] – PROGRESS REPORT #2 ([**] COMPLETION)		[**]
0003AD	<i>Noun:</i> <i>ACRN:</i>	1	U	[**] – PROGRESS REPORT #3 ([**] COMPLETION)		[**]
0003AE	<i>Noun:</i> <i>ACRN:</i>	1	U	[**] – COMMISSIONING OF CLEAN ROOMS, (100% COMPLETION)		[**]
0003AF	<i>Noun:</i> <i>ACRN:</i>	1	U	[**]		[**]
0003AG	<i>Noun:</i> <i>ACRN:</i>	1	U	[**] – PROGRESS REPORT #1 ([**] COMPLETION)		[**]
0003AH	<i>Noun:</i> <i>ACRN:</i>	1	U	[**] – PROGRESS REPORT #2 ([**] COMPLETION)		[**]
0003AJ	<i>Noun:</i> <i>ACRN:</i>	1	U	[**] – PROGRESS REPORT #3 ([**] COMPLETION)		[**]
0003AK	<i>Noun:</i> <i>ACRN:</i>	1	U	[**] – COMMISSIONING OF [**] CERTIFIED AND BLDG. OCCUPANCY		[**]
0004AA	<i>Noun:</i> <i>ACRN:</i>	1	U	[**] TEST/MONTH		[**]
0004AB	<i>Noun:</i> <i>ACRN:</i>	1	U	[**] TEST/MONTH		[**]
0004AC	<i>Noun:</i> <i>ACRN:</i>	1	U	[**] TESTS/MONTH		31 Mar 2024

(a) Inspection/Acceptance. The Contractor shall only tender for acceptance those items that conform to the requirements of this contract. The Government reserves the right to inspect or test any supplies or services that have been tendered for acceptance. The Government may require repair or replacement of nonconforming supplies or reperformance of nonconforming services at no increase in contract price. If repair/replacement or reperformance will not correct the defects or is not possible, the Government may seek an equitable price reduction or adequate consideration for acceptance of nonconforming supplies or services. The Government must exercise its post-acceptance rights

(1) Within a reasonable time after the defect was discovered or should have been discovered; and

(2) Before any substantial change occurs in the condition of the item, unless the change is due to the defect in the item.

(b) Assignment. The Contractor or its assignee may assign its rights to receive payment due as a result of performance of this contract to a bank, trust company, or other financing institution, including any Federal lending agency in accordance with the Assignment of Claims Act (31 U.S.C.3727). However, when a third party makes payment (e.g., use of the Governmentwide commercial purchase card), the Contractor may not assign its rights to receive payment under this contract.

(c) Changes. Changes in the terms and conditions of this contract may be made only by written agreement of the parties.

(d) Disputes. This contract is subject to 41 U.S.C. chapter 71, Contract Disputes. Failure of the parties to this contract to reach agreement on any request for equitable adjustment, claim, appeal or action arising under or relating to this contract shall be a dispute to be resolved in accordance with the clause at FAR 52.233-1, Disputes, which is incorporated herein by reference. The Contractor shall proceed diligently with performance of this contract, pending final resolution of any dispute arising under the contract.

(e) Definitions. The clause at FAR 52.202-1, Definitions, is incorporated herein by reference.

(f) Excusable delays. The Contractor shall be liable for default unless nonperformance is caused by an occurrence beyond the reasonable control of the Contractor and without its fault or negligence such as, acts of God or the public enemy, acts of the Government in either its sovereign or contractual capacity, fires, floods, epidemics, quarantine restrictions, strikes, unusually severe weather, and delays of common carriers. The Contractor shall notify the Contracting Officer in writing as soon as it is reasonably possible after the commencement of any excusable delay, setting forth the full particulars in connection therewith, shall remedy such occurrence with all reasonable dispatch, and shall promptly give written notice to the Contracting Officer of the cessation of such occurrence.

(g) Invoice.

(1) The Contractor shall submit an original invoice and three copies (or electronic invoice, if authorized) to the address designated in the contract to receive invoices. An invoice must include –

(i) Name and address of the Contractor;

(ii) Invoice date and number;

(iii) Contract number, line item number and, if applicable, the order number;

(iv) Description, quantity, unit of measure, unit price and extended price of the items delivered;

(v) Shipping number and date of shipment, including the bill of lading number and weight of shipment if shipped on Government bill of lading;

(vi) Terms of any discount for prompt payment offered;

(vii) Name and address of official to whom payment is to be sent;

(viii) Name, title, and phone number of person to notify in event of defective invoice; and

(ix) Taxpayer Identification Number (TIN). The Contractor shall include its TIN on the invoice only if required elsewhere in this contract.

(x) Electronic funds transfer (EFT) banking information.

(A) The Contractor shall include EFT banking information on the invoice only if required elsewhere in this contract.

(B) If EFT banking information is not required to be on the invoice, in order for the invoice to be a proper invoice, the Contractor shall have submitted correct EFT banking information in accordance with the applicable solicitation provision, contract clause (e.g., 52.232-33, Payment by Electronic Funds Transfer-System for Award Management, or 52.232-34, Payment by Electronic Funds Transfer-Other Than System for Award Management), or applicable agency procedures.

(C) EFT banking information is not required if the Government waived the requirement to pay by EFT.

(2) Invoices will be handled in accordance with the Prompt Payment Act (31 U.S.C. 3903) and Office of Management and Budget (OMB) prompt payment regulations at 5 CFR part 1315.

(h) Patent indemnity. The Contractor shall indemnify the Government and its officers, employees and agents against liability, including costs, for actual or alleged direct or contributory infringement of, or inducement to infringe, any United States or foreign patent, trademark or copyright, arising out of the performance of this contract, provided the Contractor is reasonably notified of such claims and proceedings.

(i) Payment.

(1) Items accepted. Payment shall be made for items accepted by the Government that have been delivered to the delivery destinations set forth in this contract.

(2) Prompt payment. The Government will make payment in accordance with the Prompt Payment Act (31 U.S.C. 3903) and prompt payment regulations at 5 CFR part 1315

(3) Electronic Funds Transfer (EFT). If the Government makes payment by EFT, see 52.212-5(b) for the appropriate EFT clause.

(4) Discount. In connection with any discount offered for early payment, time shall be computed from the date of the invoice. For the purpose of computing the discount earned, payment shall be considered to have been made on the date which appears on the payment check or the specified payment date if an electronic funds transfer payment is made.

(5) Overpayments. If the Contractor becomes aware of a duplicate contract financing or invoice payment or that the Government has otherwise overpaid on a contract financing or invoice payment, the Contractor shall

(i) Remit the overpayment amount to the payment office cited in the contract along with a description of the overpayment including the

date(s) of overpayment);

(A) Circumstances of the overpayment (e.g., duplicate payment, erroneous payment, liquidation errors,

(B) Affected contract number and delivery order number, if applicable;

(C) Affected line item or subline item, if applicable; and

(D) Contractor point of contact.

(ii) Provide a copy of the remittance and supporting documentation to the Contracting Officer.

(6) Interest.

(i) All amounts that become payable by the Contractor to the Government under this contract shall bear simple interest from the date due until paid unless paid within 30 days of becoming due. The interest rate shall be the interest rate established by the Secretary of the Treasury as provided in 41 U.S.C. 7109, which is applicable to the period in which the amount becomes due, as provided in (i)(6)(v) of this clause, and then at the rate applicable for each six-month period at fixed by the Secretary until the amount is paid.

(ii) The Government may issue a demand for payment to the Contractor upon finding a debt is due under the contract.

(iii) Final decisions. The Contracting Officer will issue a final decision as required by 33.211 if

(A) The Contracting Officer and the Contractor are unable to reach agreement on the existence or amount of a debt within 30 days;

(B) The Contractor fails to liquidate a debt previously demanded by the Contracting Officer within the timeline specified in the demand for payment unless the amounts were not repaid because the Contractor has requested an installment payment agreement; or

(C) The Contractor requests a deferment of collection on a debt previously demanded by the Contracting Officer (see 32.607-2).

(iv) If a demand for payment was previously issued for the debt, the demand for payment included in the final decision shall identify the same due date as the original demand for payment.

(v) Amounts shall be due at the earliest of the following dates:

(A) The date fixed under this contract.

(B) The date of the first written demand for payment, including any demand for payment resulting from a default termination.

(vi) The interest charge shall be computed for the actual number of calendar days involved beginning on the due date and ending on

(A) The date on which the designated office receives payment from the Contractor;

(B) The date of issuance of a Government check to the Contractor from which an amount otherwise payable has been withheld as a credit against the contract debt; or

(C) The date on which an amount withheld and applied to the contract debt would otherwise have become payable to the Contractor.

(vii) The interest charge made under this clause may be reduced under the procedures prescribed in 32.608-2 of the Federal Acquisition Regulation in effect on the date of this contract.

(j) Risk of loss. Unless the contract specifically provides otherwise, risk of loss or damage to the supplies provided under this contract shall remain with the Contractor until, and shall pass to the Government upon:

(1) Delivery of the supplies to a carrier, if transportation is f.o.b. origin; or

(2) Delivery of the supplies to the Government at the destination specified in the contract, if transportation is f.o.b. destination.

(k) Taxes. The contract price includes all applicable Federal, State, and local taxes and duties.

(l) Termination for the Government's convenience. The Government reserves the right to terminate this contract, or any part hereof, for its sole convenience. In the event of such termination, the Contractor shall immediately stop all work hereunder and shall immediately cause any and all of its suppliers and subcontractors to cease work. Subject to the terms of this contract, the Contractor shall be paid a percentage of the contract price reflecting the percentage of the work performed prior to the notice of termination, plus reasonable charges the Contractor can demonstrate to the satisfaction of the Government using its standard record keeping system, have resulted from the termination. The Contractor shall not be required to comply with the cost accounting standards or contract cost principles for this purpose. This paragraph does not give the Government any right to audit the Contractor's records. The Contractor shall not be paid for any work performed or costs incurred which reasonably could have been avoided.

(m) Termination for cause. The Government may terminate this contract, or any part hereof, for cause in the event of any default by the Contractor, or if the Contractor fails to comply with any contract terms and conditions, or fails to provide the Government, upon request, with adequate assurances of future performance. In the event of termination for cause, the Government shall not be liable to the Contractor for any amount for supplies or services not accepted, and the Contractor shall be liable to the Government for any and all rights and remedies provided by law. If it is determined that the Government improperly terminated this contract for default, such termination shall be deemed a termination for convenience.

(n) Title. Unless specified elsewhere in this contract, title to items furnished under this contract shall pass to the Government upon acceptance, regardless of when or where the Government takes physical possession.

(o) Warranty. The Contractor warrants and implies that the items delivered hereunder are merchantable and fit for use for the particular purpose described in this contract.

(p) Limitation of liability. Except as otherwise provided by an express warranty, the Contractor will not be liable to the Government for consequential damages resulting from any defect or deficiencies in accepted items.

(q) Other compliances. The Contractor shall comply with all applicable Federal, State and local laws, executive orders, rules and regulations applicable to its performance under this contract.

(r) Compliance with laws unique to Government contracts. The Contractor agrees to comply with 31 U.S.C. 1352 relating to limitations on the use of appropriated funds to influence certain Federal contracts; 18 U.S.C. 431 relating to officials not to benefit; 40 U.S.C. chapter 37, Contract Work Hours and Safety Standards; 41 U.S.C. chapter 87, Kickbacks; 41 U.S.C. 4712 and 10 U.S.C. 2409 relating to whistleblower protections; 49 U.S.C. 40118, Fly American; and 41 U.S.C. chapter 21 relating to procurement integrity.

(s) Order of precedence. Any inconsistencies in this solicitation or contract shall be resolved by giving precedence in the following order:

(1) The schedule of supplies/services.

(2) The Assignments, Disputes, Payments, Invoice, Other Compliances, Compliance with Laws Unique to Government Contracts, and Unauthorized Obligations paragraphs of this clause.

(3) The clause at 52.212-5.

(4) Addenda to this solicitation or contract, including any license agreements for computer software.

- (5) Solicitation provisions if this is a solicitation.
- (6) Other paragraphs of this clause.
- (7) The Standard Form 1449.
- (8) Other documents, exhibits, and attachments.
- (9) The specification.

(t) [Reserved]

(u) Unauthorized Obligations.

(1) Except as stated in paragraph (u)(2) of this clause, when any supply or service acquired under this contract is subject to any End Use License Agreement (EULA), Terms of Service (TOS), or similar legal instrument or agreement, that includes any clause requiring the Government to indemnify the Contractor or any person or entity for damages, costs, fees, or any other loss or liability that would create an Anti-Deficiency Act violation (31 U.S.C. 1341), the following shall govern:

(i) Any such clause is unenforceable against the Government.

(ii) Neither the Government nor any Government authorized end user shall be deemed to have agreed to such clause by virtue of it appearing in the EULA, TOS, or similar legal instrument or agreement. If the EULA, TOS, or similar legal instrument or agreement -is invoked through an "I agree" click box or other comparable mechanism (e.g., "click-wrap" or "browse-wrap" agreements), execution does not bind the Government or any Government authorized end user to such clause.

(iii) Any such clause is deemed to be stricken from the EULA, TOS, or similar legal instrument or agreement.

(2) Paragraph (u)(1) of this clause does not apply to indemnification by the Government that is expressly authorized by statute and specifically authorized under applicable agency regulations and procedures.

(v) Incorporation by reference. The Contractor's representations and certification, including those completed electronically via the System for Award Management (SAM), are incorporated by reference into the contract.

2. FAR 52.212-05 CONTRACT TERMS AND CONDITIONS REQUIRED TO IMPLEMENT STATUTES OR EXECUTIVE ORDERS-- COMMERCIAL ITEMS (Jan 2021)

(a) The Contractor shall comply with the following Federal Acquisition Regulation (FAR) clauses, which are incorporated in this contract by reference, to implement provisions of law or Executive orders applicable to acquisitions of commercial items:

(1) 52.203-19, Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements (Jan 2017) (section 743 of Division E, Title VII, of the Consolidated and Further Continuing Appropriations Act 2015 (Pub. L. 113-235) and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions)).

(2) 52.204-23, Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities (Jul 2018) (Section 1634 of Pub. L. 115-91).

(3) 52.204-25, Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment. (Aug 2020) (Section 889(a)(1)(A) of Pub. L. 115-232).

(4) 52.209-10, Prohibition on Contracting with Inverted Domestic Corporations (Nov 2015)

(5) 52.233-3, Protest After Award (AUG 1996) (31 U.S.C 3553).

(6) 52.233-4, Applicable Law for Breach of Contract Claim (OCT 2004) (Public Laws 108-77 and 108-78 (19 U.S.C. 3805 note)).

(b) The Contractor shall comply with the FAR clauses in this paragraph (b) that the contracting officer has indicated as being incorporated in this contract by reference to implement provisions of law or Executive orders applicable to acquisitions of commercial items:

**3. FAR 52.212-05 CONTRACT TERMS AND CONDITIONS REQUIRED TO IMPLEMENT STATUTES OR EXECUTIVE ORDERS--
COMMERCIAL ITEMS (Aug 2020) , Alternate I , (Feb 2000)**

(a) The Contractor shall comply with the following Federal Acquisition Regulation (FAR) clauses, which are incorporated in this contract by reference, to implement provisions of law or Executive orders applicable to acquisitions of commercial items:

(1) 52.203-19, Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements (Jan 2017) (section 743 of Division E, Title VII, of the Consolidated and Further Continuing Appropriations Act 2015 (Pub. L. 113-235) and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions)).

(2) 52.204-23, Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities (Jul 2018) (Section 1634 of Pub. L. 115-91).

(3) Surveillance Services or Equipment. (Aug 2020) (Section 889(a)(1)(A) of Pub. L. 115-232).

(4) 52.209-10, Prohibition on Contracting with Inverted Domestic Corporations (Nov 2015)

(5) 52.233-3, Protest After Award (AUG 1996) (31 U.S.C 3553).

(6) 52.233-4, Applicable Law for Breach of Contract Claim (OCT 2004) (Public Laws 108-77 and 108-78 (19 U.S.C. 3805 note)).

(b) The Contractor shall comply with the FAR clauses in this paragraph (b) that the contracting officer has indicated as being incorporated in this contract by reference to implement provisions of law or Executive orders applicable to acquisitions of commercial items:

(1) 52.203-06, Restrictions on Subcontractor Sales to the Government (Jun 2020), with Alternate I (Oct 1995) (41 U.S.C. 4704 and 10 U.S.C. 2402).

(2) 52.203-13, Contractor Code of Business Ethics and Conduct (Jun 2020) (41 U.S.C. 3509).

(4) 52.204-10, Reporting Executive Compensation and First-Tier Subcontract Awards (Jun 2020) (Pub. L. 109-282) (31 U.S.C. 6101 note).

(8) 52.209-06, Protecting The Government's Interest When Subcontracting With Contractors Debarred, Suspended, or Proposed For Debarment (Jun 2020) (31 U.S.C. 6101 note).

(12) (i) 52.219-04, Notice of Price Evaluation Preference for HUBZone Small Business Concerns (Mar 2020) (if the offeror elects to waive the preference, it shall so indicate in its offer.) (15 U.S.C. 657a).

(12) (ii) 52.219-04, Notice of Price Evaluation Preference for HUBZone Small Business Concerns (Mar 2020) (if the offeror elects to waive the preference, it shall so indicate in its offer.) (15 U.S.C. 657a). Alternate I (Mar 2020)

(17) (i) 52.219-09, Small Business Subcontracting Plan (Jun 2020) (15 U.S.C. 637 (d)(4)).

(17) (ii) 52.219-09, Small Business Subcontracting Plan (Mar 2020). Alternate I (Nov 2016)

(17) (iv) 52.219-09, Small Business Subcontracting Plan (Jun 2020). Alternate III (Jun 2020)

- (17) (v) 52.219-09, Small Business Subcontracting Plan (Jun 2020). Alternate IV (Jun 2020)
- (20) 52.219-16, Liquidated Damages--Subcontracting Plan (Jan 1999)(15 U.S.C. 637(d)(4)(F)(i)).
- (22) (i) 52.219-28, Post Award Small Business Program Rerepresentation (Nov 2020) (15 U.S.C. 632(a)(2)).
- (27) 52.222-03, Convict Labor (June 2003) (E.O. 11755).
- (28) 52.222-19, Child Labor Cooperation with Authorities and Remedies (Jan 2020) (E.O. 13126).
- (29) 52.222-21, Prohibition of Segregated Facilities (Apr 2015).
- (30) (i) 52.222-26, Equal Opportunity (Sept 2016) (E.O. 11246).
- (30) (ii) 52.222-26, Equal Opportunity - Alternate I (Feb 1999)
- (31) (i) 52.222-35, Equal Opportunity for Veterans (Jun 2020) (38 U.S.C.4212).
- (31) (ii) 52.222-35, Equal Opportunity for Veterans - Alternate I (July 2014).
- (32) (i) 52.222-36, Equal Opportunity for Workers with Disabilities (Jun 2020) (29 U.S.C. 793).
- (32) (ii) 52.222-36, Equal Opportunity for Workers with Disabilities – Alternate I (Jul 2014).
- (33) 52.222-37, Employment Reports on Veterans (Jun 2020) (38 U.S.C. 4212).
- (34) 52.222-40, Notification of Employee Rights Under the National Labor Relations Act (Dec 2010) (E.O. 13496).
- (44) 52.223-18, Encouraging Contractor Policies To Ban Text Messaging While Driving (Jun 2020) (E.O.13513).
- (50) 52.225-05, Trade Agreements (Oct 2019) (19 U.S.C. 2501, et seq., 19 U.S.C. 3301 note).
- (51) 52.225-13, Restrictions on Certain Foreign Purchases (June 2008) (E.O.'s, proclamations, and statutes administered by the Office of Foreign Assets Control of the Department of the Treasury).
- (58) 52.232-33, Payment by Electronic Funds Transfer-System for Award Management (Oct 2018) (31 U.S.C. 3332).
- (60) 52.232-36, Payment by Third Party (May 2014) (31 U.S.C. 3332).

(c) The Contractor shall comply with the FAR clauses in this paragraph (c), applicable to commercial services, that the Contracting Officer has indicated as being incorporated in this contract by reference to implement provisions of law or executive orders applicable to acquisitions of commercial items:

- (7) 52.222-55, Minimum Wages Under Executive Order 13658 (Nov 2020) (E.O. 13658).
- (8) 52.222-62, Paid Sick Leave Under Executive Order 13706 (Jan 2017) (E.O. 13706)
- (9) 52.226-06, Promoting Excess Food Donation to Nonprofit Organizations (Jun 2020) (42 U.S.C. 1792).

(d) Comptroller General Examination of Record. The Contractor shall comply with the provisions of this paragraph (d) if this contract was awarded using other than sealed bid, is in excess of the simplified acquisition threshold, as defined in FAR 2.101, on the date of award of this contract, and does not contain the clause at 52.215-2, Audit and Records-Negotiation.

(1) The Comptroller General of the United States, or an authorized representative of the Comptroller General, shall have access to and right to examine any of the Contractor's directly pertinent records involving transactions related to this contract.

(2) The Contractor shall make available at its offices at all reasonable times the records, materials, and other evidence for examination, audit, or reproduction, until 3 years after final payment under this contract or for any shorter period specified in FAR Subpart 4.7, Contractor Records Retention, of the other clauses of this contract. If this contract is completely or partially terminated, the records relating to the work terminated shall be made available for 3 years after any resulting final termination settlement. Records relating to appeals under the disputes clause or to litigation or the settlement of claims arising under or relating to this contract shall be made available until such appeals, litigation, or claims are finally resolved.

(3) As used in this clause, records include books, documents, accounting procedures and practices, and other data, regardless of type and regardless of form. This does not require the Contractor to create or maintain any record that the Contractor does not maintain in the ordinary course of business or pursuant to a provision of law.

(e)

(1) Notwithstanding the requirements of the clauses in paragraphs (a), (b), (c) and (d) of this clause, the Contractor is not required to flow down any FAR clause, other than those in this paragraph (e)(1) in a subcontract for commercial items. Unless otherwise indicated below, the extent of the flow down shall be as required by the clause

(i) 52.203-13, Contractor Code of Business Ethics and Conduct (Jun 2020) (41 U.S.C. 3509).

(ii) 52.203-19, Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements (Jan 2017) (section 743 of Division E, Title VII, of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113-235) and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions)).

(iii) 52.204-23, Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities (Jul 2018) (Section 1634 of Pub. L. 115-91).

(iv) 52.204-25, Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment. (Aug 2020) (Section 889(a)(1)(A) of Pub. L. 115-232).

(v) 52.219-8, Utilization of Small Business Concerns (Oct 2018) (15 U.S.C. 637(d)(2) and (3)), in all subcontracts that offer further subcontracting opportunities. If the subcontract (except subcontracts to small business concerns) exceeds the applicable threshold specified in FAR 19.702(a) on the date of subcontract award, the subcontractor must include 52.219-8 in lower tier subcontracts that offer subcontracting opportunities.

(vi) 52.222-21, Prohibition of Segregated Facilities (Apr 2015).

(vii) 52.222-26, Equal Opportunity (Sep 2015) (E.O.11246).

(viii) 52.222-35, Equal Opportunity for Veterans (Jun 2020) (38 U.S.C. 4212).

(ix) 52.222-36, Equal Opportunity for Workers with Disabilities (Jun 2020) (29 U.S.C. 793).

(x) 52.222-37, Employment Reports on Veterans (Jun 2020) (38 U.S.C. 4212).

(xi) 52.222-40, Notification of Employee Rights Under the National Labor Relations Act (Dec 2010) (E.O. 13496). Flow down required in accordance with paragraph (f) of FAR clause 52.222-40.

(xii) 52.222-41, Service Contract Labor Standards (AUG 2018) (41 U.S.C. chapter 67).

(xiii) ____ (A) 52.222-50, Combating Trafficking in Persons (Oct 2020) (22 U.S.C. Chapter 78 and E.O. 13627).

____ (B) Alternate I (Mar 2015) of 52.222-50 (22 U.S.C. Chapter 78 and E.O. 13627).

(xiv) 52.222-51, Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment-Requirements (May 2014) (41 U.S.C. chapter 67.)

(xv) 52.222-53, Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services--Requirements (May 2014) (41 U.S.C. chapter 67)

(xvi) 52.222-54, Employment Eligibility Verification (Oct 2015).

(xvii) 52.222-55, Minimum Wages Under Executive Order 13658 (Nov 2020) (E.O. 13658).

(xviii) 52.222-62, Paid Sick Leave Under Executive Order 13706 (Jan 2017) (E.O. 13706).

(xix) ____ (A) 52.224-3, Privacy Act Training (Jan 2017) (5 U.S.C. 552a).

____ (B) Alternate I (Jan 2017) of 52.224-3.

(xx) 52.225-26, Contractors Performing Private Security Functions Outside the United States (Oct 2016) (Section 862, as amended, of the National Defense Authorization Act for Fiscal Year 2008; 10 U.S.C. 2302 Note).

(xxi) 52.226-6, Promoting Excess Food Donation to Nonprofit Organizations (Jun 2020) (42 U.S.C. 1792). Flow down required in accordance with paragraph (e) of FAR clause 52.226-6.

(xxii) 52.247-64, Preference for Privately-Owned U.S. Flag Commercial Vessels (Feb 2006) (46 U.S.C. Appx 1241(b) and 10 U.S.C. 2631). Flow down required in accordance with paragraph (d) of FAR clause 52.247-64.

(2) While not required, the Contractor may include in its subcontracts for commercial items a minimal number of additional clauses necessary to satisfy its contractual obligations.

4. FAR 52.232-40 PROVIDING ACCELERATED PAYMENTS TO SMALL BUSINESS SUBCONTRACTORS (Dec 2013)

(a) Upon receipt of accelerated payments from the Government, the Contractor shall make accelerated payments to its small business subcontractors under this contract, to the maximum extent practicable and prior to when such payment is otherwise required under the applicable contract or subcontract, after receipt of a proper invoice and all other required documentation from the small business subcontractor.

(b) The acceleration of payments under this clause does not provide any new rights under the Prompt Payment Act.

(c) Include the substance of this clause, including this paragraph (c), in all subcontracts with small business concerns, including subcontracts with small business concerns for the acquisition of commercial items.

5. DFARS 252.203-7000 REQUIREMENTS RELATING TO COMPENSATION OF FORMER DOD OFFICIALS (Sep 2011)

(a) Definition. "Covered DoD official," as used in this clause, means an individual that

(1) Leaves or left DoD service on or after January 28, 2008; and

(2)(i) Participated personally and substantially in an acquisition as defined in 41 U.S.C. 131 with a value in excess of \$10 million, and serves or served

(A) In an Executive Schedule position under subchapter II of chapter 53 of Title 5, United States Code;

(B) In a position in the Senior Executive Service under subchapter VIII of chapter 53 of Title 5, United States Code; or

(C) In a general or flag officer position compensated at a rate of pay for grade O-7 or above under section 201 of Title 37, United States Code; or

(ii) Serves or served in DoD in one of the following positions: program manager, deputy program manager, procuring contracting officer, administrative contracting officer, source selection authority, member of the source selection evaluation board, or chief of a financial or technical evaluation team for a contract in an amount in excess of \$10 million.

(b) The Contractor shall not knowingly provide compensation to a covered DoD official within 2 years after the official leaves DoD service, without first determining that the official has sought and received, or has not received after 30 days of seeking, a written opinion from the appropriate DoD ethics counselor regarding the applicability of post-employment restrictions to the activities that the official is expected to undertake on behalf of the Contractor.

(c) Failure by the Contractor to comply with paragraph (b) of this clause may subject the Contractor to rescission of this contract, suspension, or debarment in accordance with 41 U.S.C. 2105(c).

6. DFARS 252.203-7003 AGENCY OFFICE OF THE INSPECTOR GENERAL (Aug 2019)

The agency office of the Inspector General referenced in paragraphs (c) and (d) of FAR clause 52.203-13, Contractor Code of Business Ethics and Conduct, is the DoD Office of Inspector General at the following address:

Department of Defense Office of Inspector General
Administrative Investigations
Contractor Disclosure Program
4800 Mark Center Drive, Suite 14L25
Alexandria, VA 22350-1500

Toll Free Telephone: 866-429-8011

Website: <https://www.dodig.mil/Programs/Contractor-Disclosure-Program/>.

7. DFARS 252.204-7012 SAFEGUARDING COVERED DEFENSE INFORMATION AND CYBER INCIDENT REPORTING (Dec 2019)

(a) Definitions, As used in this clause

"Adequate security" means protective measures that are commensurate with the consequences and probability of loss, misuse, or unauthorized access to, or modification of information.

"Compromise" means disclosure of information to unauthorized persons, or a violation of the security policy of a system, in which unauthorized intentional or unintentional disclosure, modification, destruction, or loss of an object, or the copying of information to unauthorized media may have occurred.

"Contractor attributional/proprietary information" means information that identifies the contractor(s), whether directly or indirectly, by the grouping of information that can be traced back to the contractor(s) (e.g., program description, facility locations), personally identifiable information, as well as trade secrets, commercial or financial information, or other commercially sensitive information that is not customarily shared outside of the company.

"Contractor information system" means an unclassified information system that is owned or operated by or for, a contractor and that processes, stores, or transmits covered defense information.

"Controlled technical information" means technical information with military or space application that is subject to controls on the access, use, reproduction, modification, performance, display, release, disclosure, or dissemination. Controlled technical information would meet the criteria, if disseminated, for distribution statements B through F using the criteria set forth in DoD Instruction 5230.24, Distribution Statements on Technical Documents. The term does not include information that is lawfully publicly available without restrictions.

"Covered contractor information system" means an information system that is owned, or operated by or for, a contractor and that processes, stores, or transmits covered defense information.

"Covered defense information" means unclassified controlled technical information or other information, as described in the Controlled Unclassified Information (CUI) Registry at <http://www.archives.gov/cui/registry/category-list.html>, that requires safeguarding or dissemination controls pursuant to and consistent with law, regulations, and Governmentwide policies, and is

(1) Marked or otherwise identified in the contract, task order, or delivery order and provided to the contractor by or on behalf of DoD in support of the performance of the contract; or

(2) Collected, developed, received, transmitted, used, or stored by or on behalf of the contractor in support of the performance of the contract.

"Cyber incident" means actions taken through the use of computer networks that result in a compromise or an actual or potentially adverse effect on an information system and/or the information residing therein.

"Forensic analysis" means the practice of gathering, retaining, and analyzing computer-related data for investigative purposes in a manner that maintains the integrity of the data

"Information system" means a discrete set of information resources organized for the collection, processing, maintenance, use, sharing, dissemination, or disposition of information.

"Malicious software" means computer software or firmware intended to perform an unauthorized process that will have adverse impact on the confidentiality, integrity, or availability of an information system. This definition includes a virus, worm, Trojan horse, or other code-based entity that infects a host, as well as spyware and some forms of adware.

"Media" means physical devices or writing surfaces including, but is not limited to, magnetic tapes, optical disks, magnetic disks, large-scale integration memory chips, and printouts onto which covered defense information is recorded, stored, or printed within a covered contractor information system.

"Operationally critical support" means supplies or services designated by the Government as critical for airlift, sealift, intermodal transportation services, or logistical support that is essential to the mobilization, deployment, or sustainment of the Armed Forces in a contingency operation.

"Rapidly report" means within 72 hours of discovery of any cyber incident.

"Technical information" means technical data or computer software, as those terms are defined in the clause at DFARS 252.227-7013, Rights in Technical Data-Noncommercial Items, regardless of whether or not the clause is incorporated in this solicitation or contract. Examples of technical information include research and engineering data, engineering drawings, and associated lists, specifications, standards, process sheets, manuals, technical reports, technical orders, catalog-item identifications, data sets, studies and analyses and related information, and computer software executable code and source code.

(b) Adequate security. The Contractor shall provide adequate security on all covered contractor information systems. To provide adequate security, the Contractor shall implement, at a minimum, the following information security protections:

(1) For covered contractor information systems that are part of an Information Technology (IT) service or system operated on behalf of the Government, the following security requirements apply:

(i) Cloud computing services shall be subject to the security requirements specified in the clause 252.239-7010, Cloud Computing Services, of this contract.

(ii) Any other such IT service or system (i.e., other than cloud computing) shall be subject to the security requirements specified elsewhere in this contract.

(2) For covered contractor information systems that are not part of an IT service or system operated on behalf of the Government and therefore are not subject to the security requirement specified at paragraph (b)(1) of this clause, the following security requirements apply:

(i) Except as provided in paragraph (b)(2)(ii) of this clause, the covered contractor information system shall be subject to the security requirements in National Institute of Standards and Technology (NIST) Special Publication (SP) 800-171, "Protecting Controlled Unclassified Information in Nonfederal Information Systems and Organizations," (available via the Internet at <http://dx.doi.org/10.6028/NIST.SP.800-171>) in effect at the time the solicitation is issued or as authorized by the Contracting Officer.

(ii)(A) The Contractor shall implement NIST SP 800-171, as soon as practical, but not later than December 31, 2017. For all contracts awarded prior to October 1, 2017, the Contractor shall notify the DoD Chief Information Officer (CIO), via email at osd.dibcsia@mail.mil, within 30 days of contract award, of any security requirements specified by NIST SP 800-171 not implemented at the time of contract award.

(B) The Contractor shall submit requests to vary from NIST SP 800-171 in writing to the Contracting Officer, for consideration by the DoD CIO. The Contractor need not implement any security requirement adjudicated by an authorized representative of the DoD CIO to be nonapplicable or to have an alternative, but equally effective, security measure that may be implemented in its place.

(C) If the DoD CIO has previously adjudicated the contractor's requests indicating that a requirement is not applicable or that an alternative security measure is equally effective, a copy of that approval shall be provided to the Contracting Officer when requesting its recognition under this contract.

(D) If the Contractor intends to use an external cloud service provider to store, process, or transmit any covered defense information in performance of this contract, the Contractor shall require and ensure that the cloud service provider meets security requirements equivalent to those established by the Government for the Federal Risk and Authorization Management Program (FedRAMP) Moderate baseline (<https://www.fedramp.gov/resources/documents/>) and that the cloud service provider complies with requirements in paragraphs (c) through (g) of this clause for cyber incident reporting, malicious software, media preservation and protection, access to additional information and equipment necessary for forensic analysis, and cyber incident damage assessment.

(3) Apply other information systems security measures when the Contractor reasonably determines that information systems security measures, in addition to those identified in paragraphs (b)(1) and (2) of this clause, may be required to provide adequate security in a dynamic environment or to accommodate special circumstances (e.g., medical devices) and any individual, isolated, or temporary deficiencies based on an assessed risk or vulnerability. These measures may be addressed in a system security plan.

(c) Cyber incident reporting requirement.

(1) When the Contractor discovers a cyber incident that affects a covered contractor information system or the covered defense information residing therein, or that affects the contractor's ability to the requirements of the contract that are designated as operationally critical support and identified in the contract, the Contractor shall

(i) Conduct a review for evidence of compromise of covered defense information, including, but not limited to, identifying compromised computers, servers, specific data, and user accounts. This review shall also include analyzing covered contractor information system(s) that were part of the cyber incident, as well as other information systems on the Contractor's network(s), that may have been accessed as a result of the incident in order to identify compromised covered defense information, or that affect the Contractor's ability to provide operationally critical support; and

(ii) Rapidly report cyber incidents to DoD at <https://dibnet.dod.mil>.

(2) Cyber incident report. The cyber incident report shall be treated as information created by or for DoD and shall include, at a minimum, the required elements at <https://dibnet.dod.mil>.

(3) Medium assurance certificate requirement. In order to report cyber incidents in accordance with this clause, the Contractor or subcontractor shall have or acquire a DoD-approved medium assurance certificate to report cyber incidents. For information on obtaining a DoD-approved medium assurance certificate, see <https://public.cyber.mil/eca/>.

(d) Malicious software. When the Contractor or subcontractors discover and isolate malicious software in connection with a reported cyber incident, submit the malicious software to DoD Cyber Crime Center (DC3) in accordance with instructions provided by DC3 or the Contracting Officer. Do not send the malicious software to the Contracting Officer.

(e) Media preservation and protection. When a Contractor discovers a cyber incident has occurred, the Contractor shall preserve and protect images of all known affected information systems identified in paragraph (c)(1)(i) of this clause and all relevant monitoring/packet capture data for at least 90 days from the submission of the cyber incident report to allow DoD to request the media or decline interest.

(f) Access to additional information or equipment necessary for forensic analysis. Upon request by DoD, the Contractor shall provide DoD with access to additional information or equipment that is necessary to conduct a forensic analysis.

(g) Cyber incident damage assessment activities. If DoD elects to conduct a damage assessment, the Contracting Officer will request that the Contractor provide all of the damage assessment information gathered in accordance with paragraph (e) of this clause.

(h) DoD safeguarding and use of contractor attributional/proprietary information. The Government shall protect against the unauthorized use or release of information obtained from the contractor (or derived from information obtained from the contractor) under this clause that includes contractor attributional/proprietary information, including such information submitted in accordance with paragraph (c). To the maximum extent practicable, the Contractor shall identify and mark attributional/proprietary information. In making an authorized release of such information, the Government will implement appropriate procedures to minimize the contractor attributional/proprietary information that is included in such authorized release, seeking to include only that information that is necessary for the authorized purpose(s) for which the information is being released.

(i) Use and release of contractor attributional/proprietary information not created by or for DoD. Information that is obtained from the contractor (or derived from information obtained from the contractor) under this clause that is not created by or for DoD is authorized to be released outside of DoD

(1) To entities with missions that may be affected by such information;

(2) To entities that may be called upon to assist in the diagnosis, detection, or mitigation of cyber incidents;

(3) To Government entities that conduct counterintelligence or law enforcement investigations;

(4) For national security purposes, including cyber situational awareness and defense purposes (including with Defense Industrial Base (DIB) participants in the program at 32 CFR part 236); or

(5) Government activities under a contract that includes the clause at 252.204-7009, Limitations on the Use or Disclosure of Third-Party Contractor Reported Cyber Incident Information.

(j) Use and release of contractor attributional/proprietary information created by or for DoD. Information that is obtained from the contractor (or derived from information obtained from the contractor) under this clause that is created by or for DoD (including the information submitted pursuant to paragraph (c) of this clause) is authorized to be used and released outside of DoD for purposes and activities authorized by paragraph (i) of this clause, and for any other lawful Government purpose or activity, subject to all applicable statutory, regulatory, and policy based restrictions on the Government's use and release of such information.

(k) The Contractor shall conduct activities under this clause in accordance with applicable laws and regulations on the interception, monitoring, access, use, and disclosure of electronic communications and data.

(l) Other safeguarding or reporting requirements. The safeguarding and cyber incident reporting required by this clause in no way abrogates the Contractor's responsibility for other safeguarding or cyber incident reporting pertaining to its unclassified information systems as required by other applicable clauses of this contract, or as a result of other applicable U.S. Government statutory or regulatory requirements.

(m) Subcontracts. The Contractor shall

(1) Include this clause, including this paragraph (m), in subcontracts, or similar contractual instruments, for operationally critical support, or for which subcontract performance will involve covered defense information, including subcontracts for commercial items, without alteration, except to identify the parties. The Contractor shall determine if the information required for subcontractor performance retains its identity as covered defense information and will require protection under this clause, and, if necessary, consult with the Contracting Officer; and

(2) Require subcontractors to

(i) Notify the prime Contractor (or next higher-tier subcontractor) when submitting a request to vary from a NIST SP 800-171 security requirement to the Contracting Officer, in accordance with paragraph (b)(2)(ii)(B) of this clause; and

(ii) Provide the incident report number, automatically assigned by DoD, to the prime Contractor (or next higher-tier subcontractor) as soon as practicable, when reporting a cyber incident to DoD as required in paragraph (c) of this clause.

8. DFARS 252.204-7015 NOTICE OF AUTHORIZED DISCLOSURE OF INFORMATION TO LITIGATION SUPPORT (May 2016)

a) Definitions. As used in this clause

"Computer software" means computer programs, source code, source code listings, object code listings, design details, algorithms, processes, flow charts, formulae, and related material that would enable the software to be reproduced, recreated, or recompiled. Computer software does not include computer data bases or computer software documentation.

"Litigation support" means administrative, technical, or professional services provided in support of the Government during or in anticipation of litigation.

"Litigation support contractor" means a contractor (including its experts, technical consultants, subcontractors, and suppliers) providing litigation support under a contract that contains the clause at 252.204-7014, Limitations on the Use or Disclosure of Information by Litigation Support

"Sensitive information" means controlled unclassified information of a commercial, financial, proprietary, or privileged nature. The term includes technical data and computer software, but does not include information that is lawfully, publicly available without restriction.

"Technical data" means recorded information, regardless of the form or method of the recording, of a scientific or technical nature (including computer software documentation). The term does not include computer software or data incidental to contract administration, such as financial and/or management information

(b) Notice of authorized disclosures. Notwithstanding any other provision of this solicitation or contract, the Government may disclose to a litigation support contractor, for the sole purpose of litigation support activities, any information, including sensitive information, received

(1) Within or in connection with a quotation or offer; or

(2) In the performance of or in connection with a contract.

(c) Flowdown. Include the substance of this clause, including this paragraph (c), in all subcontracts, including subcontracts for commercial items.

9. DFARS 252.204-7018 PROHIBITION ON THE ACQUISITION OF COVERED DEFENSE TELECOMMUNICATIONS EQUIPMENT OR SERVICES (Jan 2021)

(a) Definitions. As used in this clause

"Covered defense telecommunications equipment or services" means-

(1) Telecommunications equipment produced by Huawei Technologies Company or ZTE Corporation, or any subsidiary or affiliate of such entities;

(2) Telecommunications services provided by such entities or using such equipment; or

(3) Telecommunications equipment or services produced or provided by an entity that the Secretary of Defense reasonably believes to be an entity owned or controlled by, or

"Covered foreign country" means-

(1) The People's Republic of China; or

(2) The Russian Federation.

"Covered missions" means-

(1) The nuclear deterrence mission of DoD, including with respect to nuclear command, control, and communications, integrated tactical warning and attack assessment, and continuity of Government; or

(2) The homeland defense mission of DoD, including with respect to ballistic missile defense. otherwise connected to, the government of a covered foreign country.

"Critical technology" means

(1) Defense articles or defense services included on the United States Munitions List set forth in the International Traffic in Arms Regulations under subchapter M of chapter I of title 22, Code of Federal Regulations;

(2) Items included on the Commerce Control List set forth in Supplement No. 1 to part 774 of the Export Administration Regulations under subchapter C of chapter VII of title 15, Code of Federal Regulations, and controlled-

(i) Pursuant to multilateral regimes, including for reasons relating to national security, chemical and biological weapons proliferation, nuclear nonproliferation, or missile technology; or

(ii) For reasons relating to regional stability or surreptitious listening;

(3) Specially designed and prepared nuclear equipment, parts and components, materials, software, and technology covered by part 810 of title 10, Code of Federal Regulations (relating to assistance to foreign atomic energy activities);

(4) Nuclear facilities, equipment, and material covered by part 110 of title 10, Code of Federal Regulations (relating to export and import of nuclear equipment and material);

(5) Select agents and toxins covered by part 331 of title 7, Code of Federal Regulations, part 121 of title 9 of such Code, or part 73 of title 42 of such Code; or

(6) "Substantial or essential component" means any component necessary for the proper function or performance of a piece of equipment, system, or service.

(b) Prohibition. In accordance with section 1656 of the National Defense Authorization Act for Fiscal Year 2018 (Pub. L. 115-91), the contractor shall not provide to the Government any equipment, system, or service to carry out covered missions that uses covered defense telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system, unless the covered defense telecommunication equipment or services are covered by a waiver described in Defense Federal Acquisition Regulation Supplement 204.2104.

(c) Procedures. The Contractor shall review the list of excluded parties in the System for Award Management (SAM) at <https://www.sam.gov> for entities that are excluded when providing any equipment, system, or service, to carry out covered missions, that uses covered defense telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system, unless a waiver is granted.

(d) Reporting.

(1) In the event the Contractor identifies covered defense telecommunications equipment or services used as a substantial or essential component of any system, or as critical technology as part of any system, during contract performance, the Contractor shall report at <https://dibnet.dod.mil> the information in paragraph (d)(2) of this clause.

(2) The Contractor shall report the following information pursuant to paragraph (d)(1) of this clause:

(i) Within 3 business days from the date of such identification or notification: the contract number; the order number(s), if applicable; supplier name; brand; model number (original equipment manufacturer number, manufacturer part number, or wholesaler number); item description; and any readily available information about mitigation actions undertaken or recommended.

(ii) Within 30 business days of submitting the information in paragraph (d)(2)(i) of this clause: any further available information about mitigation actions undertaken or recommended. In addition, the Contractor shall describe the efforts it undertook to prevent use or submission of a covered defense telecommunications equipment or services, and any additional efforts that will be incorporated to prevent future use or submission of covered telecommunications equipment or services.

(e) Subcontracts. The Contractor shall insert the substance of this clause, including this paragraph (e), in all subcontracts and other contractual instruments, including subcontracts for the acquisition of commercial items.

10. DFARS 252.204-7020 NIST SP 800-171 DOD ASSESSMENT REQUIREMENTS (Nov 2020)

(a) Definitions.

"Basic Assessment" means a contractor's self assessment of the contractor's implementation of NIST SP 800-171 that-

(1) Is based on the Contractor's review of their system security plan(s) associated with covered contractor information system(s);

(2) Is conducted in accordance with the NIST SP 800-171 DoD Assessment Methodology; and

(3) Results in a confidence level of "Low" in the resulting score, because it is a self-generated score.

"Covered contractor information system" has the meaning given in the clause 252.204 -7012, Safeguarding Covered Defense Information and Cyber Incident Reporting, of this contract.

"High Assessment" means an assessment that is conducted by Government personnel using NIST SP 800-171A, Assessing Security Requirements for Controlled Unclassified Information that-

(1) Consists of-

(i) A review of a contractor's Basic Assessment;

(ii) A thorough document review;

(iii) Verification, examination, and demonstration of a Contractor's system security plan to validate that NIST SP 800-171 security requirements have been implemented as described in the contractor's system security plan; and

(iv) Discussions with the contractor to obtain additional information or clarification, as needed; and

(2) Results in a confidence level of "High" in the resulting score.

"Medium Assessment" means an assessment conducted by the Government that-

(1) Consists of-

(i) A review of a contractor's Basic Assessment;

(ii) A thorough document review; and

(iii) Discussions with the contractor to obtain additional information or clarification, as needed; and

(2) Results in a confidence level of "Medium" in the resulting score.

(b) Applicability. This clause applies to covered contractor information systems that are required to comply with the National Institute of Standards and Technology (NIST) Special Publication (SP) 800-171, in accordance with Defense Federal Acquisition Regulation System (DFARS) clause at 252.204-7012, Safeguarding Covered Defense Information and Cyber Incident Reporting, of this contract.

(c) Requirements. The Contractor shall provide access to its facilities, systems, and personnel necessary for the Government to conduct a Medium or High NIST SP 800-171 DoD Assessment, as described in NIST SP 800-171 DoD Assessment Methodology at https://www.acq.osd.mil/dpap/pdi/cyber/strategically_assessing_contractor_implementation_of_NIST_SP_800-171.html, if necessary.

(d) Procedures. Summary level scores for all assessments will be posted in the Supplier Performance Risk System (SPRS) (<https://www.sprs.csd.disa.mil/>) to provide DoD Components visibility into the summary level scores of strategic assessments.

(1) Basic Assessments. A contractor may submit, via encrypted email, summary level scores of Basic Assessments conducted in accordance with the NIST SP 800-171 DoD Assessment Methodology to webptsmh@navy.mil for posting to SPRS.

(i) The email shall include the following information:

(A) Version of NIST SP 800-171 against which the assessment was conducted.

(B) Organization conducting the assessment (e.g., Contractor self-assessment).

(C) For each system security plan (security requirement 3.12.4) supporting the performance of a DoD

contract-

(1) All industry Commercial and Government Entity (CAGE) code(s) associated with the information system(s) addressed by the system security plan; and

(2) A brief description of the system security plan architecture, if more than one plan exists.

(D) Date the assessment was completed

(E) Summary level score (e.g., 95 out of 110, NOT the individual value for each requirement).

(F) Date that all requirements are expected to be implemented (i.e., a score of 110 is expected to be achieved) based on information gathered from associated plan(s) of action developed in accordance with NIST SP 800-171.

(ii) If multiple system security plans are addressed in the email described at paragraph (b)(1)(i) of this section, the Contractor shall use the following format for the report:

System Security Plan

CAGE Codes supported by this plan

Brief description of the plan architecture

Date of assessment

Total Score

Date score of 110 will achieved

(2) Medium and High Assessments. DoD will post the following Medium and/or High Assessment summary level scores to SPRS for each system security plan assessed:

(i) The standard assessed (e.g., NIST SP 800-171 Rev 1).

(ii) Organization conducting the assessment, e.g., DCMA, or a specific organization (identified by Department of Defense Activity Address Code (DoDAAC)).

(iii) All industry CAGE code(s) associated with the information system(s) addressed by the system security plan.

(iv) A brief description of the system security plan architecture, if more than one system security plan exists.

(v) Date and level of the assessment, i.e., medium or high.

(vi) Summary level score (e.g., 105 out of 110, not the individual value assigned for each requirement).

(vii) Date that all requirements are expected to be implemented (i.e., a score of 110 is expected to be achieved) based on information gathered from associated plan(s) of action developed in accordance with NIST SP 800-171.

(e) Rebuttals.

(1) DoD will provide Medium and High Assessment summary level scores to the Contractor and offer the opportunity for rebuttal and adjudication of assessment summary level scores prior to posting the summary level scores to SPRS (see SPRS User's Guide https://www.sprs.csd.disa.mil/pdf/SPRS_Awardee.pdf).

(2) Upon completion of each assessment, the contractor has 14 business days to provide additional information to demonstrate that they meet any security requirements not observed by the assessment team or to rebut the findings that may be of question.

(f) Accessibility.

(1) Assessment summary level scores posted in SPRS are available to DoD personnel, and are protected, in accordance with the standards set forth in DoD Instruction 5000.79, Defense-wide Sharing and Use of Supplier and Product Performance Information (PI).

(2) Authorized representatives of the Contractor for which the assessment was conducted may access SPRS to view their own summary level scores, in accordance with the SPRS Software Us https://www.sprs.csd.disa.mil/pdf/SPRS_Awardee.pdf.

(3) A High NIST SP 800-171 DoD Assessment may result in documentation in addition to that listed in this clause. DoD will retain and protect any such documentation as "Controlled Unclassified Information (CUI)" and intended for internal DoD use only. The information will be protected against unauthorized use and release, including through the exercise of applicable exemptions under the Freedom of Information Act (e.g., Exemption 4 covers trade secrets and commercial or financial information obtained from a contractor that is privileged or confidential).

(g) Subcontracts.

(1) The Contractor shall insert the substance of this clause, including this paragraph (g), in all subcontracts and other contractual instruments, including subcontracts for the acquisition of commercial items (excluding COTS items).

(2) The Contractor shall not award a subcontract or other contractual instrument, that is subject to the implementation of NIST SP 800-171 security requirements, in accordance with DFARS clause 252.204-7012 of this contract, unless the subcontractor has completed, within the last 3 years, at least a Basic NIST SP 800-171 DoD Assessment, as described in https://www.acq.osd.mil/dpap/pdi/cyber/strategically_assessing_contractor_implementation_of_NIST_SP_800-171.html, for all covered contractor information systems relevant to its offer that are not part of an information technology service or system operated on behalf of the Government.

(3) If a subcontractor does not have summary level scores of a current NIST SP 800-171 DoD Assessment (i.e., not more than 3 years old unless a lesser time is specified in the solicitation) posted in SPRS, the subcontractor may conduct and submit a Basic Assessment, in accordance with the NIST SP 800-171 DoD Assessment Methodology, to webpntsmh@navy.mil for posting to SPRS along with the information required by paragraph (d) of this clause.

11. DFARS 252.204-7021 CYBERSECURITY MATURITY MODEL CERTIFICATION REQUIREMENT (Nov 2020)

(a) Scope. The Cybersecurity Maturity Model Certification (CMMC) CMMC is a framework that measures a contractor's cybersecurity maturity to include the implementation of cybersecurity practices and institutionalization of processes (see <https://www.acq.osd.mil/cmmc/index.html>).

(b) Requirements. The Contractor shall have a current (i.e. not older than 3 years) CMMC certificate at the CMMC level required by this contract and maintain the CMMC certificate at the required level for the duration of the contract.

(c) Subcontracts. The Contractor shall-

(1) Insert the substance of this clause, including this paragraph (c), in all subcontracts and other contractual instruments, including subcontracts for the acquisition of commercial items, excluding commercially available off-the-shelf items; and

(2) Prior to awarding to a subcontractor, ensure that the subcontractor has a current (i.e., not older than 3 years) CMMC certificate at the CMMC level that is appropriate for the information that is being flowed down to the subcontractor.

12. DFARS 252.205-7000 PROVISION OF INFORMATION TO COOPERATIVE AGREEMENT HOLDERS (Dec 1991)

(a) Definition. "Cooperative agreement holder" means a State or local government; a private, nonprofit organization; a tribal organization (as defined in section 4(c) of the Indian Self-Determination and Education Assistance Act (Pub. L. 93-268; 25 U.S.C. 450(c))); or an economic enterprise (as defined in section 3(e) of the Indian Financing Act of 1974 (Pub. L. 93-362; 25 U.S.C. 1452(e))) whether such economic enterprise is organized for profit or nonprofit purposes; which has an agreement with the Defense Logistics Agency to furnish procurement technical assistance to business entities.

(b) The Contractor shall provide cooperative agreement holders, upon their request, with a list of those appropriate employees or offices responsible for entering into subcontracts under defense contracts. The list shall include the business address, telephone number, and area of responsibility of each employee or office.

(c) The Contractor need not provide the listing to a particular cooperative agreement holder more frequently than once a year.

13. DFARS 252.211-7006 PASSIVE RADIO FREQUENCY IDENTIFICATION (Dec 2019)

(a) Definitions. As used in this clause--

"Advance shipment notice" means an electronic notification used to list the contents of a shipment of goods as well as additional information relating to the shipment, such as passive radio frequency identification (RFID) or item unique identification (IUID) information, order information, product description, physical characteristics, type of packaging, marking, carrier information, and configuration of goods within the transportation equipment.

"Bulk commodities" means the following commodities, when shipped in rail tank cars, tanker trucks, trailers, other bulk wheeled conveyances, or pipelines:

- (1) Sand.
- (2) Gravel.
- (3) Bulk liquids (water, chemicals, or petroleum products).
- (4) Ready-mix concrete or similar construction materials.
- (5) Coal or combustibles such as firewood.
- (6) Agricultural products such as seeds, grains, or animal feed.

"Case" means either a MIL-STD-129 defined exterior container within a palletized unit load or a MIL-STD-129 defined individual shipping container.

"Electronic Product Code™ (EPC)" means an identification scheme for universally identifying physical objects via RFID tags and other means. The standardized EPC data consists of an EPC (or EPC identifier) that uniquely identifies an individual object, as well as an optional filter value when judged to be necessary to enable effective and efficient reading of the EPC tags. In addition to this standardized data, certain classes of EPC tags will allow user-defined data. The EPC Tag Data Standards will define the length and position of this data, without defining its content.

"EPCglobal®" means a subscriber-driven organization comprised of industry leaders and organizations focused on creating global standards for the adoption of passive RFID technology.

"Exterior container" means a MIL-STD-129 defined container, bundle, or assembly that is sufficient by reason of material, design, and construction to protect unit packs and intermediate containers and their contents during shipment and storage. It can be a unit pack or a container with a combination of unit packs or intermediate containers. An exterior container may or may not be used as a shipping container.

"Palletized unit load" means a MIL-STD-129 defined quantity of items, packed or unpacked, arranged on a pallet in a specified manner and secured, strapped, or fastened on the pallet so that the whole palletized load is handled as a single unit. A palletized or skidded load is not considered to be a shipping container. A loaded 463L System pallet is not considered to be a palletized unit load. Refer to the Defense Transportation Regulation, DoD 4500.9-R, Part II, Chapter 203, for marking of 463L System pallets.

"Passive RFID tag" means a tag that reflects energy from the reader/interrogator or that receives and temporarily stores a small amount of energy from the reader/interrogator signal in order to generate the tag response. The only acceptable tags are EPC Class 1 passive RFID tags that meet the EPCglobal™ Class 1 Generation 2 standard.

"Radio frequency identification (RFID)" means an automatic identification and data capture technology comprising one or more reader/interrogators and one or more radio frequency transponders in which data transfer is achieved by means of suitably modulated inductive or radiating electromagnetic carriers.

"Shipping container" means a MIL-STD-129 defined exterior container that meets carrier regulations and is of sufficient strength, by reason of material, design, and construction, to be shipped safely without further packing (e.g., wooden boxes or crates, fiber and metal drums, and corrugated and solid fiberboard boxes).

(b)(1) Except as provided in paragraph (b)(2) of this clause, the Contractor shall affix passive RFID tags, at the case- and palletized-unit-load packaging levels, for shipments of items that

(i) Are in any of the following classes of supply, as defined in DoD Manual 4140.01, Volume 6, DoD Supply Chain Materiel Management Procedures: Materiel Returns, Retention, and Disposition:

(A) Subclass of Class I Packaged operational rations.

(B) Class II - Clothing, individual equipment, tentage, organizational tool kits, hand tools, and administrative and housekeeping supplies and equipment.

(C) Class IIIP - Packaged petroleum, lubricants, oils, preservatives, chemicals, and additives.

(D) Class I - Construction and barrier materials.

(E) Class VI - Personal demand items (non-military sales items).

(F) Subclass of Class VIII Medical materials (excluding pharmaceuticals, biologicals, and reagents suppliers should limit the mixing of excluded and non-excluded materials).

(G) Class IX Repair parts and components including kits, assemblies and subassemblies, repairable and consumable items required for maintenance support of all equipment, excluding medical-peculiar repair parts; and

(ii) Are being shipped to one of the locations listed at https://www.acq.osd.mil/log/sci/RFID_ship_to_locations.html or to

(A) A location outside the contiguous United States when the shipment has been assigned Transportation Priority 1, or to--

(B) The following location(s) deemed necessary by the requiring activity:

Contract Line, Subline, or Exhibit Line Location name City/State DoDAAC
Item Number

(2) The following are excluded from the requirements of paragraph (b)(1) of this clause:

(i) Shipments of bulk commodities.

(ii) Shipments to locations other than Defense Distribution Depots when the contract includes the clause at FAR 52.213-1, Fast Payment Procedures.

(c) The Contractor shall--

(1) Ensure that the data encoded on each passive RFID tag are globally unique (i.e., the tag ID is never repeated across two or more RFID tags and conforms to the requirements in paragraph (d) of this clause;

(2) Use passive tags that are readable; and

(3) Ensure that the passive tag is affixed at the appropriate location on the specific level of packaging, in accordance with MIL-STD-129 (Section 4.9.2) tag placement specifications.

(d) Data syntax and standards. The Contractor shall encode an approved RFID tag using the instructions provided in the EPC™ Tag Data Standards in effect at the time of contract award. The EPC™ Tag Data Standards are available at <http://www.gs1.org/epc-rfid>

(1) If the Contractor is an EPCglobal™ subscriber and possesses a unique EPC™ company prefix, the Contractor may use any of the identifiers and encoding instructions described in the most recent EPC™ Tag Data Standards document to encode tags

(2) If the Contractor chooses to employ the DoD identifier, the Contractor shall use its previously assigned Commercial and Government Entity (CAGE) code and shall encode the tags in accordance with the tag identifier details located in the DoD Suppliers Passive RFID Information Guide at <http://www.acq.osd.mil/log/sci/ait.html>. If the Contractor uses a third-party packaging house to encode its tags, the CAGE code of the third-party packaging house is acceptable

(3) Regardless of the selected encoding scheme, the Contractor with which the Department holds the contract is responsible for ensuring that the tag ID encoded on each passive RFID tag is globally unique, per the requirements in paragraph (c)(1).

(e) Advance shipment notice. The Contractor shall use Wide Area WorkFlow (WAWF), as required by DFARS 252.232-7003, Electronic Submission of Payment Requests, to electronically submit advance shipment notice(s) with the RFID tag ID(s) (specified in paragraph (d) of this clause) in advance of the shipment in accordance with the procedures at <https://wawf.eb.mil/>.

14. DFARS 252.219-7003 SMALL BUSINESS SUBCONTRACTING PLAN (DOD CONTRACTS) -- BASIC (Dec 2019)

This clause supplements the Federal Acquisition Regulation 52.219-9, Small Business Subcontracting Plan, clause of this contract.

(a) Definitions. As used in this clause-

"Summary Subcontract Report (SSR) Coordinator" means the individual who is registered in the Electronic Subcontracting Reporting System (eSRS) at the Department of Defense level and is

(b) Subcontracts awarded to qualified nonprofit agencies designated by the Committee for Purchase From People Who Are Blind or Severely Disabled (41 U.S.C. 8502-8504), may be counted toward the Contractor's small business subcontracting goal (section 8025 of Pub. L. 108-87).

(c) A mentor firm, under the Pilot Mentor-Protege Program established under section 831 of Public Law 101-510, as amended, may count toward its small disadvantaged business goal, subcontracts awarded to-

(1) Protege firms which are qualified organizations employing the severely disabled; and

(2) Former protege firms that meet the criteria in section 831(g)(4) of Public Law 101-510.

(d) The master plan is approved by the cognizant contract administration activity for the Contractor.

(e) In those subcontracting plans which specifically identify small businesses, the Contractor shall notify the Administrative Contracting Officer of any substitutions of firms that are not small business firms, for the small business firms specifically identified in the subcontracting plan. Notifications shall be in writing and shall occur within a reasonable period of time after award of the subcontract. Contractor-specified formats shall be acceptable.

(f)(1) For DoD, the Contractor shall submit reports in eSRS as follows:

(i) The Individual Subcontract Report (ISR) shall be submitted to the contracting officer at the procuring contracting office, even when contract administration has been delegated to the Defense Contract Management Agency

(ii) Submit the consolidated SSR for an individual subcontracting plan to the "Department of Defense."

(2) For DoD, the authority to acknowledge receipt or reject reports in eSRS is as follows:

(i) The authority to acknowledge receipt or reject the ISR resides with the contracting officer who receives it, as described in paragraph (f)(1)(i) of this clause.

(ii) The authority to acknowledge receipt of or reject SSRs submitted under an individual subcontracting plan resides with the SSR Coordinator.

(g) Include the clause at Defense Federal Acquisition Regulation Supplement (DFARS) 252.219-7004, Small Business Subcontracting Plan (Test Program), in subcontracts with subcontractors that participate in the Test Program described in DFARS 219.702-70, if the subcontract is expected to exceed the applicable threshold specified in Federal Acquisition Regulation 19.702(a) and to have further subcontracting opportunities.

15. DFARS 252.219-7003 SMALL BUSINESS SUBCONTRACTING PLAN (DOD CONTRACTS) (Dec 2019) , Alternate I , (Dec 2019

This clause supplements the Federal Acquisition Regulation 52.219-9, Small Business Subcontracting Plan, clause of this contract.

(a) Definitions. As used in this clause-

"Summary Subcontract Report (SSR) Coordinator" means the individual who is registered in the Electronic Subcontracting Reporting System (eSRS) at the Department of Defense level and is responsible for acknowledging receipt or rejecting SSRs submitted under an individual subcontracting plan in eSRS for the Department of Defense.

(b) Subcontracts awarded to qualified nonprofit agencies designated by the Committee for Purchase From People Who Are Blind or Severely Disabled (41 U.S.C. 8502-8504), may be citation 8025 of Pub. L. 108- 87).

(c) A mentor firm, under the Pilot Mentor-Protege Program established under section 831 of Public Law 101-510, as amended, may count toward its small disadvantaged business goal, subcontracts awarded to--

(1) Protege firms which are qualified organizations employing the severely disabled; and

(2) Former protege firms that meet the criteria in section 831(g)(4) of Public Law 101-510.

(d) The master plan is approved by the cognizant contract administration activity for the Contractor.

(e) In those subcontracting plans which specifically identify small businesses, the Contractor shall notify the Administrative Contracting Officer of any substitutions of firms that are not small business firms, for the small business firms specifically identified in the subcontracting plan. Notifications shall be in writing and shall occur within a reasonable period of time after award of the subcontract. Contractor-specified formats shall be acceptable.

(f)(1) For DoD, the Contractor shall submit reports in eSRS as follows:

(i) The Standard Form 294, Subcontracting Report for Individual Contracts, shall be submitted in accordance with the instructions on that form.

(ii) Submit the consolidated SSR to the "Department of Defense."

(2) For DoD, the authority to acknowledge receipt of or reject SSRs submitted under an individual subcontracting plan in eSRS resides with the SSR Coordinator.

(g) Include the clause at Defense Federal Acquisition Regulation Supplement (DFARS) 252.219-7004, Small Business Subcontracting Plan (Test Program), in subcontracts with subcontractors that participate in the Test Program described in DFARS 219.702-70, if the subcontract is expected to exceed the applicable threshold specified in Federal Acquisition Regulation 19.702(a) and to have further subcontracting opportunities.

16. DFARS 252.219-7003 SMALL BUSINESS SUBCONTRACTING PLAN (DOD CONTRACTS) (Dec 2019), Alternate II , (Dec 2019)

(a) Definitions. As used in this clause-

"Eligible contractor" means a business entity operated on a for-profit or nonprofit basis that-

(1) Employs severely disabled individuals at a rate that averages not less than 33 percent of its total workforce over the 12-month period prior to issuance of the solicitation;

(2) Pays not less than the minimum wage prescribed pursuant to 29 U.S.C. 206 to the employees who are severely disabled individuals; and

(3) Provides, for its employees, health insurance and a retirement plan comparable to those provided for employees by business entities of similar size in its industrial sector or geographic region.

"Summary Subcontract Report (SSR) Coordinator" means the individual who is registered in the Electronic Subcontracting Reporting System (eSRS) at the Department of Defense level and is responsible for acknowledging receipt or rejecting SSRs submitted under an individual subcontracting plan in eSRS for the Department of Defense.

(b)(1) Subcontracts awarded to qualified nonprofit agencies designated by the Committee for Purchase From People Who are Blind or Severely Disabled (41 U.S.C. 8502-

(2) Subcontracts awarded to eligible contractors under the Demonstration Project for Contractors Employing Persons with Disabilities (see Defense Federal Acquisition Regulation Supplement (DFARS) 226.72) may be counted toward the Contractor's small disadvantaged business subcontracting goal (section 853 of Pub. L. 108-136, as amended by division H, section 110 of Pub. L. 108-199).

(c) A mentor firm, under the Pilot Mentor-Protege Program established under section 831 of Public Law 101-510, may count toward its small disadvantaged business goal, subcontracts awarded to-

(1) Protege firms which are qualified organizations employing the severely disabled; and

(2) Former protege firms that meet the criteria in section 831(g)(4) of Public Law 101-510.

(d) The master plan is approved by the cognizant contract administration activity for the Contractor.

(e) In those subcontracting plans which specifically identify small businesses, the Contractor shall notify the Administrative Contracting Officer of any substitutions of firms that are not small business firms, for the small business firms specifically identified in the subcontracting plan. Notifications shall be in writing and shall occur within a reasonable period of time after award of the subcontract. Contractor-specified formats shall be acceptable.

(f)(1) For DoD, the Contractor shall submit reports in eSRS as follows:

(i) The Individual Subcontract Report (ISR) shall be submitted to the contracting officer at the procuring contracting office, even when contract administration has been delegated to the Defense Contract Management Agency.

(ii) Submit the consolidated SSR for an individual subcontracting plan to

(2) For DoD, the authority to acknowledge receipt or reject reports in eSRS is as follows:

(i) The authority to acknowledge receipt or reject the ISR resides with the contracting officer who receives it, as described in paragraph (f)(1)(i) of this clause.

(ii) The authority to acknowledge receipt of or reject SSRs submitted under an individual subcontracting plan resides with the SSR Coordinator.

(g) Include the clause at DFARS 252.219-7004, Small Business Subcontracting Plan (Test Program), in subcontracts with subcontractors that participate in the Test Program described in DFARS 219.702-70, if the subcontract is expected to exceed the applicable threshold specified in Federal Acquisition Regulation 19.702(a) and to have further subcontracting opportunities.

17. DFARS 252.225-7008 RESTRICTION ON ACQUISITION OF SPECIALTY METALS (Mar 2013)

(a) Definitions. As used in this clause

"Alloy" means a metal consisting of a mixture of a basic metallic element and one or more metallic, or non-metallic, alloying elements.

(i) For alloys named by a single metallic element (e.g., titanium alloy), it means that the alloy contains 50 percent or more of the named metal (by mass).

(ii) If two metals are specified in the name (e.g, nickel-iron alloy), those metals are the two predominant elements in the alloy, and together they constitute 50 percent or more of the alloy (by mass).

"Produce" means

(i) Atomization;

(ii) Sputtering; or

(iii) Final consolidation of non-melt derived metal powders.

"Specialty metal" means—

(i) Steel-

(A) With a maximum alloy content exceeding one or more of the following limits: manganese, 1.65 percent; silicon, 0.60 percent; or copper, 0.60 percent; or

(B) Containing more than 0.25 percent of any of the following elements: aluminum, chromium, cobalt, molybdenum, nickel, niobium (columbium), titanium, tungsten, or vanadium;

(ii) Metal alloys consisting of

(A) Nickel or iron-nickel alloys that contain a total of alloying metals other than nickel and iron in excess of 10 percent; or

(B) Cobalt alloys that contain a total of alloying metals other than cobalt and iron in excess of 10 percent;

(iii) Titanium and titanium alloys; or

(iv) Zirconium and zirconium alloys.

"Steel" means an iron alloy that includes between .02 and 2 percent carbon and may include other elements.

(b) Any specialty metal delivered under this contract shall be melted or produced in the United States or its outlying areas.

18. DFARS 252.225-7012 PREFERENCE FOR CERTAIN DOMESTIC COMMODITIES (Dec 2017)

(a) Definitions. As used in this clause--

"Component" means any item supplied to the Government as part of an end product or of another component.

"End product" means supplies delivered under a line item of this contract.

"Qualifying country" means a country with a reciprocal defense procurement memorandum of understanding or international agreement with the United States in which both countries agree to remove barriers to purchases of supplies produced in the other country or services performed by sources of the other country, and the memorandum or agreement complies, where applicable, with the requirements of section 36 of the Arms Export Control Act (22 U.S.C. 2776) and with 10 U.S.C. 2457. Accordingly, the following are qualifying countries:

Australia
Austria
Belgium
Canada
Czech Republic
Denmark
Egypt
Estonia
Finland
France
Germany
Greece
Israel
Italy
Japan
Latvia
Luxembourg
Netherlands
Norway
Poland
Portugal

Slovenia
Spain
Sweden
Switzerland
Turkey
United Kingdom of Great Britain and Northern Ireland.

"Structural component of a tent"—

- (i) Means a component that contributes to the form and stability of the tent (e.g., poles, frames, flooring, guy ropes, pegs);
- (ii) Does not include equipment such as heating, cooling, or lighting.

"United States" means the 50 States, the District of Columbia, and outlying areas.

"U.S. flag vessel" means a vessel of the United States or belonging to the United States, including any vessel registered or having national status under the laws of the United States.

(b) The Contractor shall deliver under this contract only such of the following items, either as end products or components, that have been grown, reprocessed, reused, or produced in the United States:

(1) Food.

(2) Clothing and the materials and components thereof, other than sensors, electronics, or other items added to, and not normally associated with, clothing and the materials and components thereof. Clothing includes items such as outerwear, headwear, underwear, nightwear, footwear, hosiery, handwear, belts, badges, and insignia.

(3)(i) Tents and structural components of tents;

(ii) Tarpaulins; or

(iii) Covers.

(4) Cotton and other natural fiber products.

(5) Woven silk or woven silk blends.

(6) Spun silk yarn for cartridge cloth.

(7) Synthetic fabric, and coated synthetic fabric, including all textile fibers and yarns that are for use in such fabrics.

(8) Canvas products.

(9) Wool (whether in the form of fiber or yarn or contained in fabrics, materials, or manufactured articles).

(10) Any item of individual equipment (Federal Supply Class 8465) manufactured from or containing fibers, yarns, fabrics, or materials listed in this paragraph (b).

(c) This clause does not apply

(1) To items listed in section 25.104(a) of the Federal Acquisition Regulation (FAR), or other items for which the Government has determined that a satisfactory quality and sufficient quantity cannot be acquired as and when needed at U.S. market prices;

(2) To incidental amounts of cotton, other natural fibers, or wool incorporated in an end product, for which the estimated value of the cotton, other natural fibers, or wool

(i) Is not more than 10 percent of the total price of the end product; and

(ii) Does not exceed the simplified acquisition threshold in FAR Part 2;

(3) To waste and byproducts of cotton or wool fiber for use in the production of propellants and explosives;

(4) To foods, other than fish, shellfish, or seafood, that have been manufactured or processed in the United States, regardless of where the foods (and any component if applicable) were grown or produced. Fish, shellfish, or seafood manufactured or processed in the United States and fish, shellfish, or seafood contained in foods manufactured or processed in the United States shall be provided in accordance with paragraph (d) of this clause;

(5) To chemical warfare protective clothing produced in a qualifying country; or

(6) To fibers and yarns that are for use in synthetic fabric or coated synthetic fabric (but does apply to the synthetic or coated synthetic fabric itself), if

(i) The fabric is to be used as a component of an end product that is not a textile product. Examples of textile products, made in whole or in part of fabric, include

(A) Draperies, floor coverings, furnishings, and bedding (Federal Supply Group 72, Household and Commercial Furnishings and Appliances);

(B) Items made in whole or in part of fabric in Federal Supply Group 83, Textile/leather/furs/apparel/findings/tents/flags, or Federal Supply Group 84, C[***]hing, Individual Equipment and Insignia;

(C) Upholstered seats (whether for household, office, or other use); and

(D) Parachutes (Federal Supply Class 1670); or

(ii) The fibers and yarns are para-aramid fibers and continuous filament para- aramid yarns manufactured in a qualifying country.

(d)(1) Fish, shellfish, and seafood delivered under this contract, or contained in foods delivered under this contract

(i) Shall be taken from the sea by U.S.-flag vessels; or

(ii) If not taken from the sea, shall be obtained from fishing within the United States; and

(2) Any processing or manufacturing of the fish, shellfish, or seafood shall be performed on a U.S.-flag vessel or in the United States.

19. DFARS 252.225-7052 RESTRICTION ON THE ACQUISITION OF CERTAIN MAGNETS, TAN-TALUM, AND TUNGSTEN (Oct 2020)

(a) Definitions. As used in this clause-

"Assembly" means an item forming a portion of a system or subsystem that-

(1) Can be provisioned and replaced as an entity; and

(2) Incorporates multiple, replaceable parts.

"Commercially available off -the-self item"-

(1) Means any item of supply that is-

(i) A commercial item (as defined in paragraph (1) of the definition of "Commercial item" in section 2.101 of the Federal Acquisition Regulation);

(ii) Sold in substantial quantities in the commercial marketplace; and

(iii) Offered to the Government, under this contract or a subcontract at any tier, without modification, in the same form in which it is sold in the commercial marketplace; and

(2) Does not include bulk cargo, as defined in 46 U.S.C. 40102(4), such as agricultural products and petroleum products.

"Component" means any item supplied to the Government as part of an end item or of another component.

"Covered country" means-

(1) The Democratic People's Republic of North Korea;

(2) The People's Republic of China;

(3) The Russian Federation; or

(4) The Islamic Republic of Iran.

"Covered material" means

(1) Samarium-cobalt magnets;

(2) Neodymium-iron-boron magnets;

(3) Tantalum metal and alloys;

(4) Tungsten metal powder; and

(5) Tungsten heavy alloy or any finished or semi-finished component containing tungsten heavy alloy.

"Electronic device" means an item that operates by controlling the flow of electrons or other electrically charged particles in circuits, using interconnections such as resistors, inductors, capacitors, diodes, switches, transistors, or integrated circuits.

"End item" means the final production product when assembled or completed and ready for delivery under a line item of this contract.

"Subsystem" means a functional grouping of items that combine to perform a major function within an end item, such as electrical power, attitude control, and propulsion.

"Tungsten heavy alloy" means a tungsten base pseudo alloy that-

(1) Meets the specifications of ASTM B777 or SAE-AMS-T-21014 for a particular class of tungsten heavy alloy; or

(2) Contains at least 90 percent tungsten in a matrix of other metals (such as nickel-iron or nickel-copper) and has density of at least 16.5 g/cm³).

(b) Restriction.

(1) Except as provided in paragraph (c) of this clause, the Contractor shall not deliver under this contract any covered material melted or produced in any covered country, or any end item, manufactured in any covered country, that contains a covered material (10 U.S.C.2533c).

(2)(i) For samarium-cobalt magnets and neodymium iron-boron magnets, this restriction includes-

(A) Melting samarium with cobalt to produce the samarium-cobalt alloy or melting neodymium with iron and boron to produce the neodymium-iron-boron alloy; and

(B) All subsequent phases of production of the magnets, such as powder formation, pressing, sintering or bonding, and magnetization.

(ii) The restriction on melting and producing of samarium-cobalt magnets is in addition to any applicable restrictions on melting of specialty metals if the clause at 252.225-7009, Restriction on Acquisition of Certain Articles Containing Specialty Metals, is included in the contract.

(3) For production of tantalum metal and alloys, this restriction includes the reduction of tantalum chemicals such as oxides, chlorides, or potassium salts, to metal powder and all subsequent phases of production of tantalum metal and alloys, such as consolidation of metal powders.

(4) For production of tungsten metal powder and tungsten heavy alloy, this restriction includes-

(i) Atomization;

(ii) Calcination and reduction into powder;

(iii) Final consolidation of non-melt derived metal powders; and

(iv) All subsequent phases of production of tungsten metal powder, tungsten heavy alloy, or any finished or semi-finished component containing tungsten heavy alloy.

(c) Exceptions. This clause does not apply-

(1) To an end item that is-

(i) A commercially available off-the-shelf item, other than-

(A) A commercially available off-the-shelf item that is 50 percent or more tungsten by weight; or

(B) such as bar, billet, slab, wire, cube, sphere, block, blank, plate, or sheet, that has not been incorporated into an end item, subsystem, assembly, or component;

(ii) An electronic device, unless otherwise specified in the contract; or

(iii) A neodymium-iron-boron magnet manufactured from recycled material if the milling of the recycled material and sintering of the final magnet takes place in the United States.

(2) If the authorized agency official concerned has made a nonavailability determination, in accordance with section 225.7018-4 of the Defense Federal Acquisition Regulation Supplement, that compliant covered materials of satisfactory quality and quantity, in the required form, cannot be procured as and when needed at a reasonable price.

(i) For tantalum metal, tantalum alloy, or tungsten heavy alloy, the term "required form" refers to the form of the mill product, such as bar, billet, wire, slab, plate, or sheet, in the grade appropriate for the

production of a finished end item to be delivered to the Government under this contract; or a finished component assembled into an end item to be delivered to the Government under the contract.

(ii) For samarium-cobalt magnets or neodymium-iron-boron magnets, the the term "required form" refers to the form and properties of the magnets.

(d) Subcontracts. The Contractor shall insert the substance of this clause, including this paragraph (d), in subcontracts and other contractual instruments that are for items containing a covered material, including subcontracts and other contractual instruments for commercial items, unless an exception in paragraph (c) of this clause applies. The Contractor shall not alter this clause other than to identify the appropriate parties.

20. DFARS 252.226-7001 UTILIZATION OF INDIAN ORGANIZATIONS, INDIAN-OWNED ECONOMIC ENTERPRISES, AND NATIVE HAWAIIAN SMALL BUSINESS CONCERNS (Apr 2019)

(a) Definitions. As used in this clause—

"Indian" means-

(1) Any person who is a member of any Indian tribe, band, group, pueblo, or community that is recognized by the Federal Government as eligible for services from the Bureau of Indian Affairs (BIA) in accordance with 25 U.S.C. 1452(c); and

(2) Any "Native" as defined in the Alaska Native Claims Settlement Act (43 U.S.C. 1601 et seq.).

"Indian organization" means the governing body of any Indian tribe or entity established or recognized by the governing body of an Indian tribe for the purposes of 25 U.S.C. Chapter 17.

"Indian-owned economic enterprise" means any Indian-owned (as determined by the Secretary of the Interior) commercial, industrial, or business activity established or organized for the purpose of profit, provided that Indian ownership constitutes not less than 51 percent of the enterprise.

"Indian tribe" means any Indian tribe, band, group, pueblo, or community, including native villages and native groups (including corporations organized by Kenai, Juneau, Sitka, and Kodiak) as defined in the Alaska Native Claims Settlement Act, that is recognized by the Federal Government as eligible for services from BIA in accordance with 25 U.S.C. 1452(c).

"Interested party" means a contractor or an actual or prospective offeror whose direct economic interest would be affected by the award of a subcontract or by the failure to award a subcontract.

"Native Hawaiian small business concern" means an entity that is-

(1) A small business concern as defined in Section 3 of the Small Business Act (15 U.S.C. 632) and relevant implementing regulations; and

(2) Owned and controlled by a Native Hawaiian as defined in 25 U.S.C. 4221(9).

(b) The Contractor shall use its best efforts to give Indian organizations, Indian-owned economic enterprises, and Native Hawaiian small business concerns the maximum practicable opportunity to participate in the subcontracts it awards, to the fullest extent consistent with efficient performance of the contract.

(c) The Contracting Officer and the Contractor, acting in good faith, may rely on the representation of an Indian organization, Indian-owned economic enterprise, or Native Hawaiian small business concern as to its eligibility, unless an interested party challenges its status or the Contracting Officer has independent reason to question that status.

(d) In the event of a challenge to the representation of a subcontractor, the Contracting Officer will refer the matter to-

(1)(i) For matters relating to Indian organizations or Indian-owned economic enterprises:

U.S. U.S. Department of the Interior
Bureau of Indian Affairs
Attn: Bureau Procurement Chief
12220 Sunrise Valley Drive
Reston, VA 20191
Phone: 703-390-6433
Website: <https://www.bia.gov/>

The BIA will determine the eligibility and will notify the Contracting Officer.

(2)(i) For matters relating to Native Hawaiian small business concerns:

Department of Hawaiian Home Lands
PO Box 1879
Honolulu, HI 96805
Phone: 808-620-9500
Website: <http://dhhhl.hawaii.gov/>

The Department of Hawaiian Home Lands will determine the eligibility and will notify the Contracting Officer.

(e) No incentive payment will be made-

- (1) While a challenge is pending; or
- (2) If a subcontractor is determined to be an ineligible participant.

(f)(1) The Contractor, on its own behalf or on behalf of a subcontractor at any tier, may request an incentive payment in accordance with this clause.

(2) The incentive amount that may be requested is 5 percent of the estimated cost, target cost, or fixed price included in the subcontract at the time of award to the Indian organization, Indian-owned economic enterprise, or Native Hawaiian small business concern.

(3) In the case of a subcontract for commercial items, the Contractor may receive an incentive payment only if the subcontracted items are produced or manufactured in whole or in part by an Indian organization, Indian-owned economic enterprise, or Native Hawaiian small business concern.

(4) The Contractor has the burden of proving the amount claimed and shall assert its request for an incentive payment prior to completion of contract performance.

(5) The Contracting Officer, subject to the terms and conditions of the contract and the availability of funds, will authorize an incentive payment of 5 percent of the estimated cost, target cost, or fixed price included in the subcontract awarded to the Indian organization, Indian-owned economic enterprise, or Native Hawaiian small business concern.

(6) If the Contractor requests and receives an incentive payment on behalf of a subcontractor, the Contractor is obligated to pay the subcontractor the incentive amount.

(g) The Contractor shall insert the substance of this clause, including this paragraph (g), in all subcontracts exceeding \$500,000.

21. DFARS 252.232-7003 ELECTRONIC SUBMISSION OF PAYMENT REQUESTS AND RECEIVING REPORTS (Dec 2018)

(a) Definitions. As used in this clause-

"Contract financing payment" means an authorized Government disbursement of monies to a contractor prior to acceptance of supplies or services by the Government.

(1) Contract financing payments include-

- (i) Advance payments;
- (ii) Performance-based payments;
- (iii) Commercial advance and interim payments;
- (iv) Progress payments based on cost under the clause at Federal Acquisition Regulation (FAR) 52.232-16,

Progress Payments;

(v) Progress payments based on a percentage or stage of completion (see FAR 32.102(e)), except those made under the clause at FAR 52.232-5, Payments Under Fixed-Price Construction Contracts, or the clause at FAR 52.232-10, Payments Under Fixed-Price Architect-Engineer Contracts; and

(vi) Interim payments under a cost reimbursement contract, except for a cost reimbursement contract for services when Alternate I of the clause at FAR 52.232-25, Prompt Payment, is used.

(2) Contract financing payments do not include-

- (i) Invoice payments;
- (ii) Payments for partial deliveries; or
- (iii) Lease and rental payments.

"Electric form" means any automated system that transmits information electronically from the initiating system to affected systems.

"Invoice payment" means a Government disbursement of monies to a contractor under a contract or other authorization for supplies or services accepted by the Government.

(1) Invoice payments include-

- (i) Payments for partial deliveries that have been accepted by the Government;
- (ii) Final cost or fee payments where amounts owed have been settled between the Government and the

contractor;

(iii) For purposes of subpart 32.9 only, all payments made under the clause at 52.232-5, Payments Under Fixed-Price Construction Contracts, and the clause at 52.232-10, Payments Under Fixed-Price Architect-Engineer Contracts; and

(iv) Interim payments under a cost-reimbursement contract for services when Alternate I of the clause at 52.232-25, Prompt payment, is used.

(2) Invoice payments do not include contract financing payments.

"Payment request" means any request for contract financing payment or invoice payment submitted by the Contractor under this contract or task or delivery order.

"Receiving report" means the data prepared in the matter and to the extent required by Appendix F, Material Inspection and Receiving Report, of the Defense Federal Acquisition Regulation Supplement.

(b) Except as provided in paragraph (d) of this clause, the Contractor shall submit payment requests and receiving reports in electronic form using Wide Area WorkFlow (WAWF). The Contractor shall prepare and furnish to the Government a receiving report at the time of each delivery of supplies or services under this contract or task or delivery order.

(c) Submit payment requests and receiving reports to WAWF in one of the following electronic formats:

- (1) Electronic Data Interchange.
- (2) Secure File Transfer Protocol.
- (3) Direct input through the WAWF website.

(d) The Contractor may submit a payment request and receiving report using methods other than WAWF only when-

(1) The Contractor has requested permission in writing to do so, and the Contracting Officer has provided instructions for a temporary alternative method of submission of payment requests and receiving reports in the contract administration data section of this contract or task or delivery order;

(2) DoD makes payment for commercial transportation services provided under a Government rate tender or a contract for transportation services using a DoD-approved electronic third party payment system or other exempted vendor payment/invoicing system (e.g., PowerTrack, Transportation Financial Management System, and Cargo and Billing System);

(3) DoD makes payment on a contract or task or delivery order for rendered health care services using the TRICARE Encounter Data System; or

(4) The Governmentwide commercial purchase card is used as the method of payment, in which case submission of only the receiving report in WAWF is required.

(e) Information regarding WAWF is available at <https://wawf.eb.mil/>.

(f) In addition to the requirements of this clause, the Contractor shall meet the requirements of the appropriate payment clauses in this contract when submitting payment requests.

22. DFARS 252.232-7006 WIDE AREA WORKFLOW PAYMENT INSTRUCTIONS (Dec 2018)

(a) Definitions. As used in this clause-

"Department of Defense Activity Address Code (DoDAAC)" is a six position code that uniquely identifies a unit, activity, or organization.

"Document type" means the type of payment request or receiving report available for creation in Wide Area Work Flow (WAWF).

"Local processing office (LPO)" is the office responsible for payment certification when payment certification is done external to the entitlement system.

"Payment request" and "receiving report" are defined in the clause at 252.232-7003, Electronic Submission of Payment Requests and Receiving Reports.

(b) Electronic invoicing. The WAWF system provides the method to electronically process vendor payment requests and receiving reports, as authorized by Defense Federal Acquisition Regulation Supplement (DFARS) 252.232-7003, Electronic Submission of Payment Requests and Receiving Reports.

(c) WAWF access. To access WAWF, the Contractor shall-

(1) Have a designated electronic business point of contact in the System for Award Management at <https://www.sam.gov>;
and

(2) Be registered to use WAWF at <https://wawf.eb.mil/> following the step-by-step procedures for self-registration available at this web site.

(d) WAWF training. The Contractor should follow the training instructions of the WAWF Web-Based Training Course and use the Practice Training Site before submitting payment requests through WAWF. Both can be accessed by selecting the "Web Based Training" link on the WAWF home page at the WAWF home page at <https://wawf.eb.mil/>

(e) WAWF methods of document submission. Document submissions may be via web entry, Electronic Data Interchange, or File Transfer Protocol.

(f) WAWF payment instructions. The Contractor shall use the following information when submitting payment requests and receiving reports in WAWF for this contract or task or delivery order:

(1) Document type. The Contractor shall submit payment requests using the following document type(s):

(i) For cost-type line items, including labor-hour or time-and-materials, submit a cost voucher.

(ii) For fixed price line items-

(A) That require shipment of a deliverable, submit the invoice and receiving report specified by the Contracting Officer.

(B) For services that do not require shipment of a deliverable, submit either the Invoice 2in1, which meets the requirements for the invoice and receiving report, or the applicable invoice and receiving report, as specified by the Contracting Officer.

(iii) For customary progress payments based on costs incurred, submit a progress payment request.

(iv) For performance based payments, submit a performance based payment request.

(v) For commercial item financing, submit a commercial item financing request.

(2) Fast Pay requests are only permitted when Federal Acquisition Regulation (FAR) 52.213-1 is included in the contract.

[Note: The Contractor may use a WAWF "combo" type to create some combinations of invoice and receiving report in one step.]

(3) Document routing. The Contractor shall use the information in the Routing Data Table below only to fill in applicable fields in WAWF when creating payment requests and receiving reports in the system.

Routing Data Table*

Field Name in WAWF Data to be entered in WAWF

Pay Official DoDAAC See 1449

Issue By DoDAAC See 1449

Admin DoDAAC See 1449

Inspect By DoDAAC FA8730

Ship To Code N/A

Ship From Code N/A

Mark For Code N/A

Service Approver (DoDAAC) FA8730
Service Acceptor (DoDAAC) FA8730
Accept at Other DoDAAC N/A
LPO DoDAAC N/A
DCAA Auditor DoDAAC N/A
Other DoDAAC(s) N/A

(*Contracting Officer: Insert applicable DoDAAC information. If multiple ship to/acceptance locations apply, insert "see Schedule" or "Not applicable.")

(**Contracting Officer: If the contract provides for progress payments or performance-based payments, insert the DoDAAC for the contract administration office assigned the functions under FAR 42.302(a)(13).)

(4) Payment request. The Contractor shall ensure a payment request includes documentation appropriate to the type of payment request in accordance with the payment clause, contract financing clause, or Federal Acquisition Regulation 52.216-7, Allowable Cost and Payment, as applicable.

(5) Receiving report. The Contractor shall ensure a receiving report meets the requirements of DFARS Appendix F.

(g) WAWF point of contact.

(1) The Contractor may obtain clarification regarding invoicing in WAWF from the following contracting activity's WAWF point of contact.

(2) Contact the WAWF helpdesk at 866-618-5988, if assistance is needed.

23. DFARS 252.232-7010 LEVIES ON CONTRACT PAYMENTS (Dec 2006)

(a) 26 U.S.C. 6331(h) authorizes the Internal Revenue Service (IRS) to continuously levy up to 100 percent of contract payments, up to the amount of tax debt.

(b) When a levy is imposed on a payment under this contract and the Contractor believes that the levy may result in an inability to perform the contract, the Contractor shall promptly notify the Procuring Contracting Officer in writing, with a copy to the Administrative Contracting Officer, and shall provide-

(1) The total dollar amount of the levy;

(2) A statement that the Contractor believes that the levy may result in an inability to perform the contract, including rationale and adequate supporting documentation; and

(3) Advice as to whether the inability to perform may adversely affect national security, including rationale and adequate supporting documentation.

(c) DoD shall promptly review the Contractor's assessment, and the Procuring Contracting Officer shall provide a written notification to the Contractor including-

(1) A statement as to whether DoD agrees that the levy may result in an inability to perform the contract, and

(2)(i) If the levy may result in an inability to perform the contract and a lack of performance will adversely affect national security, the total amount of the monies collected that should be returned to the Contractor; or

(ii) If the levy may result in an inability to perform the contract but will not impact national security, a recommendation that the Contractor promptly notify the IRS to attempt to resolve the tax situation.

(d) Any DoD determination under this clause is not subject to appeal under the Contract Disputes Act.

(a) Definitions of pertinent terms are set forth in sections 2.101, 32.001, and 32.902 of the Federal Acquisition Regulation.

(b) Notwithstanding any other payment clause in this contract, the Government will make invoice payments under the terms and conditions specified in this clause. The Government considers payment as being made on the day a check is dated or the date of an electronic funds transfer.

(c) Invoice payments.

(1) Due date.

(i) Payment will be made as soon as possible once a proper invoice is received and matched with the contract and the receiving/acceptance report.

(ii) If the contract does not require submission of an invoice for payment (e.g., periodic lease payments), the due date will be as specified in the contract.

(2) Contractor's invoice. The Contractor shall prepare and submit invoices to the designated billing office specified in the contract. A proper invoice should include the items listed in paragraphs (c)(2)(i) through (c)(2)(x) of this clause.

(i) Name and address of the Contractor.

(ii) Invoice date and invoice number. (The Contractor should date invoices as close as possible to the date of the mailing or transmission.)

(iii) Contract number or other authorization for supplies delivered or services performed (including order number and contract line item number).

(iv) Description, quantity, unit of measure, unit price, and extended price of supplies delivered or services performed.

(v) Shipping and payment terms (e.g., shipment number and date of shipment, discount for prompt payment terms). Bill of lading number and weight of shipment will be shown for shipments on Government bills of lading.

(vi) Name and address of Contractor official to whom payment is to be sent (must be the same as that in the contract or in a proper notice of assignment).

(vii) Name (where practicable), title, phone number, and mailing address of person to notify in the event of a defective invoice.

(viii) Taxpayer Identification Number (when required). The taxpayer identification number is required for all payees subject to the U.S. Internal Revenue Code.

(ix) Electronic funds transfer banking information.

(A) The Contractor shall include electronic funds transfer banking information on the invoice only if required elsewhere in this contract.

(B) If electronic funds transfer banking information is not required to be on the invoice, in order for the invoice to be a proper invoice, the Contractor shall have submitted correct electronic funds transfer banking information in accordance with the applicable solicitation provision (e.g., FAR 52.232-38, Submission of Electronic Funds Transfer Information with Offer), contract clause (e.g., FAR 52.232-33, Payment by

Electronic Funds Transfer System for Award Management, or FAR 52.232-34, Payment by Electronic Funds Transfer-Other Than System for Award Management), or applicable agency procedures.

(C) Electronic funds transfer banking information is not required if the Government waived the requirement to pay by electronic funds transfer.

(x) Any other information or documentation required by the contract (e.g., evidence of shipment).

(3) Discounts for prompt payment. The designated payment office will take cost-effective discounts if the payment is made within the discount terms of the contract.

(4) Contract financing payment. If this contract provides for contract financing, the Government will make contract financing payments in accordance with the applicable contract financing clause.

(5) Overpayments. If the Contractor becomes aware of a duplicate contract financing or invoice payment or that the Government has otherwise overpaid on a contract financing or invoice payment, the Contractor shall

(i) Remit the overpayment amount to the payment office cited in the contract along with a description of the overpayment, including the

(A) Circumstances of the overpayment (e.g., duplicate payment, erroneous payment, liquidation errors, date(s) of overpayment);

(B) Affected contract number and delivery order number, if applicable;

(C) Affected contract line item or subline item, if applicable; and

(D) Contractor point of contact; and

(ii) Provide a copy of the remittance and supporting documentation to the Contracting Officer.

(d) This clause is applicable until otherwise notified by the Contracting Officer. Upon notification by issuance of a contract modification, the appropriate FAR Prompt Payment clause in the contract becomes applicable.

25. DFARS 252.232-7017 ACCELERATING PAYMENTS TO SMALL BUSINESS SUBCONTRACTORS PROHIBITION ON FEES AND CONSIDERATION (Apr 2020)

(a) Definition. "Accelerated payment," as used in this clause, means a payment made to a small business subcontractor as quickly as possible, with a goal of 15 days or less after receipt of payment from the Government or receipt of a proper invoice from the subcontractor, whichever is later.

(b) In accordance with section 852 of Public Law 115-232, the Contractor shall not require any further consideration from or charge fees to the small business subcontractor when making accelerated payments, as defined in paragraph (a) of this clause, to subcontractors under the clause at FAR 52.232-40, Providing Accelerated Payments to Small Business Subcontractors.

(c) Subcontracts. Include the substance of this clause, including this paragraph (c), in all subcontracts with small business concerns, including those for the acquisition of commercial items.

26. DFARS 252.239-7018 SUPPLY CHAIN RISK (Feb 2019)

(a) Definitions. As used in this clause-

"Information technology" (see 40 U.S.C. 1110 (6)) means, in lieu of the definition at FAR 2.1, any equipment, or interconnected system(s) or subsystem(s) of equipment, that is used in the automatic acquisition, storage, analysis,

evaluation, manipulation, management, movement, control, display, switching, interchange, transmission, or reception of data or information by the agency.

(1) For purposes of this definition, equipment is used by an agency if the equipment is used by the agency directly or is used by a contractor under a contract with the agency that requires-

- (i) Its use; or
- (ii) To a significant extent, its use in the performance of a service or the furnishing of a product.

(2) The term "information technology" includes computers, ancillary equipment (including imaging peripherals, input, output, and storage devices necessary for security and surveillance), peripheral equipment designed to be controlled by the central processing unit of a computer, software, firmware and similar procedures, services (including support services), and related resources.

(3) The term "information technology" does not include any equipment acquired by a contractor incidental to a contract.

"Supply chain risk" means the risk that an adversary may sabotage, maliciously introduce unwanted function, or otherwise subvert the design, integrity, manufacturing, production, distribution, installation, operation, or maintenance of a covered system so as to surveil, deny, disrupt, or otherwise degrade the function, use, or operation of such system (see 10 U.S.C. 2339a).

(b) The Contractor shall mitigate supply chain risk in the provision of supplies and services to the Government.

(c) In order to manage supply chain risk, the Government may use the authorities provided by 10 U.S.C. 2339a. In exercising these authorities, the Government may consider information, public and non-public, including all-source intelligence, relating to a Contractor's supply chain.

(d) If the Government exercises the authority provided in 10 U.S.C. 2339a to limit disclosure of information, no action undertaken by the Government under such authority shall be subject to review in a bid protest before the Government Accountability Office or in any Federal court.

27. DFARS 252.243-7002 REQUESTS FOR EQUITABLE ADJUSTMENT (Dec 2012)

(a) The amount of any request for equitable adjustment to contract terms shall accurately reflect the contract adjustment for which the Contractor believes the Government is liable. The request shall include only costs for performing the change, and shall not include any costs that already have been reimbursed or that have been separately claimed. All indirect costs included in the request shall be properly allocable to the change in accordance with applicable acquisition regulations.

(b) In accordance with 10 U.S.C. 2410(a), any request for equitable adjustment to contract terms that exceeds the simplified acquisition threshold shall bear, at the time of submission, the following certificate executed by an individual authorized to certify the request on behalf of the Contractor:

I certify that the request is made in good faith, and that the supporting data are accurate and complete to the best of my knowledge and belief.

(Official's Name)

(Title)

____(c) The certification in paragraph (b) of this clause requires full disclosure of all relevant facts, including----

(1) Certified cost or pricing data if required in accordance with subsection 15.403-4 of the Federal Acquisition Regulation (FAR); and

(2) Data other than certified cost or pricing data, in accordance with subsection 15.403-3 of the FAR, including actual cost data and data to support any estimated costs, even if certified cost or pricing data are not required.

(d) The certification requirement in paragraph (b) of this clause does not apply to----

(1) Requests for routine contract payments; for example, requests for payment for accepted supplies and services, routine vouchers under a cost-reimbursement type contract, or progress payment invoices; or

(2) Final adjustment under an incentive provision of the contract.

28. DFARS 252.244-7000 SUBCONTRACTS FOR COMMERCIAL ITEMS (Oct 2020)

(a) The Contractor is not required to flow down the terms of any Defense Federal Acquisition Regulation Supplement (DFARS) clause in subcontracts for commercial items at any tier under this contract, unless so specified in the particular clause.

(b) While not required, the Contractor may flow down to subcontracts for commercial items a minimal number of additional clauses necessary to satisfy its contractual obligation.

(c) (1) In accordance with 10 U.S.C. 2380b, the Contractor shall treat as commercial items any items valued at less than \$10,000 per item that were purchased by the Contractor for use in the performance of multiple contracts with the Department of Defense and other parties and are not identifiable to any particular contract when purchased.

(2) The Contractor shall ensure that any items to be used in performance of this contract, that are treated as commercial items pursuant to paragraph (c)(1) of this clause, meet all terms and conditions of this contract that are applicable to commercial items in accordance with the clause at Federal Acquisition Regulation 52.244-6 and paragraph (a) of this clause.

(d) The Contractor shall include the terms of this clause, including this paragraph (c), in subcontracts awarded under this contract, including subcontracts for the acquisition of commercial items.

29. DFARS 252.246-7003 NOTIFICATION OF POTENTIAL SAFETY ISSUES (Jun 2013)

(a) Definitions. As used in this clause

"Credible information" means information that, considering its source and the surrounding circumstances, supports a reasonable belief that an event has occurred or will occur.

"Critical safety item" means a part, subassembly, assembly, subsystem, installation equipment or support equipment for a system that contains a characteristic, any failure, malfunction, or absence of which could have a safety impact.

"Safety impact" means the occurrence of death, permanent total disability, permanent partial disability, or injury or occupational illness requiring hospitalization; loss of a weapon system; or property damage exceeding \$1,000,000.

"Subcontractor" means any supplier, distributor, vendor, or firm that furnishes supplies or services to or for the Contractor or another subcontractor under this contract.

(b) The Contractor shall provide notification, in accordance with paragraph (c) of this clause, of

(1) All nonconformances for parts identified as critical safety items acquired by the Government under this contract; and

(2) All nonconformances or deficiencies that may result in a safety impact for systems, or subsystems, assemblies, subassemblies, or parts integral to a system, acquired by or serviced for the Government under this contract.

(c) The Contractor

(1) Shall notify the Administrative Contracting Officer (ACO) and the Procuring Contracting Officer (PCO) as soon as practicable, but not later than 72 hours, after discovering or acquiring credible information concerning nonconformances and deficiencies described in paragraph (b) of this clause; and

(2) Shall provide a written notification to the ACO and the PCO within 5 working days that includes

- (i) A summary of the defect or nonconformance;
- (ii) A chronology of pertinent events;
- (iii) The identification of potentially affected items to the extent known at the time of notification;
- (iv) A point of contact to coordinate problem analysis and resolution; and
- (v) Any other relevant information.

(d) The Contractor

(1) Is responsible for the notification of potential safety issues occurring with regard to an item furnished by any subcontractor; and

(2) Shall facilitate direct communication between the Government and the subcontractor as necessary.

(e) Notification of safety issues under this clause shall be considered neither an admission of responsibility nor a release of liability for the defect or its consequences. This clause does not affect any right of the Government or the Contractor established elsewhere in this contract.

(f)(1) The Contractor shall include the substance of this clause, including this paragraph (f), in subcontracts for

- (i) Parts identified as critical safety items;
- (ii) Systems and subsystems, assemblies, and subassemblies integral to a system; or
- (iii) Repair, maintenance, logistics support, or overhaul services for systems and subsystems, assemblies, subassemblies, and parts integral to a system.

(2) For those subcontracts, including subcontracts for commercial items, described in paragraph (f)(1) of this clause, the Contractor shall require the subcontractor to provide the notification required by paragraph (c) of this clause to

- (i) The Contractor or higher-tier subcontractor; and
- (ii) The ACO and the PCO, if the subcontractor is aware of the ACO and the PCO for the contract.

30. DFARS 252.246-7004 SAFETY OF FACILITIES, INFRASTRUCTURE, AND EQUIPMENT FOR MILITARY OPERATIONS (Oct 2010)

(a) Definition. "Discipline Working Group," as used in this clause, means representatives from the DoD Components, as defined in MIL-STD-3007F, who are responsible for the unification and maintenance of the Unified Facilities Criteria (UFC) documents for a particular discipline area.

(b) The Contractor shall ensure, consistent with the requirements of the applicable inspection clause in this contract, that the facilities, infrastructure, and equipment acquired, constructed, installed, repaired, maintained, or operated under this contract comply with Unified Facilities Criteria (UFC) 1-200-01 for

- (1) Fire protection;
- (2) Structural integrity;
- (3) Electrical systems;
- (4) Plumbing;
- (5) Water treatment;
- (6) Waste disposal; and
- (7) Telecommunications networks.

(c) The Contractor may apply a standard equivalent to or more stringent than UFC 1-20001 upon a written determination of the acceptability of the standard by the Contracting Officer with the concurrence of the relevant Discipline Working Group.

31. DFARS 252.247-7023 TRANSPORTATION OF SUPPLIES BY SEA - BASIC (Feb 2019)

(a) Definitions. As used in this clause -

"Components" means articles, materials, and supplies incorporated directly into end products at any level of manufacture, fabrication, or assembly by the Contractor or any subcontractor.

"Department of Defense" (DoD) means the Army, Navy, Air Force, Marine Corps, and defense agencies.

"Foreign-flag vessel" means any vessel that is not a U.S.-flag vessel.

"Ocean transportation" means any transportation aboard a ship, vessel, boat, barge, or ferry through international waters

"Subcontractor" means a supplier, materialman, distributor, or vendor at any level below the prime contractor whose contractual obligation to perform results from, or is conditioned upon, award of the prime contract and who is performing any part of the work or other requirement of the prime contract.

"Supplies" means all property, except land and interests in land, that is clearly identifiable for eventual use by or owned by the DoD at the time of transportation by sea.

(i) An item is clearly identifiable for eventual use by the DoD if, for example, the contract documentation contains a reference to a DoD contract number or a military destination.

(ii) "Supplies" includes (but is not limited to) public works, buildings and facilities ships; floating equipment and vessels of every character, type, and description, with parts, subassemblies, accessories, and equipment; machine tools; material; equipment; stores of all kinds; end items; construction materials; and components of the foregoing.

"U.S.-flag vessel" means a vessel of the United States or belonging to the United States, Required shipping date; including any vessel registered or having national status under the laws of the United States.

(b)(1) The Contractor shall use U.S.-flag vessels when transporting any supplies by sea under this contract.

(2) A subcontractor transporting supplies by sea under this contract shall use U.S.-flag vessels if-

(i) This contract is a construction contract; or

(ii) The supplies being transported are-

(A) Noncommercial items; or

(B) Commercial items that-

(1) The Contractor is reselling or distributing to the Government without adding value (generally, the Contractor does not add value to items that it subcontracts for f.o.b. destination shipment);

(2) Are shipped in direct support of U.S. military contingency operations, exercises, or forces deployed in humanitarian or peacekeeping operations; or

(3) Are commissary or exchange cargoes transported outside of the Defense Transportation System in accordance with 10 U.S.C. 2643.

(c) The Contractor and its subcontractors may request that the Contracting Officer authorize shipment in foreign-flag vessels, or designate available U.S.-flag vessels, if the Contractor or a subcontractor believes that-

(1) U.S.-flag vessels are not available for timely shipment;

(2) The freight charges are inordinately excessive or unreasonable; or

(3) Freight charges are higher than charges to private persons for transportation of like goods.

(d) The Contractor must submit any request for use of foreign-flag vessels in writing to the Contracting Officer at least 45 days prior to the sailing date necessary to meet its delivery schedules. The Contracting Officer will process requests submitted after such date(s) as expeditiously as possible, but the Contracting Officer's failure to grant approvals to meet the shipper's sailing date will not of itself constitute a compensable delay under this or any other clause of this contract. Requests shall contain at a minimum-

(1) Type, weight, and cube of cargo;

(2) Required shipping date;

(3) Special handling and discharge requirements;

(4) Loading and discharge points;

(5) Name of shipper and consignee;

(6) Prime contract number; and

(7) A documented description of efforts made to secure U.S.-flag vessels, including points of contact (with names and telephone numbers) with at least two U.S.-flag carriers contacted. Copies of telephone notes, telegraphic and facsimile message or letters will be sufficient for this purpose.

(e) The Contractor shall, within 30 days after each shipment covered by this clause, provide the Contracting Officer and the Maritime Administration, Office of Cargo Preference, U.S. Department of Transportation, 400 Seventh Street SW, Washington, DC 20590, one copy of the rated on board vessel operating carrier's ocean bill of lading, which shall contain the following information-

- (1) Prime contract number;
- (2) Name of vessel;
- (3) Vessel flag of registry;
- (4) Date of loading;
- (5) Port of loading;
- (6) Port of final discharge;
- (7) Description of commodity;
- (8) Gross weight in pounds and cubic feet if available;
- (9) Total ocean freight in U.S. dollars; and
- (10) Name of steamship company.

(f) If this contract exceeds the simplified acquisition threshold, the Contractor shall provide with its final invoice under this contract a representation that to the best of its knowledge and belief

- (1) No ocean transportation was used in the performance of this contract;
- (2) Ocean transportation was used and only U.S.-flag vessels were used for all ocean shipments under the contract;
- (3) Ocean transportation was used, and the Contractor had the written consent of the Contracting Officer for all foreign-flag ocean transportation; or

(4) Ocean transportation was used and some or all of the shipments were made on foreign-flag vessels without the written consent of the Contracting Officer. The Contractor shall describe these shipments in the following format:

ITEM DESCRIPTION	CONTRACT LINE ITEMS	QUANTITY TOTAL
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(g) If this contract exceeds the simplified acquisition threshold and the final invoice does not include the required representation, the Government will reject and return it to the Contractor as an improper invoice for the purposes of the Prompt Payment clause of this contract. In the event there has been unauthorized use of foreign-flag vessels in the performance of this contract, the Contracting Officer is entitled to equitably adjust the contract, based on the unauthorized use.

(h) If the Contractor indicated in response to the solicitation provision, Representation of Extent of Transportation by Sea, that it did not anticipate transporting by sea any supplies; however, after the award of this contract, the Contractor learns that supplies will be transported by sea, the Contractor shall-

- (1) Notify the Contracting Officer of that fact; and
- (2) Comply with all the terms and conditions of this clause.

(i) In the award of subcontracts for the types of supplies described in paragraph (b)(2) of this clause, including subcontracts for commercial items, the Contractor shall flow down the requirements of this clause as follows:

(1) The Contractor shall insert the substance of this clause, including this paragraph (i), in subcontracts that exceed the simplified acquisition threshold in Part 2 of the Federal Acquisition Regulation.

(2) The Contractor shall insert the substance of paragraphs (a) through (e) of this clause, and this paragraph (i), in subcontracts that are at or below the simplified acquisition threshold in Part 2 of the Federal Acquisition Regulation.

32. AF 5352.201-9101 OMBUDSMAN (Oct 2019)

(a) An ombudsman has been appointed to hear and facilitate the resolution of concerns from offerors, potential offerors, and others for this acquisition. When requested, the ombudsman will maintain strict confidentiality as to the source of the concern. The existence of the ombudsman does not affect the authority of the program manager, contracting officer, or source selection official. Further, the ombudsman does not participate in the evaluation of proposals, the source selection process, or the adjudication of protests or formal contract disputes. The ombudsman may refer the interested party to another official who can resolve the concern.

(b) Before consulting with an ombudsman, interested parties must first address their concerns, issues, disagreements, and/or recommendations to the contracting officer for resolution. Consulting an ombudsman does not alter or postpone the timelines for any other processes (e.g., agency level bid protests, GAO bid protests, requests for debriefings, employee-employer actions, contests of OMB Circular A-76 competition performance decisions).

(c) If resolution cannot be made by the contracting officer, the interested party may contact the ombudsman, ESC Ombudsman
Bldg 1606
9 Eglin Street
Hanscom AFB, MA 01731
Telephone #: 781-225-1628
Facsimile #: 781-225-2250

E-Mail: ESC.Ombudsman@hanscom.af.mil. Concerns, issues, disagreements, and recommendations that cannot be resolved at the Center/MAJCOM/DRU/SMC ombudsman level, may be brought by the interested party for further consideration to the Air Force ombudsman, Associate Deputy Assistant Secretary (ADAS) (Contracting), SAF/AQC, 1060 Air Force Pentagon, Washington DC 20330-1060, phone number (571) 256-2395, facsimile number (571) 256-2431.

(a) The ombudsman has no authority to render a decision that binds the agency.

(b) Do not contact the ombudsman to request copies of the solicitation, verify offer due date, or clarify technical requirements. Such inquiries shall be directed to the Contracting Officer

DOCUMENT	PGS	DATE	TITLE
ATTACHMENT 1	9	12 SEP 2021	STATEMENT OF WORK

OraSure Technologies, Inc Industrial Base Expansion
Statement of Work (SOW)
14 Sep 2021

1. SCOPE

This project will expand the increase production capacity of COVID-19 Rapid Antigen Self-Tests by +100M test kits annually or 8.3M test kits per month.

2. BACKGROUND

The World Health Organization declared a pandemic due to the worldwide outbreak of COVID-19 caused by the novel SARS-CoV-2 virus and the President of the United States declared a national emergency associated with this pandemic. The COVID-19 pandemic has created a requirement for widely available, accurate, easy to use, Point of Care (POC) testing technologies with the potential for in-home use in order to enable Americans to seek care, begin self-isolation, or quarantine sooner, and to help stop the spread of the virus.

Multiple government agencies, including the Department of Health and Human Services (HHS), are working to address immediate COVID-19 testing needs. This effort will be conducted under the Health Care Enhancement Act (HCEA) to expand the domestic production of COVID-19 Rapid Antigen Self-Tests.

Currently, the Contractor has the capability and capacity to produce COVID-19 Rapid Antigen Self-Tests, at 100M kits per year at their factory OraSure Technologies Inc. in Bethlehem, Pennsylvania. In order to meet this domestic demand. OraSure Technologies Inc. is looking at increasing production capacity further by an additional 100M kits per year [***]. This effort will require additional [***] equipment to be purchased as well as modification done to the existing factory for increasing production capacity. This effort will replicate existing proven manufacturing process with more [***], made at identified [***] manufacturer in the U.S. for the U.S. market.

3. REQUIREMENTS

The Contractor shall employ its existing program management practices and policies to manage and implement this effort. The Contractor shall maintain ultimate responsibility for the implementation of contract requirements when sub-Contractors are used to service or implement those requirements.

3.1. Program Management, Administration, and Reporting

3.1.1. Kick-Off / Pre-Proposal Meeting. The Contractor shall conduct a Kick-Off / Pre-Proposal meeting not later than 10 business days after Contract Award. The contractor shall present an initial, detailed program schedule at the meeting. The scope of the meeting shall include, but not be limited to a review of: Requirements, manufacturing certifications being followed, expected facility assembly line layouts, list of suppliers, and program schedule including resource allocation for each task. The exact time of this meeting will be mutually agreed upon by OraSure and AFLCMC/HBS. The post award minutes will be captured by OraSure (A001).

3.1.2. Schedule. The Contractor shall generate and deliver a program schedule displaying the planned and actual start dates, duration, and completion dates of all key program activities and deliver a monthly program status report (A003)

3.1.3. Status Reporting. The Contractor shall participate as a member of an Integrated Product Team (IPT) with the AFLCMC/HBS team. The Contractor shall conduct weekly IPT conference calls to convey program status and discuss/resolve any open program issues. Contractor will provide meeting minutes from the Bi-Weekly IPT meetings (**A002**) In support of installment payment plan execution, the Contractor shall generate and deliver on a monthly basis, a top level expenditure report which provides percentage of completion of the project.

3.1.4. The Contractor shall track and report actual and forecasted monthly expenditures against the baseline (**A004**).

3.1.5. Certifications. The Contractor shall ensure planning, execution, and follow through regarding all necessary certifications of proposed facility and production equipment upgrades to comply with appropriate local, state, and federal regulations.

3.1.6. Risk Management. The Contractor shall identify and actively manage project risks, to include, but not limited to, supply chain risks. The Contractor should notify the Government, as soon as possible, where it may be able to assist in risk mitigation.

Contractors will also be required to report supply chain data on a on a bimonthly basis no later than the 1st and 15th of each month (**A005**). The purpose of this reporting is to provide situational awareness to the supply chains and logistics that may impact elements of the contract timeline or capacities. In the event of a potential or realized risk or constraint, contractors shall report the situation to the JRAC as early as possible for awareness and support. Specific questions that will be required to be answered are below:

Supply Chain Bimonthly Reporting

- Weekly production (product, quantity)
- Weekly production capacity
- Equipment expansion status (lines, machines, testing status)
- Status of facility procurement, construction, and/or renovation (including permits, construction material, and project timeline updates)
- Primary suppliers of material and product components
- Alternate suppliers of material and product components

Supply Chain Resources Inquiry (risk or constraint)

- Are you currently experiencing or anticipating any supply chain issues?*
- What product?
- What is the products part number and supplier?
- Is this a sole source supplier?
- What is this product used for?
- What is the original lead time?
- What is the lead time with the delay?
- What are the impacts of this delay?
- *Including unplanned global or regional catastrophes

3.2. Technical

3.2.1. Facility Upgrades. The Contractor shall design, procure, and implement production facility upgrades to accommodate the installation and the efficient, effective employment of the production equipment cited in section

3.2.2. Facility modifications may include, but are not limited to, upgrades to the following:

- [***]
- [***]
- [***]
- [***]
- [***]
- [***]
- [***]
- [***]
- [***]
- [***]
- [***]

The purchase, delivery, and installation of this equipment will be documented in the Bi- Monthly project schedule (A003). The contractor will provide a list of each machine in the productions process that the government will be funding.

3.2.2. Production Machinery. The Contractor shall procure / produce the following equipment:

- [***] equipment

Factory Acceptance Test/ Site Acceptance Test. Qualification of the production process (manually and automated) shall be **FAT (Factory Acceptance Test)** and **SAT (Site Acceptance Test)**.

FAT (Factory Acceptance Test): Verify all components intended to be used for production of the product performance according to requirements.

SAT (Site Factory Test): Verify production facility and equipment placed at the final production location is complete and according to requirements. SAT is combined with the installation Qualification (IQ).

Contractor will satisfy the conditions and meet the parameters defined by standard operating procedures (SOP) for the product as covered by their Quality System, good manufacturing practices (GMP) and as required by FDA.

3.3. Equipment Title

While the Government shall retain title to all Government Furnished Property throughout the term of the Contract in accordance with FAR 52.245-1, unless otherwise provided in the contract, title to all real Property, equipment and tangible personal property acquired, fabricated, or otherwise provided by the Contractor for performance of this contract shall vest with the Contractor upon completion of the requirements of this Contract, as determined by the Contracting Officer and a notice of completion is provided to the Contractor, or upon termination of this Contract, at which time all rights and legal obligations of the Government

regarding such property shall cease. During the time in which the Government retains title to all real property and equipment purchased under this Contract, the Contractor shall have unrestricted, exclusive right to possess, operate, maintain, improve, and use that equipment at no cost.

3.4. Acceptance and Verification

Government acceptance will be provided in writing via DD250 and be based on evidence of successful completion of all tests in Section 3.2.2 and verification (via demonstration or analysis) that Contractor's upgraded production facilities and purchased equipment are capable of producing the required COVID-19 Rapid Antigen Self-Tests per month. The Contractor's increased production capacity is the ultimate goal of this effort; the Government is not taking possession of any equipment.

The contractor shall submit deliverables for each Contract Line Item/task as identified in Attachment 1 to this document.

At conclusion of installation and operation of the [***] completing validation and verification testing, the company will provide a Final Report including list of all equipment (with system part numbers and source location), any warranties on parts, facility drawings showing layout of equipment, proof of Verification of product performance (handling and performance) on OraSure COVID-19 Rapid Antigen Self-Tests according to requirements to confirm product quality (A006).

3.5. Potential Future Transfer of Contract

This contract was initially issued by the Department of the Air Force using authorities and clauses required by the Air Force Federal Acquisition Regulation Supplement (AFFARS) and the Defense Federal Acquisition Regulation Supplement (DFARS). The parties recognize this contract may be transferred to an agency outside the Department of the Air Force during performance.

4. REQUIRED REPORTS

The Contractor shall submit the following required reports:

Report Number	Report Name	Document Description	Submittals Due	Format
A001	Contract Award Minutes	The contractor shall generate meeting minutes to include, but not limited to, decisions, action items and next steps.	5 days after Post- Award Kick-Off Meeting	Microsoft Word
A002	Bi-Monthly IPT Minutes	The contractor shall generate meeting minutes to include, but not limited to, decisions, action items, and next steps.	Bi-Monthly, Submit	Microsoft Word
A003	Schedule	The contractor shall generate and provide a schedule with tasks identified by start and finish dates; indication of task progress to date; and brief explanation for any tasks behind schedule.	Bi-Monthly, Submit	Microsoft Project
A004	Expenditure Report	The Contractor shall track and report actual and forecasted monthly expenditures against the baseline.	Monthly, Submit the 5 th day of the month	Microsoft Word
A005	Status Report	The contractor shall generate and provide a status report to include a discussion of: a. the risks and their mitigation b. issues and their proposed resolution c. successes d. supply chain data	Bi-Monthly, Submit the 1st and 15th of the month	Microsoft Word
A006	Test Report	The contractor shall report on the results of tests conducted on each piece of installed production and packaging equipment. The contractor shall verify each piece of installed equipment is capable of producing up to its design limits.	10 days after test	Microsoft Word

ATTACHMENT 1: CONTRACT LINE ITEM DELIVERABLES

Each deliverable noted shall be submitted to the Government and used as confirmation of task completion and payment release.

CLIN No	SubCLIN	Item	Deliverable
0001		Equipment Line Expansion	
	0001AA	Equipment Order Group 1	Ordering of Group 1 equipment (as defined in the SOW) as evidenced by a procurement document.
	0001AB	Equipment Order Group 2	Ordering of Group 2 equipment (as defined in the SOW) as evidenced by a procurement document.
	0001AC	Equipment Order Group 3	Ordering of Group 3 equipment (as defined in the SOW) as evidenced by a procurement document.
	0001AD	Equipment Group 1 - Design Review/Material Order	Design finalized and signed off. Vendor will invoice for design acceptance and material order
	0001AE	Equipment Group 2 - Design Review/Material Order	Design finalized and signed off. Vendor will invoice for design acceptance and material order
	0001AF	Equipment Group 3 - Design Review/Material Order	Vendor will invoice for material order.
	0001AG	Equipment Group 1 – [***]	Report documenting [***] Equipment in Group 1
	0001AH	Equipment Group 2 - [***]	Report documenting [***] for Equipment in Group 2
	0001AJ	Equipment Group 3 - [***]	Report documenting [***] for Equipment in Group 3
	0001AK	Equipment Group 1 - [***]	Report documenting [***] for Equipment in Group 1 / Validation completed by DCMA at the contractor's facility
	0001AL	Equipment Group 2 - [***]	Report documenting [***] for Equipment in Group 2 / Validation completed by DCMA at the contractor's facility
	0001AM	Equipment Group 3 - [***]	Report documenting [***] for Equipment in Group 3 / Validation completed by DCMA at the contractor's facility
	0001AN	Equipment Expansion Engineering/Program Management	Submission of Bi-Monthly Reports as identified in the Statement of Work
0002		[***] Expansion	
	0002AA	[***] Equipment Order	Ordering of [***] Equipment (as defined in the SOW) as evidenced by a procurement document.
	0002AB	First Article Inspection & Approval	Ordering of Design Review/Material (as defined in the SOW) as evidenced by a procurement document.
	0002AC	Completion of [***] Expansion	Progress Report describing completion of [***] Expansion including photos of equipment and summary of completion qualification / Validation completed by DCMA at the contractor's facility
0003		OraSure Facility Expansion	
	0003AA	[***] - Signing of Contract/Master Validation List	Report evidencing signed contract / Receipt of Master Validation List
	0003AB	[***] - Progress Report #1 ([***] Completion)	Report evidencing construction project status, updated construction project lead time, and confirmation documentation related to identified long lead time construction items
	0003AC	[***] - Progress Report #2 ([***] Completion)	Report evidencing construction project status, updated construction project lead time, and confirmation documentation related to identified long lead time construction items
	0003AD	[***] - Progress Report #3 ([***] Completion)	Report evidencing construction project status, updated construction project lead time, and confirmation documentation related to identified long lead time construction items
	0003AE	[***] - Commissioning of [***], Certified and Building Occupancy Received ([***] Completion)	Report evidencing completed [***] construction and qualification / Validation completed by DCMA at the contractor's facility

CLIN No	SubCLIN	Item	Deliverable
	0003AF	[***]	Report evidencing fully executed lease agreement
	0003AG	[***] - Progress Report #1 ([***] Completion)	Report evidencing construction project status, updated construction project lead time, and confirmation documentation related to identified long lead time construction items
	0003AH	[***] - Progress Report #2 ([***] Completion)	Report evidencing construction project status, updated construction project lead time, and confirmation documentation related to identified long lead time construction items
	0003AJ	[***] - Progress Report #3 ([***] Completion)	Report evidencing construction project status, updated construction project lead time, and confirmation documentation related to identified long lead time construction items
	0003AK	[***], Certified and Building Occupancy Received	Report evidencing completion of new building construction and qualification. Report will evidence [***] of construction activities including the Certificate of occupancy or equivalent/ Validation completed by DCMA at the contractor's facility
0004		Increased Production Capacity	
	0004AA	[***] test/month	Completion of approved equipment validation reports for the equipment required to produce a minimum of [***] tests per month
	0004AB	[***] tests/month	Completion of approved equipment validation reports for the equipment required to produce a minimum of [***] tests per month
	0004AC	[***] tests/month	Completion of approved equipment validation reports for the equipment required to produce a minimum of [***] tests per month. DCMA will observe the manufacturing process and verify the final production numbers of [***] tests per month.

Certification

I, Stephen S. Tang, 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: November 4, 2021

/s/Stephen S. Tang

Stephen S. Tang
President and Chief Executive Officer
(*Principal Executive Officer*)

Certification

I, Scott Gleason, 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: November 4, 2021

/s/ Scott Gleason

Scott Gleason
Interim 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 September 30, 2021 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I, Stephen S. Tang, 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/ Stephen S. Tang

Stephen S. Tang
President and Chief Executive Officer

November 4, 2021

**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 September 30, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Scott Gleason, Interim 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/ Scott Gleason

Scott Gleason
Interim Chief Financial Officer

November 4, 2021
