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

FORM 10-Q

QUARTERLY REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

FOR THE QUARTERLY PERIOD ENDED MARCH 31, 2017

OR

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

Commission file number: 01-37691

ARALEZ PHARMACEUTICALS INC.

(Exact Name of Registrant as Specified in its Charter)

British Columbia, Canada

(State or other jurisdiction of incorporation or organization)

98-1283375

(I.R.S. Employer Identification No.)

7100 West Credit Avenue, Suite 101, Mississauga, Ontario, Canada L5N 0E4

(Address of registrant's principal executive offices)

(905) 876-1118

(Registrant's telephone number, including area code)

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

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

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

Emerging growth company

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

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

As of the close of business on May 4, 2017 65,845,754 common shares (no par value per share) of the registrant were issued and outstanding.

Aralez Pharmaceuticals Inc.
Form 10-Q
For the Quarter Ended March 31, 2017

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PART I. FINANCIAL INFORMATION

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

ARALEZ PHARMACEUTICALS INC.
CONDENSED CONSOLIDATED BALANCE SHEETS (unaudited)
(in thousands, except share and per share data)

	<u>March 31, 2017</u>	<u>December 31, 2016</u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 73,729	\$ 64,943
Accounts receivable, net	9,048	20,405
Inventory	4,132	4,548
Prepaid expenses and other current assets	4,774	2,435
Total current assets	<u>91,683</u>	<u>92,331</u>
Property and equipment, net	8,172	7,316
Goodwill	77,384	76,694
Other intangible assets, net	332,306	340,194
Other long-term assets	1,017	842
Total assets	<u>\$ 510,562</u>	<u>\$ 517,377</u>
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 25,942	\$ 8,833
Accrued expenses	26,275	32,141
Short-term contingent consideration	10,266	10,430
Other current liabilities	6,288	5,870
Total current liabilities	<u>68,771</u>	<u>57,274</u>
Long-term debt, net	274,467	274,441
Deferred tax liability	3,305	3,273
Long-term contingent consideration	65,167	60,685
Other long-term liabilities	2,630	2,218
Total liabilities	<u>414,340</u>	<u>397,891</u>
Commitments and Contingencies		
Preferred shares, no par value; unlimited shares authorized, issuable in series; none outstanding	—	—
Common shares, no par value, unlimited shares authorized, 65,845,754 and 65,640,607 shares issued and outstanding at March 31, 2017 and December 31, 2016, respectively	—	—
Additional paid-in capital	355,268	352,336
Accumulated other comprehensive income	6,097	4,816
Accumulated deficit	<u>(265,143)</u>	<u>(237,666)</u>
Total shareholders' equity	<u>96,222</u>	<u>119,486</u>
Total liabilities and shareholders' equity	<u>\$ 510,562</u>	<u>\$ 517,377</u>

The accompanying unaudited notes are an integral part of the condensed consolidated financial statements.

ARALEZ PHARMACEUTICALS INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (unaudited)
(in thousands, except per share data)

	<u>Three Months Ended March 31,</u>	
	<u>2017</u>	<u>2016</u>
Revenues:		
Product revenues, net	\$ 6,686	\$ 3,565
Other revenues	19,283	4,492
Total revenues, net	<u>25,969</u>	<u>8,057</u>
Costs and expenses:		
Cost of product revenues (exclusive of amortization shown separately below)	2,756	2,538
Selling, general and administrative	30,846	37,459
Research and development	94	4,412
Amortization of intangible assets	8,513	1,272
Change in fair value of contingent consideration	4,443	—
Total costs and expenses	<u>46,652</u>	<u>45,681</u>
Loss from operations	(20,683)	(37,624)
Interest expense	(6,653)	(307)
Other income, net	411	4,797
Loss before income taxes	(26,925)	(33,134)
Income tax expense	552	654
Net loss	<u>\$ (27,477)</u>	<u>\$ (33,788)</u>
Basic net loss per common share	\$ (0.42)	\$ (0.65)
Diluted net loss per common share	\$ (0.42)	\$ (0.73)
Shares used in computing basic net loss per common share	65,690	52,156
Shares used in computing diluted net loss per common share	65,690	52,491

The accompanying unaudited notes are an integral part of the condensed consolidated financial statements.

ARALEZ PHARMACEUTICALS INC.
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS (unaudited)
(in thousands)

	<u>Three Months Ended March 31,</u>	
	<u>2017</u>	<u>2016</u>
Net loss	\$ (27,477)	\$ (33,788)
Other comprehensive income:		
Foreign currency translation adjustments	1,281	9,700
Other comprehensive income	1,281	9,700
Total comprehensive loss	<u>\$ (26,196)</u>	<u>\$ (24,088)</u>

The accompanying unaudited notes are an integral part of the condensed consolidated financial statements.

ARALEZ PHARMACEUTICALS INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (unaudited)
(in thousands)

	Three Months Ended March 31,	
	2017	2016
Operating Activities		
Net loss	\$ (27,477)	\$ (33,788)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation and amortization	8,875	1,311
Amortization of debt issuance costs	26	15
Change in fair value of contingent consideration	4,443	—
Unrealized foreign currency transaction (gain) loss	7	(154)
Gain of sale of property and equipment	(266)	—
Change in fair value of warrants liability	(24)	(4,581)
Share-based compensation expense	2,824	3,910
Benefit from deferred income taxes	—	(305)
Changes in operating assets and liabilities:		
Accounts receivable	11,421	(879)
Inventory	452	(533)
Prepaid expenses and other current assets	(1,302)	(1,424)
Accounts payable	17,109	460
Accrued expenses	(6,380)	(8,189)
Other liabilities	545	2,844
Other, net	235	—
Net cash provided by (used in) operating activities	<u>10,488</u>	<u>(41,313)</u>
Investing activities		
Acquisitions of businesses, net of cash acquired	—	(17,887)
Purchases of property and equipment	(1,461)	(399)
Other	(215)	—
Net cash used in investing activities	<u>(1,676)</u>	<u>(18,286)</u>
Financing activities		
Proceeds from issuance of convertible debt	—	75,000
Proceeds from issuance of common stock	—	75,000
Payment of debt and equity issuance costs	—	(673)
Payment of contingent consideration	(125)	—
Proceeds (payments) related to settlement of stock awards	108	(700)
Net cash (used in) provided by financing activities	<u>(17)</u>	<u>148,627</u>
Net increase in cash and cash equivalents	8,795	89,028
Effect of change in foreign exchange rates on cash and cash equivalents	(9)	182
Cash and cash equivalents at beginning of period	64,943	24,816
Cash and cash equivalents at end of period	<u>\$ 73,729</u>	<u>\$ 114,026</u>
Supplemental disclosure of cash flow information:		
Taxes paid	\$ 5	\$ —
Interest paid	\$ 4,719	\$ —

The accompanying unaudited notes are an integral part of the condensed consolidated financial statements.

ARALEZ PHARMACEUTICALS INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)
(tabular dollars and shares in thousands, except per share data)

1. ORGANIZATION, BASIS OF PRESENTATION AND ACCOUNTING POLICIES

Organization

Aralez Pharmaceuticals Inc., together with its wholly-owned subsidiaries (“Aralez” or the “Company”), is a global specialty pharmaceutical company focused on delivering meaningful products to improve patients’ lives while creating shareholder value by acquiring, developing and commercializing products primarily in cardiovascular, pain and other specialty areas. Aralez’s global headquarters is located in Mississauga, Ontario, Canada, its U.S. headquarters is located in Princeton, New Jersey, United States, and its Irish headquarters is located in Dublin, Ireland. The Company’s common shares are listed on the NASDAQ Global Market under the trading symbol “ARLZ” and on the Toronto Stock Exchange under the trading symbol “ARZ.” Aralez was formed for the purpose of facilitating the business combination of POZEN Inc., a Delaware corporation (“Pozen”), and Tribute Pharmaceuticals Canada Inc., a corporation incorporated under the laws of the Province of Ontario, Canada (“Tribute”), which closed on February 5, 2016.

On February 5, 2016, pursuant to an Agreement and Plan of Merger and Arrangement between Aralez Pharmaceuticals Inc., Pozen, Tribute and other related parties (as amended, the “Merger Agreement”), Aralez completed the acquisition of Tribute by way of a court approved plan of arrangement in a stock transaction with a purchase price of \$137.6 million made up of (i) \$115.1 million related to Tribute shares, equity awards and certain warrants outstanding and (ii) \$22.5 million in repayments of Tribute indebtedness. In connection with this transaction, Pozen and Tribute were combined under and became wholly-owned subsidiaries of Aralez (the “Merger”). Pursuant to Rule 12g-3(a) under the Securities Exchange Act of 1934, as amended, Aralez Pharmaceuticals Inc. is the successor issuer to Pozen.

On September 6, 2016, Aralez Pharmaceuticals Trading DAC, a wholly-owned subsidiary of Aralez (“Aralez Ireland”), acquired the U.S. and Canadian rights to Zontivity® (vorapaxar), pursuant to an asset purchase agreement (the “Zontivity Asset Purchase Agreement”) with Schering-Plough (Ireland) Company, an Irish private unlimited company and an affiliate of Merck & Co., Inc. (“Merck”).

On September 15, 2016, the Company announced that the U.S. Food and Drug Administration (“FDA”) approved Yosprala® (aspirin and omeprazole) for the secondary prevention of cardiovascular and cerebrovascular events in patients at risk for aspirin-associated gastric ulcers.

On October 31, 2016, Aralez Ireland acquired the U.S. rights to Toprol-XL® (metoprolol succinate) and its currently marketed authorized generic (the “AG”) pursuant to an asset purchase agreement (the “Toprol-XL Asset Purchase Agreement”) entered into between AstraZeneca AB (“AstraZeneca”), Aralez Ireland and Aralez Pharmaceuticals Inc.

Basis of Presentation and Consolidation

For financial reporting and accounting purposes, Pozen was the acquirer of Tribute pursuant to the Merger in a business combination that was completed on February 5, 2016. Aralez’s condensed consolidated financial statements for the three months ended March 31, 2016 include the results of Tribute only from the closing date of the Merger, but do not include the results of Zontivity or Toprol-XL and the AG as these acquisitions were completed on September 6, 2016 and October 31, 2016, respectively. Aralez’s results of operations for the three months ended March 31, 2017 include the results of Tribute, Zontivity and Toprol-XL and the AG (See Note 2).

The accompanying condensed consolidated financial statements are unaudited and have been prepared by Aralez in accordance with accounting principles generally accepted in the United States of America (“GAAP”), and pursuant to, and in accordance with, the instructions to Form 10-Q and Article 10 of Regulation S-X. The condensed consolidated balance sheet at December 31, 2016 was derived from audited financial statements, but certain information

and footnote disclosures normally included in the Company's annual financial statements have been condensed or omitted. These condensed consolidated financial statements should be read in conjunction with the audited financial statements contained in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission ("SEC") and with applicable Canadian securities regulators on SEDAR on March 13, 2017 (the "2016 Form 10-K").

The condensed consolidated financial statements, in the opinion of management, reflect all normal and recurring adjustments necessary for a fair statement of the Company's financial position and results of operations. Certain reclassifications with respect to the presentation of accrued expenses were made to prior year figures to conform with current year presentation.

The accompanying condensed consolidated financial statements include the accounts of Aralez Pharmaceuticals Inc. and its wholly-owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation. The results of operations for the interim periods are not necessarily indicative of the results of operations to be expected for any future period or the entire fiscal year.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires the extensive use of estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses and related disclosures. The most significant assumptions are employed in estimates used in determining values of: inventories; long-lived assets, including goodwill, in-process research and development ("IPR&D"), and other intangible assets; accrued expenses; contingent consideration; income taxes; share-based compensation expense; as well as estimates used in accounting for contingencies and revenue recognition. Actual results could differ from these estimates.

Concentration of Risk

Financial instruments, which potentially subject the Company to concentrations of credit risk, consist principally of cash and cash equivalents, including money market funds. The Company's investment policy places restrictions on credit ratings, maturities, and concentration by type and issuer. The Company is exposed to credit risk in the event of a default by the financial institutions holding its cash and cash equivalents to the extent recorded on the balance sheet.

The Company is also subject to credit risk from accounts receivable related to product sales and monitors its exposure within accounts receivable and records a reserve against uncollectible accounts receivable as necessary. The Company extends credit to pharmaceutical wholesale distributors and specialty pharmaceutical distribution companies, primarily in Canada and the United States, and to other international distributors. Customer creditworthiness is monitored and collateral is not required.

Cash and Cash Equivalents

Cash and cash equivalents consists of cash and short-term, interest-bearing instruments with original maturities of 90 days or less at the date of purchase.

Inventory

Inventories are stated at the lower of cost or net realizable value on a first-in, first-out basis. Cost is determined to be the purchase price for raw materials and the production cost, including materials, labor and indirect manufacturing costs, for work-in-process and finished goods. The Company analyzes its inventory levels quarterly and writes-down inventory that has become obsolete, inventory that has a cost basis in excess of its expected net realizable value, inventory in excess of expected sales requirements or inventory that fails to meet commercial sale specifications to cost of product revenues. Expired inventory is disposed of and the related costs are written off to cost of product revenues.

Intangible Assets

Goodwill

Goodwill relates to amounts that arose in connection with the acquisitions of Tribute, Zontivity and Toprol-XL and the AG. Goodwill represents the excess of the purchase price over the fair value of the net assets acquired when accounted for using the acquisition method of accounting for business combinations. Goodwill is not amortized but is evaluated for impairment on an annual basis, in the fourth quarter, or more frequently if an event occurs or circumstances change that would more-likely-than-not reduce the fair value of the Company's reporting unit below its carrying amount.

Other Intangible Assets, net

Other intangible assets consist of acquired technology rights. The Company amortizes its intangible assets using the straight-line method over their estimated economic lives. Costs to obtain, maintain and defend the Company's patents are expensed as incurred. The Company will evaluate the potential impairment of other intangible assets if events or changes in circumstances indicate that the carrying amount of the assets may not be fully recoverable or that the useful lives of these assets are no longer appropriate. Events giving rise to impairment are an inherent risk in the pharmaceutical industry and many factors cannot be predicted. Factors that are considered in deciding when to perform an impairment review include significant changes in forecasted projections for the asset or asset group for reasons including, but not limited to, significant under-performance of a product in relation to expectations, significant changes or planned changes in the Company's use of the assets, significant negative industry or economic trends, and new or competing products that enter the marketplace. The impairment test is based on a comparison of the undiscounted cash flows expected to be generated from the use of the asset group and its eventual disposition to the carrying value of the asset group. If impairment is indicated, the asset is written down by the amount by which the carrying value of the asset exceeds the related fair value of the asset with the related impairment charge recognized within the statements of operations. Such impairment charges may be material to the Company's results. The valuation techniques utilized in performing the initial valuation of other intangible assets or subsequent quantitative impairment tests incorporate significant assumptions and judgments to estimate the fair value. The use of different valuation techniques or assumptions could result in significantly different fair value estimates.

Contingent Consideration

Certain of the Company's business acquisitions involve the potential for future payment of consideration that is contingent upon the achievement of operational and commercial milestones and royalty payments on future product sales. The fair value of contingent consideration liabilities is determined at the acquisition date using unobservable inputs. These inputs include the estimated amount and timing of projected cash flows, the probability of success (achievement of the contingent event) and the risk-adjusted discount rate used to present value the probability-weighted cash flows. Subsequent to the acquisition date, at each reporting period, the contingent consideration liability is remeasured at current fair value with changes recorded in the consolidated statements of operations. Changes in any of the inputs may result in a significantly different fair value adjustment.

Revenue Recognition

Principal sources of revenue are (i) net revenues from sales of Zontivity, Toprol-XL and the AG, and Yosprala (ii) product sales from the product portfolio acquired with the Company's acquisition of Tribute, and (iii) royalty revenues from sales of VIMOVO by the Company's commercialization partners. In all instances, revenue is recognized only when the price is fixed or determinable, persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered, and collectibility of the resulting receivable is reasonably assured.

Product Sales

Revenues from the sale of products acquired by the Company in the Tribute acquisition are distributed through Canadian wholesalers to Canadian retail pharmacies and are recorded net of discounts, wholesaler fees, chargebacks, rebates, returns and allowances, and are recognized when legal title to the goods and risk of ownership has been passed

to the customer which in this case is the Canadian wholesaler. Discounts, wholesaler fees, chargebacks, rebates, returns and allowances are not significant for these product sales and are not expected to be significant in the future given the Canadian marketplace.

Revenues from the sale of Yosprala® in the United States are recorded on a sell through method since the Company does not have sufficient historical data to estimate returns. As such, the Company defers revenue and costs of inventory for all Yosprala products shipped to wholesalers in the United States until the product is sold through to the end customer. Revenue recorded from product sales of Yosprala in the United States was not significant during the first quarter of 2017. Product sales from Fibrivor® are recorded on a sell in method and were not significant during the first quarter of 2017.

All of the Company's products have a returns policy that allows the customer to return pharmaceutical products within a specified period of time both prior to and subsequent to the product's expiration date. The Company's estimate of the provision for returns for those products that use a sell in method is analyzed quarterly and is based upon many factors, including historical data of actual returns and analysis of the level of inventory in the distribution channel, if any. The Company believes that the reserves it has established are reasonable based upon current facts and circumstances. Applying different judgments to the same facts and circumstances could result in the estimated amount for reserves to vary. If actual results vary with respect to the Company's reserves, the Company may need to adjust its estimates, which could have a material effect on the Company's results of operations in the period of adjustment. To date, such adjustments have not been material.

Other Revenues

Other revenues principally include revenues from licensing arrangements with other biopharmaceutical companies (principally royalty revenues from VIMOVO), including milestones payments and royalties. Revenue from royalties is recognized when the Company has fulfilled the terms in accordance with contractual agreements and has no future obligation, and the amount of the royalty fee is determinable. Royalty revenue that is reasonably estimable and determinable is recognized based on estimates utilizing information reported to the Company by its commercialization partners.

Other revenues also include net revenues from sales of Zontivity, from its acquisition date, recognized net of related cost of product revenues and fees paid to Merck under a transition services agreement in effect through March 31, 2017. Similarly, the Company also includes net revenues from sales of Toprol-XL and the AG from its acquisition date, recognized net of related cost of product revenues and fees paid to AstraZeneca under a transition services agreement in effect through December 31, 2017 (as extended from July 31, 2017 pursuant to an amendment to the transition services agreement). The Company records these revenues net of related cost since it is not the principal in the arrangements and expects to record this revenue similar to a royalty arrangement until the Company is deemed to be the principal in the sales and marketing of these products, at which point it will record net sales and costs of revenue separately. Effective March 31, 2017, the Company will record revenues of Zontivity on a sell in method, which will be classified as product sales.

Income Taxes

The Company accounts for income taxes using the liability method in accordance with Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC"), Topic 740, "Income Taxes" ("ASC 740"). Deferred tax assets and liabilities are determined based on temporary differences between financial reporting and tax basis assets and liabilities and are measured by applying enacted rates and laws to taxable years in which differences are expected to be recovered or settled. Further, the effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that the rate changes. A valuation allowance is required when it is "more-likely-than-not" that all or a portion of deferred tax assets will not be realized. Since the Company's inception, substantial cumulative losses have been incurred and substantial and recurring losses may be incurred in future periods. The utilization of the loss carryforwards to reduce future income taxes will depend on the Company's ability to generate sufficient taxable income prior to the expiration of the loss carryforwards. In addition, the maximum annual use of net operating loss and research credit carryforwards is limited in certain situations where changes occur in stock ownership.

Aralez files federal and state income tax returns, as applicable, with the tax authorities in various jurisdictions including Canada, Ireland and the United States. Pozen is no longer subject to U.S. federal or North Carolina state income tax examinations by tax authorities for years before 2013. Tribute is no longer subject to Canadian income tax examinations by tax authorities for years before 2011. However, the loss and credit carryforwards generated by Pozen and Tribute may still be subject to change to the extent these losses and credits are utilized in a year that is subject to examination by tax authorities.

ASC 740 prescribes a comprehensive model for how a company should recognize, measure, present and disclose in its financial statements uncertain tax positions that the company has taken or expects to take on a tax return, including a decision whether to file or not file a return in a particular jurisdiction. The financial statements reflect expected future tax consequences of such positions presuming the taxing authorities' full knowledge of the position and all relevant facts. The Company recognizes any interest and penalties accrued related to unrecognized tax benefits as income tax expense.

Share-Based Compensation

The Company expenses the fair value of employee share-based compensation over the employees' service periods, which are generally the vesting period of the equity award. For awards with performance conditions granted, the Company recognizes compensation cost over the expected period to achieve the performance conditions, provided achievement of the performance conditions are deemed probable. Awards with market-based conditions are expensed over the service period regardless of whether achievement of the market condition is deemed probable or is ultimately achieved. Compensation expense is measured using the fair value of the award at the grant date, adjusted for estimated forfeitures.

In order to determine the fair value of option awards on the grant date, the Company uses the Black-Scholes option pricing model. Inherent in this model are assumptions related to expected share price volatility, estimated option life, risk-free interest rate and dividend yield. The expected share price volatility assumption is based on the historical volatility of the Company's common shares, which is obtained from public data sources. The expected life represents the weighted average period of time that share-based awards are expected to be outstanding giving consideration to vesting schedules, historical exercise patterns and post-vesting cancellations for terminated employees that have been exhibited historically, adjusted for specific factors that may influence future exercise patterns. The risk-free interest rate is based on factual data derived from public sources. The Company uses a dividend yield of zero as it has no intention to pay cash dividends in the foreseeable future. For performance-based awards with market conditions, the Company uses a Monte Carlo simulation model to determine the fair value of awards on the date of grant.

Determining the appropriate amount to expense for awards with performance conditions based on the achievement of stated goals requires judgment, including forecasting future performance results. The estimate of expense is revised periodically based on the probability of achieving the required performance targets and adjustments are made as appropriate. The cumulative impact of any revisions is reflected in the period of change. If any applicable financial performance goals are not met, no compensation cost is recognized and any previously recognized compensation cost is reversed.

In the first quarter of 2017, the Company adopted Accounting Standards Update ("ASU") 2016-09, Compensation – Stock Compensation (Topic 718), ("ASU 2016-09"). As a result of the adoption of ASU 2016-09, the Company recognizes, on a prospective basis, the impact of forfeitures when they occur, with no adjustment for estimated forfeitures, and recognizes excess tax benefits as a reduction of income tax expense regardless of whether the benefit reduces income taxes payable. Additionally, the Company now recognizes the cash flow impact of such excess tax benefits in operating activities in its condensed consolidated statements of cash flows. The classification of excess tax benefits on the statement of cash flows for the prior period have not been adjusted. There was no net impact on the Company's opening accumulated deficit upon application of this guidance using the modified retrospective transition method as the total cumulative-effect adjustment for previously deferred excess tax benefits was offset by a related change in the valuation allowance.

Fair Value Measurements

The accounting standard for fair value measurements defines fair value, establishes a framework for measuring fair value in accordance with GAAP, and requires detailed disclosures about fair value measurements. Under this standard, fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The valuation techniques are based on observable and unobservable inputs. Observable inputs reflect readily obtainable data from independent sources, while unobservable inputs reflect certain market assumptions. This standard classifies these inputs into the following hierarchy:

- *Level 1 Inputs* — Quoted prices for identical instruments in active markets.
- *Level 2 Inputs* — Quoted prices for similar instruments in active markets; quoted prices for identical or similar instruments in markets that are not active; and model-derived valuations whose inputs are observable or whose significant value drivers are observable.
- *Level 3 Inputs* — Instruments with primarily unobservable value drivers.

The fair value hierarchy level is determined by asset class based on the lowest level of significant input. In periods of market inactivity, the observability of prices and inputs may be reduced for certain instruments. This condition could cause an instrument to be reclassified between levels.

The carrying amount of cash and cash equivalents approximates its fair value due to the short-term nature of these amounts. The warrants liability is carried at fair value and is included within other current liabilities on the consolidated balance sheet at March 31, 2017. The significant unobservable inputs used in the fair value measurement of the Company's warrants liability, which uses a Black-Scholes valuation model, include the volatility of the Company's common shares and the expected term. The contingent consideration liability is also carried at fair value, and is recorded as separate short and long-term balances on the consolidated balance sheet at March 31, 2017. The significant unobservable inputs used in the fair value measurement of the Company's contingent consideration liability include the estimated amount and timing of projected cash flows, the probability of success (achievement of the contingent event) and the risk-adjusted discount rate used to present value the probability-weighted cash flows. The use of different inputs in the valuation of either the warrants liability or the contingent consideration liability could result in materially different fair value estimates.

Foreign Currency

The Company's reporting currency is the U.S. dollar. The assets and liabilities of the Company's subsidiaries that have a functional currency other than the U.S. dollar, primarily the Canadian dollar, are translated into U.S. dollars at the exchange rates in effect at the balance sheet date with the results of operations of subsidiaries translated at average exchange rates for the period. The cumulative foreign currency translation adjustment is recorded as a component of accumulated other comprehensive income within shareholders' equity.

Transactions in foreign currencies are remeasured into the functional currency of the relevant subsidiary at the exchange rate in effect at the date of the transaction. Any monetary assets and liabilities arising from these transactions are translated into the functional currency at exchange rates in effect at the balance sheet date or on settlement. Resulting gains and losses are recorded in other income, net within the condensed consolidated statements of operations.

Accumulated Other Comprehensive Income

A company is required to present, either on the face of the statement where net income is presented, in a separate statement of comprehensive income or in the notes, significant amounts reclassified out of accumulated other comprehensive income by the respective line items of net income. There were no amounts reclassified out of accumulated other comprehensive income for the three months ended March 31, 2017 and 2016. Other comprehensive income for the three months ended March 31, 2017 related to foreign currency translation adjustments.

Recent Accounting Pronouncements

In May 2014, the FASB issued ASU 2014-09, *Revenue from Contracts with Customers (Topic 606)*, which requires revenue recognition based on the transfer of promised goods or services to customers in an amount that reflects consideration Aralez expects to be entitled to in exchange for goods or services. In August 2015, the FASB issued updated guidance deferring the effective date of the revenue recognition standard. The new rules supersede prior revenue recognition requirements and most industry-specific accounting guidance. In March, April and May 2016, the FASB issued additional updated guidance, which clarifies certain aspects of the ASU and the related implementation guidance issued by the FASB-IASB Joint Transition Resource Group for Revenue Recognition. The ASU will be effective for Aralez in the first quarter of 2018, with either full retrospective or modified retrospective application required. Although the Company is still evaluating the full impact of this ASU, the Company expects to use a modified retrospective approach with the most significant impact of the new guidance relating to the recognition of variable consideration. The new guidance requires the Company to estimate variable consideration and include in revenue amounts for which it is probable that a significant revenue reversal will not occur. This may result in revenue being recognized earlier than under the current guidance, particularly for products where the Company uses the sell through revenue recognition model.

In August 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2014-15, *Presentation of Financial Statements—Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*, which defines management's responsibility to assess an entity's ability to continue as a going concern, and to provide related footnote disclosures if there is substantial doubt about its ability to continue as a going concern. The new standard is effective for the annual period ending after December 15, 2016, and for interim periods thereafter. The Company adopted ASU 2014-15 in the fourth quarter of 2016, which resulted in no change to the Company's financial statements. Additionally, the Company is required to perform quarterly evaluations to identify current conditions which may raise substantial doubt about the entity's ability to continue as a going concern within one year after the date that the financial statements are issued.

As noted in its liquidity disclosure, the Company's principal sources of liquidity are cash generated from the royalty payments received from its commercialization partners for net sales of VIMOVO; the operating income of Tribute; sales of Fibricor and its authorized generic, Yosprala, Zontivity, and Toprol-XL and the AG; and the financings completed on February 5, 2016 and October 31, 2016. The Company's principal liquidity requirements are for working capital; operational expenses; commercialization activities for products, including Yosprala, Zontivity, Toprol-XL and the AG, Fibricor and the Company's Canadian product portfolio, and product candidates; contractual obligations, including any royalty and milestone payments that may become due; capital expenditures; and debt service payments. As of March 31, 2017, the Company had approximately \$73.7 million of cash and cash equivalents which, together with cash expected to be generated from its business, it currently believes is sufficient to fund its operations for at least the next twelve months, including its principal liquidity requirements set forth above.

Since the merger with Tribute in February 2016, the Company has incurred significant net losses. The Company has incurred net losses of \$27.5 million for the three months ended March 31, 2017, and \$103.0 million for the year ended December 31, 2016. The Company's ability to become profitable and/or to generate positive cash from operations depends upon, among other things, its ability to generate revenues from sales of its products and prudently manage its expenses. New sources of product revenue have only recently been approved, in the case of Yosprala in the United States and Blexten in Canada, or acquired by the Company, in the case of Zontivity in the United States and Canada and Toprol-XL and the AG in the United States. If the Company does not generate sufficient product revenues, or prudently manage its expenses, its business, financial condition, cash flows and results of operations could be materially and adversely affected.

The Company has begun implementing a program of cost savings initiatives, which include a 32% reduction in its U.S. sales force and realignment of certain financial resources to support the launch of Zontivity, together with a significant decrease in marketing spend on Yosprala and other cost reductions across the business. In addition, the Company is actively exploring other initiatives, such as business development opportunities and refinancing options, to improve its future liquidity. There can be no assurances that these other initiatives will be available on reasonable terms, or at all. If the Company is not successful in any or all of these initiatives, or if the Company's future operations fail to

meet its current expectations, the Company's projected future liquidity may be limited, which may impact its assessment under this accounting standard in the future and could materially and adversely affect its business, financial condition, cash flows and results of operations.

In January 2016, the FASB issued ASU 2016-01, *Financial Instruments—Overall (Subtopic 825-10)*, which requires equity investments to be measured at fair value with changes in fair value recognized in net income. It allows an entity to choose to measure equity investments that do not have readily determinable fair values at cost minus impairment. It also simplifies the impairment assessment of equity investments without readily determinable fair values and eliminates the requirements to disclose the methods used to estimate fair value for instruments measured at amortized cost on the balance sheet. The amendments in the ASU are effective for Aralez in the first quarter of 2018. The Company does not expect the adoption to have a material impact on the consolidated financial statements.

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)*, which supersedes current lease accounting guidance. The primary difference between current GAAP and the new standard is the recognition of lease assets and lease liabilities by lessees for those leases classified as operating leases under current GAAP. The standard requires a modified retrospective approach upon adoption, with practical expedients that may be available to elect. The standard is effective for Aralez in the first quarter of 2019 and early adoption is permitted. The Company is evaluating the impact of the ASU on the consolidated financial statements.

In August 2016, the FASB issued ASU 2016-15, *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments*, providing additional guidance on eight specific cash flow classification issues. The goal of the ASU is to reduce diversity in practice of classifying certain items. The amendments in the ASU are effective for Aralez in the first quarter of 2018 using a retrospective transition method, and early adoption is permitted. The Company is evaluating the impact of the ASU on the consolidated financial statements.

In January 2017, the FASB issued ASU 2017-01, *Business Combinations (Topic 805): Clarifying the Definition of a Business*, in an effort to clarify the definition of a business with the objective of adding guidance to assist entities with evaluating whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses. The amendments of this ASU are effective for Aralez in the first quarter of 2018 on a prospective basis and early adoption is permitted.

2. BUSINESS AGREEMENTS

Agreements with AstraZeneca for Toprol-XL

On October 31, 2016, Aralez Ireland acquired the U.S. rights to Toprol-XL (metoprolol succinate) and the AG pursuant to the Toprol-XL Asset Purchase Agreement entered into between AstraZeneca, Aralez Ireland and Aralez Pharmaceuticals Inc. Toprol-XL is a cardioselective beta-blocker indicated for the treatment of hypertension, alone or in combination with other antihypertensives, the long term treatment of angina pectoris and treatment of stable, symptomatic (NYHA class II or III) heart failure of specific origins. The purchase price consists of (i) a payment of \$175 million by Aralez Ireland to AstraZeneca, which was made on the closing date of the acquisition; (ii) certain milestone payments payable by Aralez Ireland subsequent to the closing of the acquisition upon the occurrence of certain milestone events based on the annual aggregate net sales of Toprol-XL and the AG and other contingent events, which in no event will exceed \$48 million in the aggregate; (iii) royalty payments of (A) 15% of total quarterly net sales of Toprol-XL and any other authorized or owned generic version of Toprol-XL that is marketed, distributed or sold by or on behalf of, or under a license or sublicense from, Aralez (other than the AG), and (B) 15% of quarterly net sales of the AG, but for purposes of royalty payments and clause (B) only, net sales do not include the supply price paid for the AG by Aralez Ireland to AstraZeneca under the supply agreement entered into between Aralez Ireland and AstraZeneca in respect of the applicable period and (iv) a payment for the value of the finished inventory of Toprol-XL and the AG at closing of the transaction, not to exceed a cap specified in the Toprol-XL Asset Purchase Agreement.

On October 31, 2016, in connection with the Toprol-XL acquisition, Aralez Ireland entered into a Supply Agreement (the "Toprol-XL Supply Agreement") with AstraZeneca. Pursuant to the terms of the Toprol-XL Supply Agreement and except as otherwise expressly set forth therein, AstraZeneca will be the exclusive manufacturer and

supplier to Aralez Ireland of Toprol-XL and the AG, each in finished bottled form for exploitation and commercialization in the United States. The initial term of the Toprol-XL Supply Agreement is 10 years (the “Toprol-XL Supply Initial Term”). The Toprol-XL Supply Agreement will continue indefinitely following the expiration of the Toprol-XL Supply Initial Term unless terminated in accordance with its terms. Except in the case of certain uncured material breaches of the Toprol-XL Supply Agreement by Aralez Ireland or certain insolvency related events affecting Aralez Ireland, AstraZeneca may not terminate the Toprol-XL Supply Agreement unless it satisfies certain conditions related to, among other things, the transfer of technology. In addition to termination rights upon certain uncured material breaches of the Toprol-XL Supply Agreement by AstraZeneca or certain insolvency related events affecting AstraZeneca, Aralez Ireland may terminate the Toprol-XL Supply Agreement at any time following the Toprol-XL Supply Initial Term upon providing 12 months prior written notice to AstraZeneca. AstraZeneca also provides certain transition services to Aralez Ireland through December 31, 2017 (as extended from July 31, 2017) to facilitate the transition of the supply, sale and distribution of Toprol-XL and the AG, in exchange for compensation specified in the transition services agreement.

Agreement with the United States Government Regarding Toprol-XL

On February 23, 2017, Aralez Pharmaceuticals US Inc. (“Aralez US”), a Delaware company and a wholly-owned, indirect subsidiary of Aralez Pharmaceuticals Inc., entered into a Novation Agreement (the “Novation Agreement”) with AstraZeneca Pharmaceuticals LP (“AstraZeneca LP”) and the United States of America (the “Government”) pursuant to which all of the rights and responsibilities of AstraZeneca LP under that certain VA National Contract signed February 11, 2016 and effective April 29, 2016 between AstraZeneca LP and the Government were novated to Aralez US (as novated, the “VA Contract”). The Novation Agreement was entered into pursuant to the Toprol-XL Asset Purchase Agreement.

Under the VA Contract, Aralez US provides all requirements of certain pharmaceutical products containing metoprolol succinate as the active pharmaceutical ingredient at fixed prices for the U.S. Department of Veterans Affairs and certain other United States federal government agencies. The VA Contract has a one-year term expiring April 28, 2017, renewable at the option of the Government for four successive additional one year terms. The VA Contract is terminable at the convenience of the Government at any time. On April 6, 2017, Aralez US and the Government entered into a Modification of Contract with respect to the VA Contract, pursuant to which the Government exercised its first renewal option under the VA Contract, extending the term of the VA Contract by one year to April 28, 2018 with reduced pricing for the duration thereof. See Note 13 – Subsequent Events.

Agreements with Merck for Zontivity

On September 6, 2016, Aralez Ireland acquired the U.S. and Canadian rights to Zontivity (vorapaxar), pursuant to the Zontivity Asset Purchase Agreement with Merck. Zontivity represents an addition to the Company’s product portfolio in cardiovascular disease and is the first and currently the only approved therapy shown to inhibit the protease-activated receptor-1 (PAR-1), the primary receptor for thrombin, which is considered to be the most potent activator of platelets. The purchase price for Zontivity consists of (i) a payment of \$25 million by Aralez Ireland to Merck, which was made on the closing date of the acquisition, (ii) certain milestone payments payable by Aralez Ireland subsequent to the closing of the acquisition upon the occurrence of certain milestone events based on the annual aggregate net sales of Zontivity, any combination product containing vorapaxar sulphate and one or more other active pharmaceutical ingredients or any line extension thereof, which in no event will exceed \$80 million in the aggregate, and (iii) royalty payments in the low double digits based on the annual aggregate net sales of Zontivity, any combination product containing vorapaxar sulphate and one or more other active pharmaceutical ingredients or any line extension thereof.

Pursuant to the terms of the Zontivity Asset Purchase Agreement and certain ancillary agreements entered into in connection with the acquisition, Merck has agreed to supply Zontivity to Aralez Ireland for a period of up to three years following the closing of the acquisition (although, the packaging component must be transferred within one year). Merck also provided certain transition services to Aralez Ireland following the closing of the acquisition through March 31, 2017 to facilitate the transition of the supply, sale and distribution of Zontivity, including distributing Zontivity on behalf of Aralez Ireland in exchange for compensation specified in the transition services agreement. In addition, in connection with the foregoing transactions, Merck granted Aralez Ireland, among other things, (i) an

exclusive and royalty-free license to certain trademarks solely to exploit Zontivity in the U.S. and Canada and their respective territories, and (ii) an exclusive and royalty-free license to certain know-how solely in connection with the manufacture of Zontivity for exploitation in the U.S. and Canada and their respective territories.

Agreement with AstraZeneca/Horizon regarding VIMOVO®

In August 2006, the Company entered into a collaboration and license agreement, effective September 7, 2006 (the “Original AZ Agreement”), with AstraZeneca regarding the development and commercialization of proprietary fixed dose combinations of the proton pump inhibitor (“PPI”) esomeprazole magnesium with the non-steroidal anti-inflammatory drug (“NSAID”) naproxen in a single tablet for the management of pain and inflammation associated with conditions such as osteoarthritis and rheumatoid arthritis in patients who are at risk for developing NSAID-associated gastric ulcers. Under the terms of the Original AZ Agreement, the Company granted to AstraZeneca an exclusive, fee-bearing license, in all countries of the world except Japan, under the Company’s patents and know-how relating to combinations of gastroprotective agents and NSAIDs (other than aspirin and its derivatives). The Company developed VIMOVO with AstraZeneca pursuant to this collaboration arrangement, with AstraZeneca responsible for commercialization of VIMOVO.

During 2013, AstraZeneca decided to cease promotion and sampling of VIMOVO in certain countries, including the United States and all countries in Europe, other than Spain and Portugal, which have pre-existing contractual relationships with third parties. In November 2013, AstraZeneca divested of all of its rights, title and interest to develop, commercialize and sell VIMOVO in the United States to Horizon Pharma USA, Inc. (“Horizon”). In connection with this divestiture, in November 2013, the Company and AstraZeneca entered into an Amended and Restated Collaboration and License Agreement for the United States (the “U.S. Agreement”) and an Amended and Restated License and Collaboration Agreement for outside the United States and Japan (the “ROW Agreement”), which agreements collectively amended and restated the Original AZ Agreement (as amended prior to the date of the U.S. Agreement and ROW Agreement). With the Company’s consent pursuant to a letter agreement among the Company, AstraZeneca and Horizon, AstraZeneca subsequently assigned the U.S. Agreement to Horizon in connection with the divestiture. Further, the letter agreement establishes a process for AstraZeneca and Horizon to determine if certain sales milestones are achieved on a global basis and provides other clarifications and modifications required as a result of the contractual framework implemented among, or as otherwise agreed by, the parties. An additional \$260.0 million is potentially payable to the Company if such sales milestones are achieved.

Under the U.S. Agreement, Horizon is obligated to pay us a 10% royalty on net sales of VIMOVO and certain other products covered thereby in the United States. Pursuant to an amendment of the U.S. Agreement (the “Amendment to the U.S. Agreement”) between the Company and Horizon, the Company is guaranteed an annual minimum royalty amount of \$7.5 million each calendar year, provided that the patents owned by the Company which cover such products are in effect and certain types of competing products are not in the marketplace (including competing products entering pursuant to a license to enter the market prior to expiration of the applicable patents). The Amendment to the U.S. Agreement also provides that Horizon has assumed AstraZeneca’s right to lead the on-going Paragraph IV litigation relating to VIMOVO currently pending in the United States District Court for the District of New Jersey and will assume all patent-related defense costs relating to such litigation, including reimbursement up to specified amounts of the cost of any counsel retained by us, amends certain time periods for Horizon’s delivery of quarterly sales reports to the Company, and provides for quarterly update calls between the parties to discuss performance of VIMOVO and Horizon’s commercialization efforts.

Pursuant to the ROW Agreement, AstraZeneca retained the rights to commercialize VIMOVO and certain other products covered thereby outside of the United States and Japan and paid us a royalty of 6% on net sales within the applicable territory through 2015 and started paying us a royalty of 10% of net sales commencing in the first quarter of 2016.

The royalty rates above may be reduced due to the loss of market share as a result of certain competition inside and outside of the United States, as applicable (including competing products entering pursuant to a license to enter the market prior to expiration of the applicable patents). Furthermore, the Company’s right to receive royalties from AstraZeneca or Horizon, as applicable, expires on a country-by country basis upon the later of (a) expiration of the last-

to expire of certain patent rights related to the applicable product(s) in that country, and (b) ten years after the first commercial sale of such product(s) in such country. As the result of an unfavorable outcome in certain patent litigation in Canada, Mylan's generic naproxen/esomeprazole magnesium tablets recently became available in Canada. See Note 11 – Commitments and Contingencies, for more information.

Agreements with Patheon regarding Yosprala

In December 2011, the Company entered into a Manufacturing Services Agreement with Patheon Pharmaceuticals, Inc. ("Patheon"), as amended in July 2013 (as amended, the "Supply Agreement"), pursuant to which Patheon has agreed to manufacture, and the Company has agreed to purchase, a specified percentage of the Company's requirements of Yosprala 325/40 and Yosprala 81/40 for sale in the United States. The term of the Supply Agreement extends until December 31st of the fourth year after the date that is 60 days after the Company submits its first firm order to Patheon under the Supply Agreement (the "Initial Term"), and will automatically renew thereafter for periods of two years, unless terminated by either party upon 18 months' written notice prior to the expiration of the Initial Term or 12 months' written notice prior to the expiration of any renewal term. In addition to usual and customary termination rights which allow each party to terminate the Supply Agreement for material, uncured breaches by the other party, the Company can terminate the Supply Agreement upon 30 days' prior written notice if a governmental or regulatory authority takes any action or raises any objection that prevents the Company from importing, exporting, purchasing or selling Yosprala or if it is determined that the formulation or sale of Yosprala infringes any patent rights or other intellectual property rights of a third-party. The Company can also terminate the Supply Agreement upon 24 months' prior written notice if it licenses, sells, assigns or otherwise transfers any rights to commercialize Yosprala in the United States to a third-party. The Supply Agreement contains general and customary commercial supply terms and conditions, as well as establishes pricing, subject to annual adjustments, for bulk product and different configurations of packaged product.

Agreement to Acquire MFI

In June 2015, Tribute acquired Medical Futures Inc. ("MFI") pursuant to a Share Purchase Agreement between Tribute and the former shareholders of MFI ("MFI Purchase Agreement"). The MFI acquisition diversified Tribute's product portfolio with the addition of both marketed products, including Proferrin, and product candidates. The amounts payable pursuant to the MFI Purchase Agreement included (a) \$8.5 million (CAD) in cash on closing (including a \$0.2 million (CAD) deposit previously paid) to the former MFI shareholders, (b) \$5.0 million (CAD) through the issuance of 3,723,008 Tribute Shares to the former MFI shareholders, (c) \$5.0 million (CAD) in the form of a one-year unsecured convertible promissory note from Tribute to the former owner of MFI (the "MFI Note"), (d) retention payments of \$0.5 million (CAD) to MFI employees, (e) consent payments of \$3.35 million (CAD) and \$2.35 million (CAD) to the former MFI shareholders payable on receipt of certain third party consents, and (f) two payments of \$1.25 million (CAD) to the former MFI shareholders payable on regulatory approval of two product candidates, respectively, or change of control of Tribute. The MFI Note was repaid in June 2016. The \$3.35 million (CAD) consent payment was made in 2015 and the \$2.35 million (CAD) consent payment has not been made. The two \$1.25 million (CAD) payments became payable upon the closing of the Merger. One such payment was made in full to the former shareholders of MFI and the second was paid in part with the remainder offset in settlement of certain indemnity claims by the Company against the former shareholders of MFI, in each case in 2016.

Certain Other Agreements

Agreements with Sun Pharma and Frontida for Fibrivor®

In May 2015, Tribute Pharmaceuticals International Inc. ("TPII"), a Barbados corporation and a wholly-owned subsidiary of Tribute, acquired the U.S. rights to Fibrivor and its related authorized generic (collectively, the "Fibrivor Products") from a wholly-owned step-down subsidiary of Sun Pharmaceutical Industries Ltd. ("Sun Pharma"). Financial terms include a total payment of \$10.0 million of which approximately \$3.0 million was included as a liability assumed in the Merger and subsequently paid in May 2016. In connection with its acquisition of Fibrivor, TPII also entered into a supply agreement with Sun Pharma pursuant to which Sun Pharma agreed to manufacture and supply the Fibrivor Products to TPII. On June 3, 2016, Sun Pharma assigned the supply agreement to Frontida BioPharm, Inc. On June 30, 2016, TPII assigned its interest in the Fibrivor Products to Aralez Ireland.

Agreements with Novartis for Fiorinal®

In 2014, Tribute entered into an asset purchase agreement (the “Asset Purchase Agreement”) with Novartis AG and Novartis Pharma AG (collectively, “Novartis”) pursuant to which Tribute acquired from Novartis the Canadian rights to manufacture, market, promote, distribute and sell Fiorinal, Fiorinal C, Visken® and Viskazide® for the relief of pain from headache and for the treatment of cardiovascular conditions (the “Novartis Products”), as well as certain other assets relating to the Novartis Products, including certain intellectual property, marketing authorizations and related data, medical, commercial and technical information, and the partial assignment of certain manufacturing and supply agreements and tenders with third parties (the “Acquired Assets”). Tribute also assumed certain liabilities arising out of the Acquired Assets and the Licensed Assets (as defined below) after the acquisition, including product liability claims or intellectual property infringement claims by third parties relating to the sale of the Novartis Products by Tribute in Canada. In connection with the acquisition of the Acquired Assets, and pursuant to the terms of the Asset Purchase Agreement, Tribute concurrently entered into a license agreement with Novartis AG, Novartis Pharma AG and Novartis Pharmaceuticals Canada Inc., under which the Novartis entities agreed to license to Tribute certain assets relating to the Novartis Products, including certain intellectual property, marketing authorizations and related data, and medical, commercial and technical information (the “Licensed Assets”).

Agreement with Faes for Blexten™

In 2014, Tribute entered into an exclusive license and supply agreement with Faes Farma, S.A. (“Faes”), a Spanish pharmaceutical company, for the exclusive right to sell bilastine, a product for the treatment of allergic rhinitis and chronic idiopathic urticaria (hives) in Canada, which is now named Blexten. The exclusive license is inclusive of prescription and non-prescription rights for Blexten, as well as adult and pediatric presentations in Canada. On March 31, 2016, Tribute assigned its interest in Blexten to Aralez Ireland. Regulatory approval to sell Blexten in Canada was received from Health Canada in April 2016 and the Company began commercializing Blexten in Canada in December 2016. The Company will owe sales-based milestone payments of \$1.7 million to Faes if certain sales targets are met.

Agreement with Nautilus for Cambia®

In 2010, Tribute signed a license agreement with Nautilus Neurosciences, Inc. (“Nautilus”) for the exclusive rights to develop, register, promote, manufacture, use, market, distribute and sell Cambia in Canada. In 2011, Tribute and Nautilus executed the first amendment to the license agreement and in 2012 executed the second amendment to the license agreement. Up to \$6.0 million in sales-based milestone payments may be payable over time. Royalty rates are tiered and payable at rates ranging from 22.5% to 25.0% of net sales.

Agreement with Actavis for Bezalip® SR and Soriatane®

In 2008, Tribute signed a Sales, Marketing and Distribution Agreement with Actavis Group PTC ehf (“Actavis”) to perform certain sales, marketing, distribution, finance and other general management services in Canada in connection with the importation, marketing, sales and distribution of Bezalip SR and Soriatane (the “Actavis Products”). In 2010, a first amendment was signed with Actavis to grant Tribute the right and obligation to more actively market and promote the Actavis Products in Canada. In 2011, a second amendment was signed with Actavis that extended the term of the agreement, modified certain of the other terms of the agreement and increased Tribute’s responsibilities to include the day-to-day management of regulatory affairs, pharmacovigilance and medical information relating to the Actavis Products. Tribute pays Actavis a sales and distribution fee based on a percentage of the aggregate net sales of the products. In 2011, Tribute signed a Product Development and Profit Share Agreement with Actavis to develop, obtain regulatory approval of and market Bezalip SR in the United States. Aralez may owe a milestone payment of \$5.0 million to Actavis in the event that the Company pursues and obtains regulatory approval to market Bezalip SR in the U.S.

Agreements with GSK, Pernix and CII regarding MT 400 (including Treximet®)

In June 2003, the Company entered into an agreement with Glaxo Group Limited, d/b/a GlaxoSmithKline (“GSK”) for the development and commercialization of proprietary combinations of a triptan (5-HT_{1B/1D} agonist) and a

long-acting NSAID (the “GSK Agreement”). The combinations covered by the GSK Agreement are among the combinations of MT 400 (including Treximet®). Under the terms of the GSK Agreement, GSK had exclusive rights in the United States to commercialize all combinations which combine GSK’s triptans, including Imitrex® (sumatriptan succinate) or Amerge® (naratriptan hydrochloride), with a long-acting NSAID. The Company was responsible for development of the first combination product, while GSK provided formulation development and manufacturing.

In November 2011, the Company entered into a purchase agreement with CPPIB Credit Investments Inc. (“CII”), pursuant to which the Company sold, and CII purchased, the Company’s right to receive future royalty payments arising from U.S. sales of MT 400, including Treximet. By virtue of the agreement, the Company will receive a 20% interest in royalties, if any, paid on net sales of Treximet and such other products in the United States to CII relating to the period commencing in the second quarter of 2018.

In May 2014, the Company, GSK, CII and Pernix Therapeutics Holdings, Inc. (“Pernix”), entered into certain agreements in connection with GSK’s divestiture of all of its rights, title and interest to develop, commercialize and sell Treximet in the United States to Pernix. Upon the closing of the transaction in August 2014, with the Company’s consent, GSK assigned the GSK Agreement to Pernix. Pernix assumed the obligation to pay two sales performance milestones totaling up to \$80.0 million if certain sales thresholds are achieved as well as royalties on all net sales of marketed products until at least the expiration of the last-to-expire issued applicable patent based upon the scheduled expiration of currently issued patents. Pernix may reduce, but not eliminate, the royalty payable to the Company if generic competitors attain a pre-determined share of the market for the combination product, or if Pernix owes a royalty to one or more third parties for rights it licenses from such third parties to commercialize the product. Immediately following the closing of the transaction, the Company entered into an amendment to the GSK Agreement with Pernix. This amendment, among other things, amends the royalty provisions to provide for a guaranteed quarterly minimum royalty of \$4 million for the calendar quarters commencing in January 2015 and ending in March 2018 and requires that Pernix continue certain of GSK’s ongoing development activities and to undertake certain new activities, for which the Company will provide reasonable assistance. This amendment to the GSK Agreement also eliminates restrictions in the GSK Agreement on the Company’s right to develop and commercialize certain dosage forms of sumatriptan/naproxen combinations outside of the United States and permits the Company to seek approval for these combinations on the basis of the approved NDA for Treximet.

Agreement with Endo Regarding Toprol-XL AG

The Company is party to a Distribution Agreement with Endo Ventures Limited (“Endo”) pursuant to which Endo distributes the Toprol-XL AG (the “Toprol-XL AG Agreement”). The agreement was originally entered into by AstraZeneca with PAR Pharmaceutical, Inc. (“PAR”) in August 2006 and was assigned by PAR to Endo in February 2016 in connection with Endo International plc’s acquisition of PAR. AstraZeneca assigned such agreement to Aralez in connection with the Company’s acquisition of Toprol-XL and the AG in October 2016. Pursuant to the Toprol-XL AG Agreement, Endo has the exclusive rights in the United States to promote the AG, while Aralez retains the right to promote the branded Toprol-XL and to promote the AG to certain mail service pharmacy providers. Pursuant to the terms of the Toprol-XL AG Agreement, the Company supplies the AG product to Endo for a base purchase price, which ranges depending on dosage strength. In addition to the base purchase price, Endo pays to the Company, on a monthly basis, a deferred purchase price equal to a certain percentage of the specified profit of this business for the applicable period. The agreement expires at the end of 2017 and may be terminated by either party under certain circumstances, including performance measures.

3. BUSINESS COMBINATIONS AND ACQUISITIONS

Pro Forma Impact of Business Combinations

The following supplemental unaudited pro forma information presents Aralez's financial results as if the acquisitions of Tribute, which was completed on February 5, 2016, Zontivity, which was completed on September 6, 2016, and Toprol-XL and the AG, which was completed on October 31, 2016, had each occurred on January 1, 2016:

	Three Months Ended March 31,	
	2017	2016
	Actual	Pro forma
Total revenues, net	\$ 25,969	\$ 32,843
Net loss	\$ (27,477)	\$ (16,584)
Diluted net loss per share	\$ (0.42)	\$ (0.32)

The above unaudited pro forma information was determined based on the historical GAAP results of Aralez, Tribute, Zontivity and Toprol-XL and the AG. The unaudited pro forma consolidated results are provided for informational purposes only and are not necessarily indicative of what Aralez's consolidated results of operations actually would have been had the acquisition been completed on the dates indicated or what the consolidated results of operations will be in the future. The pro forma consolidated net loss includes pro forma adjustments relating to the following significant recurring and non-recurring items directly attributable to the business combinations, net of the pro forma tax impact utilizing applicable statutory tax rates, as follows:

- (i) elimination of \$12.0 million of expense for excise tax equalization payments for the three months ended March 31, 2016;
- (ii) elimination of \$3.5 million of severance charges for the three months ended March 31, 2016;
- (iii) elimination of \$0.7 million of the inventory fair value step-up for the three months ended March 31, 2016;
- (iv) elimination of \$0.5 million of stock based compensation expense for the three months ended March 31, 2016;
- (v) elimination of \$12.4 million of transaction costs incurred by the combined Company for the three months ended March 31, 2016;
- (vi) elimination of \$0.3 million for the three months ended March 31, 2016, and the addition of amortization of finite-lived intangible assets acquired of \$7.3 million for the months ended March 31, 2016; and
- (vii) elimination of \$0.3 million of interest expense related to the Tribute acquisition for the three months ended March 31, 2016, and the addition of \$6.2 million in interest expense related to the financing of the Zontivity and Toprol-XL acquisitions for the three months ended March 31, 2016.

4. FAIR VALUE

The following tables set forth the Company's assets and liabilities that are measured at fair value on a recurring basis at:

	March 31, 2017			
	Financial Instruments Carried at Fair Value			
	Quoted prices in active markets for identical items (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
Assets:				
Cash and cash equivalents	\$ 73,729	\$ —	\$ —	\$ 73,729
Liabilities:				
Contingent consideration	\$ —	\$ —	\$ 75,433	\$ 75,433
Warrants liability	\$ —	\$ —	\$ —	\$ —

	December 31, 2016			
	Financial Instruments Carried at Fair Value			
	Quoted prices in active markets for identical items (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
Assets:				
Cash and cash equivalents	\$ 64,943	\$ —	\$ —	\$ 64,943
Liabilities:				
Contingent consideration	\$ —	\$ —	\$ 71,115	\$ 71,115
Warrants liability	\$ —	\$ —	\$ 24	\$ 24

Warrants Liability

In connection with the acquisition of Tribute, the Company assumed a liability for warrants that are treated as derivatives under accounting guidance for derivatives and hedging as they were issued with exercise prices denominated in a currency different than the Company's reporting currency. Approximately 46 thousand of the total 0.9 million common shares underlying the warrants outstanding as of March 31, 2017 are classified as liabilities. The warrants liability is valued using a Black-Scholes valuation model, which incorporates Level 3 assumptions including the volatility of the underlying share price and the expected term. A decrease in the fair value of the warrants liability of \$24 thousand and \$4.6 million for the three months ended March 31, 2017 and 2016, respectively, is included within other income, net in the condensed consolidated statements of operations. See Note 9, "Earnings Per Share," for additional information.

Contingent Consideration

In connection with the acquisitions of Zontivity and Toprol-XL and the AG, the Company recorded short-term and long-term contingent consideration liabilities for future cash payments based on the occurrence of certain milestone events and royalty payments. The contingent consideration liability for both Zontivity and Toprol-XL and the AG is valued using a model, which incorporates Level 3 assumptions, including the estimated amount and timing of projected cash flows, the probability of success (achievement of the contingent event) and the risk-adjusted discount rate used to present value the probability-weighted cash flows. During the three months ended March 31, 2017, the Zontivity contingent consideration liability increased by \$0.6 million, while the fair value of the Toprol-XL contingent consideration liability increased by \$3.7 million for the same period. There was no corresponding contingent consideration liability recorded during the three months ended March 31, 2016.

Level 3 Disclosures

The following table provides quantitative information associated with the fair value measurement of the Company's Level 3 inputs at March 31, 2017:

		Valuation technique	Unobservable Inputs	Range of Inputs Utilized
Contingent consideration	\$ 75,433	Monte Carlo	Volatility Discount rate	33% - 68% 13%
Warrants liability	\$ —	Black-Scholes	Volatility Expected term in years	120% 0.1

The significant unobservable inputs used in the fair value measurement of the Company's warrants liability include the volatility of the Company's share price and the expected term. Significant increases or decreases in the volatility and expected term utilized would result in a significantly higher or lower fair value measurement, respectively. The significant unobservable inputs used in the fair value measurement of the Company's contingent consideration liability include the estimated amount and timing of projected cash flows, the probability of success (achievement of the contingent event) and the risk-adjusted discount rate used to calculate the present value of the probability-weighted cash flows.

The table below provides a roll-forward of the warrants liability fair value balances that used Level 3 inputs:

Balance at December 31, 2016	\$ 24
Change in fair value during the period	(24)
Impact of foreign exchange	—
Balance at March 31, 2017	\$ —

The table below provides a roll-forward of the contingent consideration liability fair value balances that used Level 3 inputs:

Balance at December 31, 2016	\$ 71,115
Cash payments	(125)
Change in fair value during the period	4,443
Balance at March 31, 2017	\$ 75,433

5. INVENTORY

Inventory consisted of the following at:

	March 31, 2017	December 31, 2016
Raw materials	\$ 1,110	\$ 1,129
Work-in-process	211	189
Finished goods	2,811	3,230
Total Inventory	\$ 4,132	\$ 4,548

Inventories are net of reserves for excess and obsolete inventory of approximately \$0.6 million and \$0.1 million as of March 31, 2017 and December 31, 2016, respectively.

6. GOODWILL AND OTHER INTANGIBLE ASSETS, NET*Goodwill*

The table below provides a roll-forward of the Company's goodwill balances:

Goodwill balance at December 31, 2016	\$ 76,694
Impact of foreign exchange	690
Goodwill balance at March 31, 2017	<u>\$ 77,384</u>

Other Intangible Assets, Net

Other intangible assets, net consisted of the following at:

	<u>March 31, 2017</u>			Weighted Average Life <small>(in years)</small>
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	
Toprol-XL	\$ 224,600	\$ (9,358)	\$ 215,242	10
ZONTIVITY	40,800	(2,231)	38,569	11
Tribute Merger and other	87,961	(9,466)	78,495	11
Acquired technology rights	<u>\$ 353,361</u>	<u>\$ (21,055)</u>	<u>\$ 332,306</u>	

The gross carrying amount of acquired technology rights increased by \$0.7 million due to the impact of foreign currency translation adjustments between the Canadian and U.S. dollars. Amortization expense was \$8.5 million and \$1.3 million for the three months ended March 31, 2017 and 2016, respectively.

The estimated aggregate amortization of intangible assets as of March 31, 2017, for each of the five succeeding years and thereafter is as follows:

<u>For the Years Ending December 31,</u>	<u>Estimated Amortization Expense</u>
Remainder of 2017	\$ 25,609
2018	34,145
2019	34,145
2020	34,145
2021	34,145
Thereafter	170,117
Total amortization expense	<u>\$ 332,306</u>

7. ACCRUED EXPENSES

Accrued expenses consisted of the following at:

	<u>March 31, 2017</u>	<u>December 31, 2016</u>
Accrued professional fees	\$ 6,397	\$ 6,258
Accrued marketing fees	2,350	4,852
Accrued revenue reserves	3,393	3,783
Accrued royalties	4,339	2,996
Accrued employee-related expenses	2,471	9,153
Accrued interest	6,627	4,715
Other accrued liabilities	698	384
Total accrued expenses	<u>\$ 26,275</u>	<u>\$ 32,141</u>

Exit and Disposal Activities

In connection with the Merger, the Company incurred certain exit costs, primarily severance benefits to former Pozen and Tribute employees. The following table summarizes the exit activity within accrued expenses and other long-term liabilities in the condensed consolidated balance sheets:

Accrued severance balance at December 31, 2016	\$ 2,300
Cash payments	(1,246)
Impact of foreign exchange	8
Accrued severance balance at March 31, 2017	<u>\$ 1,062</u>

The Company expects to pay the remaining accrued severance balance of \$1.1 million during the remainder of 2017.

8. DEBT

Convertible Notes

On February 5, 2016, Aralez issued \$75.0 million aggregate principal of 2.5% senior secured convertible notes due February 2022 ("2022 Notes") resulting in net proceeds to Aralez, after debt issuance costs, of \$74.5 million in connection with the Second Amended and Restated Debt Facility Agreement (the "Facility Agreement"), dated December 7, 2015, among Aralez Pharmaceuticals Inc., Pozen, Tribute ("the Credit Parties") and certain lenders party thereto. The 2022 Notes are convertible into common shares of Aralez at an initial conversion premium of 32.5%, subject to adjustment upon certain events, which is equivalent to an initial conversion price of approximately \$8.28 per common share. Holders of the 2022 Notes may convert the 2022 Notes at any time and the 2022 Notes are not pre-payable by Aralez. Interest is payable to the note holders quarterly in arrears on the first business day of each January, April, July and October. Interest expense for the three months ended March 31, 2017 and March 31, 2016 was \$0.5 million and \$0.3 million, respectively, which includes the amortization of debt issuance costs. The Company estimated the fair value of the \$75.0 million aggregate principal amount of the outstanding 2022 Notes to be approximately \$52.9 million as of March 31, 2017, using a bond plus call option model that utilizes Level 3 fair value inputs. The carrying amount of the 2022 Notes was \$74.6 million as of March 31, 2017, which is the principal amount outstanding, net of \$0.4 million of unamortized debt issuance costs to be amortized over the remaining term of the 2022 Notes.

Credit Facility

Under the terms of the Facility Agreement, Aralez also had the ability to borrow from the lenders up to \$200.0 million under a credit facility until April 30, 2017. On October 31, 2016, Aralez drew down \$25.0 million under the credit facility to replenish the Company's cash balance for the initial upfront payment of the \$25.0 million in cash

previously paid at the closing of the Zontivity acquisition in September 2016 and drew down an additional \$175.0 million to finance the upfront cash payment for the acquisition of Toprol-XL and the AG. Amounts drawn under the credit facility must be repaid on the sixth anniversary from each draw, bear an interest rate of 12.5% per annum and are prepayable in whole or in part at any time following the end of the sixth month after the funding date of each draw. The Facility Agreement contains various representations and warranties, and affirmative and negative covenants, customary for financings of this type, including, among other things, limitations on asset sales, mergers and acquisitions, indebtedness, liens and dividends.

Interest is payable to the noteholders under the credit facility quarterly in arrears on the first business day of each January, April, July and October. Interest expense for the three months ended March 31, 2017 was \$6.2 million, which includes the amortization of debt issuance costs. The Company estimated the fair value of the \$200.0 million aggregate principal amount of the outstanding borrowings under the credit facility under the Facility Agreement to be approximately \$210.0 million as of March 31, 2017, using a bond model that utilizes Level 3 fair value inputs. The carrying amount of the borrowings under the credit facility was \$199.9 million as of March 31, 2017, which is the principal amount outstanding, net of \$0.1 million of unamortized debt issuance costs to be amortized over the remaining term of the credit facility.

In addition, pursuant to a consent to the Facility Agreement entered into in connection with the acquisition of Toprol-XL and the AG, the lenders under the Facility Agreement agreed that they and/or affiliated funds will have available sufficient capital to make additional loans to Aralez in an aggregate amount of up to \$250.0 million for the payment of the purchase price of any acquisitions permitted by the terms of the Facility Agreement (as modified by such consent) with respect to target businesses mutually approved by, and as otherwise mutually agreed upon, by Aralez and the lenders, subject to the satisfaction of certain conditions set forth in the Facility Agreement. At the time of such consent, the Facility Agreement was amended to include additional financial performance thresholds, including a minimum adjusted EBITDA threshold and a minimum specified revenue threshold relating to net sales of Toprol-XL and the AG received by the Company.

9. EARNINGS PER SHARE

Basic and Diluted Net Loss Per Common Share

Basic net loss per common share has been computed by dividing net loss by the weighted average number of shares outstanding during the period. Except where the result would be antidilutive to income from continuing operations, diluted net loss per common share is computed assuming the conversion of convertible obligations and the elimination of the interest expense related to the 2022 Notes, the exercise of options to purchase common shares, the exercise of warrants, and the vesting of restricted stock units ("RSUs"), as well as their related income tax effects. Diluted net loss per common share differs from basic net loss per common share for the three months ended March 31, 2017 given potential common shares underlying the warrants liability are dilutive when considering the unrealized gain recognized for the change in the fair value of the warrants during the period.

	Three Months Ended March 31,	
	2017	2016
Net loss, basic	\$ (27,477)	\$ (33,788)
Effect of dilutive securities:		
Change in fair value of warrants liability	(24)	(4,581)
Net loss, diluted	<u>\$ (27,501)</u>	<u>\$ (38,369)</u>
Shares used in calculating basic net loss per common share	65,690	52,156
Effect of dilutive securities:		
Effect of dilutive stock options, RSUs	—	—
Warrants to purchase common shares - liability-classified	—	335
Shares used in calculating diluted net loss per common share	<u>65,690</u>	<u>52,491</u>
Net loss per common share, basic	\$ (0.42)	\$ (0.65)
Net loss per common share, diluted	\$ (0.42)	\$ (0.73)

Potential common shares excluded from the calculation of diluted net loss per common share as their inclusion would have been antidilutive were:

	Three Months Ended March 31,	
	2017	2016
Options to purchase common shares, RSUs and PSUs	8,441	8,652
Warrants to purchase common shares - equity-classified	930	992
2022 Notes convertible into common shares	9,057	9,057

The Company assumed outstanding warrants in connection with the acquisition of Tribute. The warrants are classified either as a liability, if the exercise price is denominated in Canadian dollars, or as equity if the exercise price is denominated in U.S. dollars. The following is a summary of warrants outstanding and exercisable as of March 31, 2017, and grouped in accordance with their respective expiration dates, with Canadian dollar exercise prices translated to U.S. dollars at the foreign exchange rate in effect at March 31, 2017:

Quarterly period of expiration	No. of Warrants	Weighted-Average
	Outstanding	Exercise Price
Q2 2017	46	\$ 4.74
Q1 2018	599	4.12
Q3 2018	16	3.78
Q4 2019	108	4.81
Q3 2020	110	4.09
Q1 2021	51	2.91
	<u>930</u>	<u>\$ 4.16</u>

10. SHARE-BASED COMPENSATION

Summary of Share-Based Compensation Plans

In December 2015, the Company's Board of Directors adopted the Aralez Pharmaceuticals 2016 Long-Term Incentive Plan (the "2016 Plan"), which became effective on February 5, 2016, upon consummation of the Merger. The 2016 Plan is the only existing plan in which the Company is authorized to grant equity-based awards. The 2016 Plan provides for grants of stock options, stock appreciation rights, stock awards, stock units, performance shares, performance units, and other stock-based awards to employees, directors, and consultants. Under the 2016 Plan, the Company initially reserved 2,300,000 common shares for grant plus (i) the number of shares available for issuance under both the Pozen Inc. 2010 Equity Compensation Plan and the Amended and Restated Option Plan of Tribute

Pharmaceuticals Canada Inc. that were not subject to outstanding awards upon the effective date and (ii) the number of shares required to cover each stock option granted in substitution of stock options held by employees of Tribute, as required to consummate the Merger. At March 31, 2017, there were approximately 1,000 common shares remaining available for grant under the 2016 Plan. On May 3, 2017, the Company's shareholders approved the Amended and Restated 2016 Long-Term Incentive Plan (the "Plan"), which increases the number of common shares covered by and reserved for issuance under this Plan by 4,300,000 common shares.

Summary of Share-Based Compensation Expense

Share-based compensation expense recorded in the condensed consolidated statements of operations for the three months ended March 31, 2017 and 2016, was as follows:

	Three Months Ended March 31,	
	2017	2016
Selling, general and administrative	\$ 2,820	\$ 3,583
Research and development	4	327
Total non-cash share-based compensation expense	\$ 2,824	\$ 3,910

Included in the table above is approximately \$0.5 million of share-based compensation expense related to the accelerated vesting of certain Tribute equity awards upon consummation of the Merger, which was recorded as selling, general and administrative expense for the three months ended March 31, 2016. There was no such charge for the three months ended March 31, 2017.

Options to Purchase Common Shares

A summary of option activity for the three months ended March 31, 2017 is as follows:

Stock Option Awards	Underlying	Weighted-Average	Weighted-Average	Intrinsic
	Shares	Exercise	Remaining	
		Price	Contractual Term	Value
Outstanding at December 31, 2016	3,065	\$ 5.85	4.8 years	
Granted	390	\$ 2.37		
Exercised	(41)	\$ 2.63		
Forfeited or expired	(343)	\$ 12.03		
Outstanding at March 31, 2017	3,071	\$ 4.76	5.7 years	\$ 6
Exercisable at March 31, 2017	1,818	\$ 5.48	1.9 years	\$ 6

The weighted average grant date fair value for option awards granted during the three months ended March 31, 2017 was \$1.52 per option.

As of March 31, 2017, there was approximately \$4.7 million of unrecognized compensation costs related to option awards, which are expected to be recognized over a remaining weighted average period of 2.1 years.

RSUs and PSUs

A summary of RSU, including performance restricted stock units (“PSUs”), activity for the three months ended March 31, 2017, is as follows:

Restricted Stock Units, including PSUs	Underlying Underlying Shares	Weighted- Average Grant Date Fair Value
Nonvested restricted stock units at December 31, 2016	4,324	\$ 6.62
Granted	1,230	\$ 2.34
Vested	(164)	\$ 3.83
Forfeited or expired	(20)	\$ 4.07
Nonvested restricted stock units at March 31, 2017	<u>5,370</u>	<u>\$ 5.74</u>

During the three months ended March 31, 2017, approximately 1,072,000 PSUs with both market-based and service conditions were granted with an aggregate grant-date fair value of \$2.5 million. The PSUs vest at the end of a three-year performance period based on the achievement of pre-determined market-based performance goals.

As of March 31, 2017, there was approximately \$23.0 million of unrecognized compensation costs related to RSUs, which are expected to be recognized over a remaining weighted average period of 2.2 years.

11. COMMITMENTS AND CONTINGENCIES

Operating Leases

The Company leases office space and certain equipment under cancellable and non-cancelable operating lease agreements.

Supply Agreements

The Company has various supply, license, distribution and manufacturing agreements with third parties that include purchase minimums or minimum royalties.

See the “Contractual Obligations” section on page 44 of this Quarterly Report on Form 10-Q for a summary of the Company’s operating lease obligations and commitments under supply agreements.

Legal Proceedings

The Company is currently party to legal proceedings arising in the normal course of business, principally patent litigation matters. The Company has assessed such legal proceedings and does not believe that it is probable that a liability has been incurred or that the amount of any potential liability or range of losses can be reasonably estimated. As a result, the Company has not recorded any loss contingencies for any of these matters as of March 31, 2017. While it is not possible to determine the outcome of these matters, in the event of an adverse outcome or outcomes, the Company’s business could be materially harmed. The Company intends to vigorously defend its intellectual property rights.

VIMOVO® ANDA Litigation

Between March 14, 2011 and May 16, 2013, Pozen, now a subsidiary of the Company, received Paragraph IV Notice Letters from Dr. Reddy’s Laboratories (“DRL”), Lupin Ltd. (“Lupin”), Watson Laboratories, Inc. – Florida (“Watson,” now “Actavis”), and Mylan Pharmaceuticals Inc. (“Mylan”), stating that each had filed an Abbreviated New Drug Application (“ANDA”) with the FDA seeking regulatory approval to market a generic version of our VIMOVO product before the expiration of U.S. Patent No. 6,926,907 (the “’907 patent”). On November 20, 2012, Pozen received a second Notice Letter from DRL stating that DRL had filed a second ANDA with the FDA seeking regulatory approval to market a different generic formulation of the VIMOVO product before the expiration of the ‘907 patent. The ‘907 patent

is assigned to Pozen and listed for the VIMOVO product in the FDA's publication titled "Approved Drug Products with Therapeutic Equivalence Evaluations" (also known as the "Orange Book").

On April 21, 2011, Pozen filed suit against the first ANDA filer, DRL, in the United States District Court for the District of New Jersey (the "District Court"), asserting infringement of the '907 patent. Pozen subsequently filed suit against the other three ANDA filers within 45 days of receipt of their respective Paragraph IV Notice Letters. Horizon, the Company's current marketing partner for the VIMOVO product in the U.S., is Pozen's co-plaintiff in each suit. The first suit against DRL is considered the lead case and has been consolidated with other suits for the purpose of pre-trial and discovery. On December 19, 2012, the District Court conducted a pre-trial Markman hearing to determine the proper claim construction of certain claims disputed by the parties. On May 1, 2013, the District Court issued a Markman Order construing the disputed claims. A scheduling order for the consolidated suits was issued by the District Court on June 27, 2014.

On October 15, 2013, the United States Patent & Trademark Office ("USPTO") issued to Pozen U.S. Patent No. 8,557,285 (the "'285 patent"). The '285 patent is listed in the Orange Book for the VIMOVO product and is related to the '907 patent. On October 23, 2013, Pozen filed suits against DRL, Lupin, Watson and Mylan in the District Court asserting infringement of the '285 patent. These suits have each been consolidated with the above referenced suits involving the '907 patent. On May 12, 2016, the court granted DRL's motion for summary judgment of non-infringement of the '907 patent with respect DRL's second ANDA. The ruling does not apply to DRL's first-filed ANDA, nor does it apply to the other patents asserted against DRL's second ANDA. In January 2017, Judge Cooper conducted a six day bench trial in the lead case involving Defendants DRL and Mylan relating solely to the validity and infringement of the '907 and '285 patents. The parties provided post-trial submissions to the District Court on April 24, 2017 and the closing arguments are scheduled for May 17, 2017.

On October 7, 2014, the USPTO issued to Pozen U.S. Patent No. 8,852,636 (the "'636 patent"). On October 14, 2014, the USPTO issued to Pozen U.S. Patent No. 8,858,996 (the "'996 patent"). In addition, on October 21, 2014, the USPTO issued to Pozen U.S. Patent No. 8,865,190 (the "'190 patent"). The '636, '996 and '190 patents are each listed in the Orange Book for the VIMOVO product and are each related to the '907 and '285 patents.

On February 3, 2015, the USPTO issued to Pozen U.S. Patent No. 8,945,621 (the "'621 patent"). The '621 patent is listed in the Orange Book for the VIMOVO product.

On May 13, 2015, Pozen and Horizon filed suit against DRL, Lupin, Actavis (formerly known as Watson) and Mylan in the District Court asserting infringement of the '636 and '996 patents. On June 18, 2015, Pozen filed Amended Complaints in each of the suits to assert infringement of the '190 patent.

On October 20, 2015, the USPTO issued to Pozen U.S. Patent No. 9,161,920 (the "'920 patent"). On December 1, 2015, the USPTO issued to Pozen U.S. Patent No. 9,198,888 (the "'888 patent"). The '920 and '888 patents are each listed in the Orange Book for the VIMOVO product and are each related to the '907 and '285 patents.

On December 29, 2015, the USPTO issued to Pozen U.S. Patent No. 9,220,698 (the "'698 patent"). The '698 patent is listed in the Orange Book for the VIMOVO product.

On May 24, 2016, the USPTO issued to Pozen U.S. Patent No. 9,345,695 (the "'695 patent"). The '695 patent is listed in the Orange Book for the VIMOVO product and is related to the '907 and '285 patents.

On January 25, 2016, Pozen and Horizon filed suit against Actavis in the District Court asserting infringement of the '920 and '888 patents. On March 16, 2016, the District Court consolidated this suit with the suit filed against Actavis on May 13, 2015. On February 10, 2016, Pozen filed Amended Complaints against DRL, Lupin and Mylan to assert infringement of the '920 and '888 patents. On August 11, 2016, Pozen and Horizon filed suit against DRL, Lupin, Actavis and Mylan in the District Court asserting infringement of the '621, '698, and '695 patents. These suits are in the initial phase and a full schedule has not yet been set by the District Court.

On July 19, 2016, the USPTO issued to Pozen U.S. Patent No. 9,393,208 (the “‘208 patent”). The ‘208 patent is listed in the Orange Book for the VIMOVO product and is related to the ‘698 patent.

On December 6, 2016, Pozen and Horizon filed Amended Complaints in the suits against Mylan, Lupin, and Actavis to assert infringement of the ‘208 patent. On December 6, 2016, Pozen and Horizon filed suit against DRL in the District Court asserting infringement of the ‘208 patent. On March 8, 2017, the District Court consolidated this suit with the suit filed against DRL on August 11, 2016.

On December 30, 2016, the District Court granted Actavis’ motion to enforce an alleged settlement agreement resolving all claims and counterclaims between Actavis and co-plaintiffs Pozen and Horizon in the lawsuits relating to VIMOVO. Pozen and Horizon contend that they did not agree to the settlement, and Pozen and Horizon filed notices of appeal of the District Court’s decision, on February 8, 2017 and February 9, 2017, respectively.

The suits against DRL, Mylan, and Lupin involving the ‘636, ‘996, ‘190, ‘621, ‘920, ‘888, ‘698, ‘695, and ‘208 patents have been consolidated for the purpose of pre-trial and discovery.

As with any litigation proceeding, we cannot predict with certainty the outcome of the patent infringement suits against DRL, Lupin, Mylan and Actavis relating to generic versions of VIMOVO. Furthermore, while Horizon is responsible for this litigation, including the costs of same, we nevertheless will have to incur additional expenses in connection with the lawsuits relating to VIMOVO, which may be substantial. Moreover, responding to and defending pending litigation results in a significant diversion of management’s attention and resources and an increase in professional fees.

Inter Partes Review

DRL filed a Petition for review (“IPR Petition”) of the ‘285 patent with the Patent Trial and Appeal Board (“PTAB”) of the USPTO on February 24, 2015, which was denied on October 9, 2015. The Coalition for Affordable Drugs VII L.L.C. (“CFAD”) filed IPR Petitions of the ‘907 patent, the ‘996 patent and the ‘636 patent with the PTAB on May 21, 2015, June 5, 2014 and August 7, 2015, respectively, each of which was denied on December 8, 2015, December 17, 2015 and February 11, 2016, respectively.

On August 12, 2015, CFAD filed an IPR Petition of the ‘621 patent with the PTAB. On February 22, 2016 the PTAB instituted review of the claims of the ‘621 patent. Pozen and Horizon filed a response on June 23, 2016. CFAD filed a reply to this response on September 22, 2016. Oral argument before the PTAB was held on November 16, 2016. On February 21, 2017, the PTAB entered a Final Written Decision in which it concluded that CFAD had not carried its burden of proving that the claims of the ‘621 patent were unpatentable.

On August 19, 2015, Lupin filed three separate IPR Petitions of the ‘996, ‘636 and ‘190 patents with the PTAB. On March 1, 2016 the PTAB denied Lupin’s petition for review of the ‘636 patent and instituted review of a limited number of the claims in each of the ‘996 and ‘190 patents. Pozen and Horizon filed responses to the petitions for review of the ‘996 and ‘190 patents on June 27, 2016. Lupin filed replies to these responses on September 16, 2016. Oral arguments before the PTAB for these matters were held on November 29, 2016. On February 28, 2017, the PTAB entered Final Written Decisions in which it concluded that Lupin had not carried its burden of proving that the claims of the ‘996 and ‘190 patents were unpatentable.

Canada VIMOVO[®] Litigation

On January 20, 2015, the Company’s Canadian licensee, AstraZeneca Canada Inc. (“AstraZeneca Canada”) received a Notice of Allegation from Mylan Pharmaceuticals ULC (“Mylan Canada”) informing them that Mylan Canada has filed an Abbreviated New Drug Submission in Canada (“ANDS”) for approval of its naproxen/esomeprazole magnesium tablets and alleging non-infringement of some of the claims and invalidity of Pozen’s Canadian Patent No. 2,449,098 (the “‘098 patent”). A Notice of Allegation is served pursuant to the Patented Medicines (Notice of Compliance) Regulations in Canada and is similar to a Paragraph IV Notice Letter in the United States. In response, Pozen and AstraZeneca Canada commenced a proceeding in the Federal Court of Canada (the “Canada Court”) in

relation to the '098 patent on March 5, 2015 seeking to prohibit Health Canada from approving Mylan Canada's generic naproxen/esomeprazole product until the expiry of the '098 patent. The Canadian proceeding is summary in nature and intended to decide only whether approval for Mylan Canada's naproxen/esomeprazole magnesium tablets should be prohibited until the expiry of the '098 patent because none of Mylan Canada's allegations in respect of the '098 patent are justified. The matter was heard on November 21 to 23, 2016. On February 7, 2017, the Court dismissed Pozen and AstraZeneca Canada's request to prohibit the Minister from approving Mylan's naproxen/esomeprazole products, deciding that certain of Mylan Canada's allegations in respect of the '098 patent are justified (the "Decision"). However, this summary proceeding did not decide the '098 patent validity or infringement. The '098 patent expires on May 31, 2022. Following the Decision, the Minister issued approval for Mylan's 500/20mg strength naproxen/esomeprazole magnesium tablets on February 8, 2017.

On March 23, 2016, AstraZeneca Canada received another Notice of Allegation from Mylan Canada in respect of the '098 patent, informing them that Mylan Canada has filed a supplemental submission for one of the strengths of its naproxen/esomeprazole magnesium tablets. This Notice of Allegation states that Mylan Canada withdrew from its ANDS the 375/20 mg strength and re-filed a supplemental submission for this strength. In this circumstance, Mylan is required to file, and has provided another Notice of Allegation in respect of the '098 patent. The allegations in respect of the '098 patent are identical to those asserted in the first Notice of Allegation. In response, Pozen and AstraZeneca Canada commenced another proceeding in the Federal Court of Canada on May 5, 2016 seeking to prohibit Health Canada from approving Mylan Canada's 375/20 mg strength naproxen/esomeprazole magnesium tablet until the expiry of the '098 patent. As the allegations made in respect of the '098 patent are identical, on the parties' consent, the Court stayed the proceeding and the parties agreed that the outcome of the first proceeding discussed above, will determine the outcome for this new proceeding. Following the Decision, this proceeding was discontinued on February 10, 2017. The Minister issued approval for Mylan's 375/20 mg strength naproxen/esomeprazole magnesium tablets on February 10, 2017. Mylan's generic naproxen/esomeprazole magnesium tablets recently became available in Canada.

Yosprala Paragraph IV Certification

On November 4, 2016, the FDA website indicated that an ANDA for a generic version of Yosprala 81mg/40mg was submitted to the FDA on October 14, 2016. The Company ultimately received the related Paragraph IV Notice Letter on December 12, 2016, as described below.

On December 12, 2016, the Company received a Paragraph IV Notice Letter from Teva Pharmaceuticals USA, Inc. ("Teva") stating that it had filed an ANDA with the FDA seeking regulatory approval to market generic versions of Yosprala 325mg/40 mg and 81mg/40mg prior to the expiration of the '907 patent, U.S. Patent No. 8,206,741 (the "'741 patent'"), and U.S. Patent No. 9,364,439 (the "'439 patent'"). The '907, '741, and '439 patents are assigned to Pozen and listed in the Orange Book for the Yosprala product.

On January 10, 2017, the USPTO issued to Pozen U.S. Patent No. 9,539,214 (the "'214 patent'"). The '214 patent is listed in the Orange Book for the Yosprala product. On March 13, 2017, the Company received a Paragraph IV Notice Letter regarding the '214 patent.

On January 23, 2017, Aralez Parent and its subsidiaries Aralez Pharmaceuticals Trading DAC, Aralez Pharmaceuticals US Inc., and Pozen Inc. filed a lawsuit in the United States District Court for the Eastern District of Texas against Teva and Teva Pharmaceutical Industries Ltd. for infringement of the '907, '741, '439, and '214 patents. The lawsuit was filed within 45 days of receipt of Teva's Paragraph IV Notice Letter. In accordance with the Hatch-Waxman Act, as a result of having filed a timely lawsuit against Teva, a stay of approval will be imposed by the FDA on Teva's ANDA for 30 months after the date of the Company's receipt of Teva's Paragraph IV Notice Letter on December 12, 2016 or until a final court decision is entered in the infringement suit in favor of Teva, whichever is earlier.

On April 13, 2017, the parties entered a joint stipulation to dismiss the complaint against Teva Pharmaceutical Industries Ltd. based on Teva Pharmaceutical Industries Ltd.'s agreement to be bound by any judgment, order, or decision in the lawsuit. The lawsuit will continue against Teva. The suit remains in the initial phase and a full schedule has not yet been set.

As with any litigation proceeding, we cannot predict with certainty the outcome of the infringement suit relating to generic versions of Yosprala.

12. SEGMENT INFORMATION

Aralez has one operating segment, the acquisition, development and commercialization of products primarily in cardiovascular, pain and other specialty areas for the purpose of delivering meaningful products to improve patients' lives while focusing on creating shareholder value. The Company's entire business is managed by a single management team, which reports to the Chief Executive Officer.

13. SUBSEQUENT EVENTS

Modification of Contract with Government Regarding Toprol-XL

On April 6, 2017, Aralez US and the Government entered into a Modification of Contract pursuant to which the Government exercised its first renewal option under the VA Contract, extending the term of the VA Contract by one year to April 28, 2018 with reduced pricing for the duration thereof.

Sales Force Reduction and Other Cost Initiatives

On April 5, 2017, the Company announced that it has begun implementing a program of cost savings initiatives, which included a 32% reduction in its U.S. sales force and realignment of certain financial resources to support the launch of Zontivity, together with a significant decrease in marketing spend on Yosprala. As a result of this sales force reduction, the Company anticipates it will incur cash severance costs of approximately \$0.6 million in the second quarter of 2017.

License Agreement

On May 8, 2017, Pozen entered into a license agreement with a multi-national pharmaceutical company pursuant to which Pozen granted a non-exclusive license to such company under a Japanese patent owned by Pozen. The non-exclusive license is limited to Japan. In consideration for this non-exclusive license, Pozen will receive an upfront payment of \$4.0 million, plus contingent milestones payments and royalties under certain circumstances.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q includes "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and within the meaning of applicable securities laws in Canada. Forward-looking statements include, but are not limited to, statements about execution of our commercialization strategy with our expanded product portfolio, including Yosprala® (aspirin and omeprazole), Fibracor® (fenofibric acid) and its authorized generic, Toprol-XL® (metoprolol succinate) and its currently marketed authorized generic and Zontivity® (vorapaxar), which we plan to fully relaunch in the United States in June 2017, cash and cash equivalents together with cash expected to be generated from our business is currently believed to be sufficient to fund our operations for at least the next twelve months, cost savings initiatives, business development plans, our operating model and financial discipline, our objective to achieve sustained long-term growth, product launches, our strategies, plans, objectives, financial forecasts, goals, prospects, prospective products or product approvals, future performance or results of current and anticipated products, exposure to foreign currency exchange rate fluctuations, interest rate changes and other statements that are not historical facts, and such statements are typically identified by use of terms such as "may," "will," "would," "should," "could," "expect," "plan," "intend," "anticipate," "believe," "estimate," "predict," "likely," "potential," "continue" or the negative or similar words, variations of these words or other comparable words or phrases, although some forward-looking statements are expressed differently. You should be aware that the forward-looking statements included herein represent management's current judgment and expectations, but our actual results, events and performance could differ materially from those in the forward-looking statements. The forward-looking statements are subject to a number of risks and uncertainties which are discussed in the section entitled "Part II – Item 1A. Risk Factors" in this Quarterly Report on Form 10-Q and in our Annual Report on Form 10-K filed with the Securities and Exchange Commission ("SEC") and with applicable Canadian securities regulators on SEDAR on March 13, 2017 and those described from time to time in our future reports filed with the SEC and securities regulatory authorities in Canada. Although we believe that the expectations reflected in our forward-looking statements are reasonable, we cannot guarantee future results, events, levels of activity, performance or achievement. We undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, unless required by law.

All dollar amounts are expressed in U.S. dollars unless otherwise noted. Amounts are expressed on an as-converted from Canadian dollar to U.S. dollar basis, as applicable, and are calculated using the conversion rates as of and for the periods ended March 31, 2017 unless otherwise noted.

Unless the context indicates otherwise, when we refer to "we," "us," "our," "Aralez" or the "Company" in this Quarterly Report on Form 10-Q, we are referring to Aralez Pharmaceuticals Inc. together with its wholly-owned subsidiaries.

This Management's Discussion and Analysis of Financial Condition and Results of Operations ("MD&A") is provided in addition to the condensed consolidated financial statements and accompanying notes to assist readers in understanding our results of operations, financial condition and cash flows. We have organized the MD&A as follows:

- *Overview*—this section provides financial highlights, our business strategy, a summary of our marketed products, our product pipeline update, and a summary of our out-licensed products.
- *Results of Operations*—this section provides a review of our results of operations for the three months ended March 31, 2017 and 2016.
- *Liquidity and Capital Resources*—this section provides a summary of our financial condition, including our sources and uses of cash, capital resources, commitments and liquidity.

- *Commitments and Contingencies*—this section provides a summary of our material legal proceedings and a summary of our contractual obligations.
- *Critical Accounting Policies and Estimates*—this section describes our critical accounting policies and the significant judgments and estimates that we have made in preparing our condensed consolidated financial statements.
- *Recent Accounting Pronouncements*—this section provides a summary of accounting pronouncements that have been issued, but not yet adopted by the Company.

Overview

Aralez is a global specialty pharmaceutical company focused on delivering meaningful products to improve patients' lives while creating shareholder value by acquiring, developing and commercializing products primarily in cardiovascular, pain and other specialty areas. Our parent corporation, Aralez Pharmaceuticals Inc., was incorporated under the British Columbia Business Corporations Act ("BCBCA") on December 2, 2015. Our global headquarters is located in Mississauga, Ontario, Canada, our U.S. headquarters is located in Princeton, New Jersey, United States, and our Irish headquarters is located in Dublin, Ireland. Aralez was formed for the purpose of facilitating the business combination of POZEN Inc., a Delaware corporation ("Pozen"), and Tribute Pharmaceuticals Canada Inc., a corporation incorporated under the laws of the Province of Ontario, Canada ("Tribute"), which transaction closed on February 5, 2016.

On February 5, 2016, pursuant to an Agreement and Plan of Merger and Arrangement between Aralez Pharmaceuticals Inc., Pozen, Tribute and other related parties (as amended, the "Merger Agreement"), Aralez completed the acquisition of Tribute by way of a court approved plan of arrangement in a stock transaction with a purchase price of \$137.6 million made up of (i) \$115.1 million related to Tribute shares, equity awards and certain warrants outstanding and (ii) \$22.5 million in repayments of Tribute indebtedness. In connection with the transaction, Pozen and Tribute were combined under and became subsidiaries of Aralez Pharmaceuticals Inc., with Pozen treated as the acquiring company for accounting purposes (the "Merger"). Pursuant to Rule 12g-3(a) under the Exchange Act, Aralez Pharmaceuticals Inc. is the successor issuer to Pozen. The Merger provides the combined company with increased financial strength and product portfolio diversity and is expected to meaningfully accelerate our operating strategies.

On September 6, 2016, Aralez Pharmaceuticals Trading DAC, a wholly-owned subsidiary of Aralez ("Aralez Ireland"), acquired the U.S. and Canadian rights to Zontivity[®] (vorapaxar) pursuant to an asset purchase agreement with Schering-Plough (Ireland) Company, an Irish private unlimited company and an affiliate of Merck & Co., Inc. ("Merck"). Zontivity represents an addition to our product portfolio in cardiovascular disease and is the first and only approved therapy shown to inhibit the protease-activated receptor-1 (PAR-1), the primary receptor for thrombin, which is considered to be the most potent activator of platelets.

On September 15, 2016, we announced that the U.S. Food and Drug Administration ("FDA") approved Yosprala[®] (aspirin and omeprazole) for the secondary prevention of cardiovascular and cerebrovascular events in patients at risk for aspirin-associated gastric ulcers.

On October 31, 2016, Aralez Ireland acquired the U.S. rights to Toprol-XL[®] (metoprolol succinate) and the currently marketed authorized generic (the "AG") pursuant to an asset purchase agreement (the "Toprol-XL Asset Purchase Agreement") entered into between AstraZeneca AB ("AstraZeneca"), Aralez Ireland and Aralez Pharmaceuticals Inc. Toprol-XL is a cardioselective beta-blocker indicated for the treatment of hypertension, alone or in combination with other antihypertensives; the long term treatment of angina pectoris and treatment of stable, symptomatic (NYHA class II or III) heart failure of specific origins. Toprol-XL and the AG further expands our cardiovascular portfolio.

Financial Highlights

The following table is a summary of our financial results for the periods presented:

	Three Months Ended March 31,	
	2017	2016
Revenues:		
Product revenues, net	\$ 6,686	\$ 3,565
Other revenues	19,283	4,492
Total revenues, net	<u>25,969</u>	<u>8,057</u>
Costs and expenses:		
Cost of product revenues (exclusive of amortization shown separately below)	2,756	2,538
Selling, general and administrative	30,846	37,459
Research and development	94	4,412
Amortization of intangible assets	8,513	1,272
Change in fair value of contingent consideration	4,443	—
Total costs and expenses	<u>46,652</u>	<u>45,681</u>
Loss from operations	(20,683)	(37,624)
Interest expense	(6,653)	(307)
Other income, net	411	4,797
Loss before income taxes	<u>(26,925)</u>	<u>(33,134)</u>
Income tax expense	552	654
Net loss	<u>\$ (27,477)</u>	<u>\$ (33,788)</u>
Basic net loss per common share	\$ (0.42)	\$ (0.65)
Diluted net loss per common share	\$ (0.42)	\$ (0.73)

Business Strategy

Our management team has a strong track record of success in creating, leading and expanding specialty pharmaceutical companies with marketing and sales capabilities. Driven by this leadership and leveraging our competitive platform, our focus on acquiring high potential growth opportunities through aggressive business development and licensing and strategic transactions, and commercializing our product portfolio to provide enhanced value to a range of stakeholders, is driven by the following primary strategies:

- **Maximize value of expanded portfolio** – We plan to continue our focus on execution of our commercialization strategy with respect to our broadened cardiovascular portfolio, including Zontivity, which we acquired in September 2016 and commenced the first phase of our commercial relaunch in the United States in April 2017 (with the full relaunch planned for June 2017), Yosprala, which was approved by the FDA in September 2016, Fibricor® (fenofibric acid) and its authorized generic, and Toprol-XL and the AG, which we acquired in October 2016.
- **Business Development through selective acquisitions** – While we completed several transactions in 2016 to expand our portfolio offering, we plan to continue to pursue value-driven business development opportunities as they arise with a focus on strategic M&A, targeting companies with commercially available, cash flow generating products and revenues that offer synergies and growth potential, particularly in the cardiovascular and pain anchor areas. We will also continue to assess the addition of other specialty therapeutic areas through M&A activity with a similar focus on opportunities that we anticipate are or will become synergistic, revenue and cash flow generating.
- **Leverage platform for growth** – We intend to maintain a lean, nimble and performance-oriented operating model with strong financial discipline. Our objective is to achieve sustained long-term growth, both organically, through products such as Yosprala, and through business development initiatives that could include M&A

and/or product acquisitions, such as the recently completed purchases of Zontivity and Toprol-XL and the AG, while at all times maintaining our focus on creating shareholder value.

Marketed Products – United States

Yosprala®

Yosprala is currently the only prescription fixed-dose combination of aspirin (acetylsalicylic acid), an anti-platelet agent, and omeprazole, a proton pump inhibitor (“PPI”), in the United States. It is indicated for patients who require aspirin for secondary prevention of cardiovascular and cerebrovascular events and who are at risk of developing aspirin associated gastric ulcers. Yosprala is designed to support both cardio- and gastro-protection for at-risk patients through the proprietary Intelli-COAT™ system, which is formulated to sequentially deliver immediate-release omeprazole (40 mg) followed by a delayed-release, enteric-coated aspirin core in either 81 mg or 325 mg dose strengths. Yosprala is currently protected by four U.S. patents, the latest expiring in late 2032 with potential patent term adjustment into early 2033. We received FDA approval for Yosprala on September 14, 2016 and began commercialization in the United States on October 3, 2016. The competition for PPI-aspirin (“PA”) products, such as Yosprala, may come from aspirin itself, other aspirin-combination products that may be introduced, as well as other anti-platelet products used for secondary prevention of cardiovascular and cerebrovascular events.

The Company is committed to perform two post-marketing requirements related to Yosprala. One is an in-vitro study to examine the breakdown products of omeprazole at different pH levels. Pending the results of that study, the FDA has requested a *pharmacokinetics* study measuring the levels of these degradants in serum compared to enteric-coated omeprazole.

Toprol-XL® and its Authorized Generic

Toprol-XL is a cardioselective beta-blocker indicated for the treatment of hypertension, alone or in combination with other antihypertensives, the long term treatment of angina pectoris and treatment of stable, symptomatic (NYHA class II or III) heart failure of specific origins. Toprol-XL is an extended-release tablet that belongs to a family of high blood pressure medications known as beta-blockers. Extended-release tablets need to be taken only once a day. After swallowing Toprol-XL, the coating of the tablet dissolves, releasing a multitude of controlled release pellets filled with metoprolol succinate. Each pellet acts as a separate drug delivery unit and is designed to deliver metoprolol continuously over the dosage interval of 24 hours. We acquired the U.S. rights to Toprol-XL and the AG from AstraZeneca on October 31, 2016 in exchange for an upfront payment of \$175.0 million, a payment for certain inventory and certain future royalties and contingent milestone payments, as described in Note 2, “Business Agreements,” in the accompanying notes to condensed consolidated financial statements in more detail. Toprol-XL and the AG compete against several generic offerings for metoprolol succinate.

Fibricor® and its Authorized Generic

Fibricor is indicated as a complementary therapy along with diet for the treatment of severe hypertriglyceridemia and as a complementary therapy along with diet to reduce elevated LDL-C, Total-C, TG, and Apo B, and to increase HDL-C in patients with primary hypercholesterolemia or mixed dyslipidemia. Fibricor is currently protected by four U.S. patents extending to August 20, 2027. In May 2015, we acquired the U.S. rights to Fibricor (fenofibric acid) and its related authorized generic. We began promoting Fibricor in the United States during the second quarter of 2016 with a 25-person U.S. sales force, which was expanded in September 2016 in connection with the U.S. launch of Yosprala. Fibricor and its authorized generic compete against other cholesterol-lowering drugs known as fibrates. The large fibrate market is heavily genericized.

Zontivity®

Zontivity is the first and currently the only approved therapy shown to inhibit the protease-activated receptor-1 (PAR-1), the primary receptor for thrombin on the platelet, which is considered to be the most potent activator of platelets. In the United States, Zontivity is indicated for the reduction of thrombotic cardiovascular events in patients

with a history of heart attack (myocardial infarction) or in patients with narrowing of leg arteries, called peripheral arterial disease (PAD), and should be used in combination with daily aspirin and/or clopidogrel according to their indications or standard of care. We acquired the U.S. and Canadian rights to Zontivity from Merck on September 6, 2016 in exchange for an upfront payment of \$25 million and certain future royalties and milestone payments, as described in Note 2, “Business Agreements,” in the accompanying notes to condensed consolidated financial statements in more detail.

We have commenced the commercial preparations and the first phase of the relaunch of Zontivity by our U.S. sales force (with the full relaunch planned for June 2017) and are currently assessing our plans with respect to the commercialization of Zontivity in Canada. Zontivity competes with certain products referred to as oral anti-platelets, which market is dominated by the generic offerings for clopidogrel bisulfate. There are also two newer, competitive anti-platelet offerings in this class: Effient® and Brilinta®.

Marketed Products – Canada

Cambia®

Cambia® (diclofenac potassium for oral solution) is a non-steroidal anti-inflammatory drug (“NSAID”) and currently the only prescription NSAID available and approved in Canada for the acute treatment of migraine attacks with or without aura in adults 18 years of age or older. Cambia was licensed from Nautilus Neurosciences, Inc. (“Nautilus”) in November 2010, which was acquired by Depomed, Inc. in December 2013. Cambia was approved by Health Canada in March 2012 and was commercially launched to specialists in Canada in October 2012 and broadly to all primary care physicians in February 2013.

We consider the competitive market for Cambia to be the triptan class of drugs or 5-HT₁ receptor agonists as they are known, which include sumatriptan (Imitrex®), rizatriptan (Maxalt®), zolmitriptan (Zomig®), almotriptan (Axert®), naratriptan (Amerge®), eletriptan (Relpax®) and frovatriptan (Frova®).

Fiorinal®/Fiorinal® C

Fiorinal® (acetylsalicylic acid, caffeine and butalbital tablets and capsules) and Fiorinal® C (acetylsalicylic acid, caffeine, butalbital and codeine capsules) were originally approved by Health Canada in 1971 and 1970, respectively, for the relief of tension-type headaches. Fiorinal is a fixed dose combination drug that combines the analgesic properties of acetylsalicylic acid, with the anxiolytic and muscle relaxant properties of butalbital, and the central nervous system stimulant properties of caffeine. Fiorinal C expands on the properties of Fiorinal with the additional analgesic effect of codeine. Fiorinal and Fiorinal C are currently the only prescription products in Canada indicated for relief of tension type headaches. Fiorinal and Fiorinal C were acquired from Novartis AG and Novartis Pharma AG in October 2014.

We consider the competitive market for Fiorinal and Fiorinal C as the prescription NSAID class, which includes Naprosyn®, Anaprox®, Toradol®, and prescription analgesic/opiate combination class, which includes Percocet® and Tylenol® with codeine.

Soriatane®

Soriatane® (acitretin) is indicated for the treatment of severe psoriasis (including erythrodermic and pustular types) and other disorders of keratinization. Soriatane is a retinoid, an aromatic analog of vitamin A. Soriatane was approved in Canada in 1994 and is the first and currently the only oral retinoid indicated for severe psoriasis. Soriatane is often used when milder forms of psoriasis treatments like topical steroids, emollients and topical tar-based therapies have failed. Soriatane is under license from Actavis Group PTC ehf (“Actavis”), an Allergan affiliate, and we have the exclusive rights to market Soriatane in Canada.

We consider the competitive market for Soriatane to be biologic therapies such as Enbrel®, Humira® and Remicade®, and oral agents such as Cyclosporine and methotrexate.

Bezalip® SR

Bezalip® SR (bezafibrate) is an established pan-peroxisome proliferator-activated receptor activator. Bezalip SR, used to treat hyperlipidemia (high cholesterol), has over 25 years of therapeutic use globally. Bezalip SR helps lower LDL-C and triglycerides while raising HDL-C levels. It also improves insulin sensitivity and reduces blood glucose levels, which in combination with the cholesterol effects may significantly lower the incidence of cardiovascular events and development of diabetes in patients with features of metabolic syndrome. Bezalip SR is contraindicated in patients with hepatic and renal impairment, pre-existing gallbladder disease, hypersensitivity to bezafibrate, or pregnancy or lactation. Bezalip SR is under license from Actavis, and we have the exclusive rights to market Bezalip SR in Canada and the United States. At this time, we are only marketing Bezalip SR in Canada.

We consider the competitive market for Bezalip SR to be the fibrates class of cholesterol-lowering treatments, which is composed of three competing molecules: (1) gemfibrozil (Lopid®), (2) bezafibrate (Bezalip SR), and (3) fenofibrate (Lipidil® in Canada or Tricor® in the United States).

Proferrin®

Proferrin® (heme iron polypeptide) is an iron supplement used to prevent or treat those at risk of iron deficiency. We have the exclusive right to import and distribute Proferrin in Canada pursuant to a distribution agreement with Colorado Biolabs, Inc.

We consider the competitive market for Proferrin to be in the Heme iron class of iron supplements, which is composed of two directly competing products: (1) Hema-Fer, and (2) JAMP Heme iron, and the following indirectly competing products: (1) Polyride® and Feramax® (Polysaccharide-iron complex), and (2) Palafer® and Eurofer® (Ferrous fumarate).

Blexten™(bilastine)

Bilastine is a second generation antihistamine drug for the symptomatic relief of allergic rhinitis and chronic spontaneous urticaria. Bilastine exerts its effect as a selective histamine H1 receptor antagonist, and has an effectiveness similar to other second generation antihistamines such as cetirizine, fexofenadine and desloratadine. It was developed in Spain by FAES Farma, S.A. In April 2016, Health Canada approved bilastine with the brand name Blexten (bilastine 20mg oral tablet) for the treatment of the symptoms of SAR and CSU (such as itchiness and hives). We began commercializing Blexten in Canada in December 2016.

We consider the competitive market for Blexten to be first generation selective histamine H1 receptor antagonists (Aerius® – desloratadine, Claritin® - loratadine, Allegra® – fexofenadine, Reactine® – cetirizine); and second generation selective histamine H1 receptor antagonist (Rupall™ – rupatadine; and Benadryl® – diphenhydramine and Atarax® – hydroxyzine).

Product Pipeline Updates

The Company plans to consider various avenues to commercialize Yosprala outside of the U.S., and, to this end, in January 2017, submitted a Marketing Authorization Application to the European Medicines Agency for its investigational candidate, PA10040 (aspirin and omeprazole, which is marketed in a tablet form under the brand name Yosprala in the United States), for the secondary prevention of cardiovascular disease in patients at risk for aspirin-induced gastric ulcers.

Out-Licensed Products

VIMOVO®

VIMOVO® (naproxen/esomeprazole magnesium) is the brand name for a proprietary fixed-dose combination of enteric-coated naproxen, a pain-relieving NSAID and immediate-release esomeprazole magnesium, a PPI, in a single

delayed-release tablet. We developed VIMOVO in collaboration with AstraZeneca. On April 30, 2010, the FDA approved VIMOVO for the relief of the signs and symptoms of osteoarthritis, rheumatoid arthritis, and ankylosing spondylitis, and to decrease the risk of developing gastric ulcers in patients at risk of developing NSAID-associated gastric ulcers.

In 2010, we officially transferred to AstraZeneca the investigational new drug application (“IND”) and new drug application (“NDA”) for the product such that AstraZeneca became responsible for the commercialization of VIMOVO. In November 2013, AstraZeneca entered into an agreement for Horizon Pharma USA, Inc. (“Horizon”) to acquire the U.S. rights for VIMOVO. Under the terms of the agreement, we receive from Horizon a 10% royalty on net sales of VIMOVO sold in the United States, with guaranteed annual minimum royalty payments of \$7.5 million. The guaranteed annual minimum royalty payments are applicable for each calendar year that certain patents which cover VIMOVO are in effect and certain types of competing products are not on the market in the United States (including competing products entering pursuant to a license to enter the market prior to expiration of the applicable patents). Horizon’s royalty payment obligation with respect to VIMOVO expires on the later of (a) the last to expire of certain patents covering VIMOVO, and (b) ten years after the first commercial sale of VIMOVO in the United States. The royalty rate may be reduced to the mid single digits in the event of a loss of market share as a result of certain competing products (including competing products entering pursuant to a license to enter the market prior to expiration of the applicable patents).

AstraZeneca will continue to have rights to commercialize VIMOVO outside of the United States and Japan and paid us a royalty of 6% on all sales within its territory through 2015, which increased to 10% commencing in the first quarter of 2016. AstraZeneca’s royalty payment obligation with respect to VIMOVO expires on a country-by country basis upon the later of (a) expiration of the last-to-expire of certain patent rights related to VIMOVO in that country, and (b) ten years after the first commercial sale of VIMOVO in such country. The royalty rate may be reduced to the mid single digits in the event of a loss of market share as a result of certain competing products (including competing products entering pursuant to a license to enter the market prior to expiration of the applicable patents). As the result of an unfavorable outcome in certain patent litigation in Canada, Mylan’s generic naproxen/esomeprazole magnesium tablets recently became available in Canada. See Note 11, “Commitments and Contingencies” in the accompanying notes to condensed consolidated financial statements within Item 1 of Part I in this report for more information.

Treximet®

Treximet (sumatriptan/naproxen sodium) is a migraine medicine that we developed in collaboration with Glaxo Group Limited, d/b/a GlaxoSmithKline (“GSK”). The product is formulated with our patented technology of combining a triptan, sumatriptan 85mg, with an NSAID, naproxen sodium 500mg, and GSK’s RT Technology™ in a single tablet. In 2008, the FDA approved Treximet for the acute treatment of migraine attacks, with or without aura, in adults. Treximet is currently available in the United States only.

In 2008, we transferred the IND and NDA for the product to GSK, which subsequently sold its rights in Treximet, including the related trademark, to Pernix Therapeutics Holdings, Inc. (“Pernix”) in 2014. As part of GSK’s divestiture to Pernix, restrictions on our right to develop and commercialize certain additional dosage forms of sumatriptan/naproxen combinations outside of the United States had been eliminated, allowing us to seek approval for these combinations on the basis of the approved NDA. GSK was previously, and Pernix is currently, responsible for the commercialization of Treximet in the United States, while we receive royalties based on net sales. In 2011, we sold to a financial investor, CPPIB Credit Investments Inc. (“CII”), for an upfront lump-sum, our rights to future royalty and milestone payments relating to Treximet sales in the United States and certain other products containing sumatriptan/naproxen sodium developed and sold by Pernix in the United States. By virtue of the agreement, we will also be entitled to receive a 20% interest in royalties, if any, paid on net sales of Treximet and such other products in the United States to CII relating to the period commencing in the second quarter of 2018.

Results of Operations for the three months ended March 31, 2017 and 2016**Revenues**

The following table sets forth net revenues for the periods presented:

	Three Months Ended March 31,	
	2017	2016
Revenues:		
Product revenues, net	\$ 6,686	\$ 3,565
Other revenues	19,283	4,492
Total revenues, net	<u>\$ 25,969</u>	<u>\$ 8,057</u>

Product Revenues, net

Net product revenues for the three months months ended March 31, 2017 were \$6.7 million, an increase of \$3.1 million, compared to \$3.6 million for the three months ended March 31, 2016. The increase related to the product portfolio we acquired with the acquisition of Tribute on February 5, 2016 and primarily include revenues from sales of Bezalip, Fiorinal, Soriatane, Proferrin and Fibracor for the full quarter in 2017. Net product revenues for the first quarter of 2017 also includes sales of Blexten and Yosprala, which received regulatory approval in April 2016 and September 2016, respectively. Net product revenues for the first quarter of 2016 only include sales from the date of the Tribute merger on February 5, 2016.

Other Revenues

Other revenues for the three months ended March 31, 2017 were \$19.3 million, an increase of \$14.8 million, compared to \$4.5 million for the three months ended March 31, 2016. The increase related primarily to net revenues totaling \$15.6 million for Zontivity and Toprol-XL and the AG, which were acquired in September 2016 and October 2016, respectively, and are being sold on our behalf by Merck and AstraZeneca, respectively, for an interim period post acquisition. The increase was offset by a decrease of approximately \$0.8 million in net royalties from VIMOVO during the first quarter of 2017.

Costs and Expenses

The following table sets forth costs and expenses for the periods presented:

	Three Months Ended March 31,	
	2017	2016
Costs and expenses:		
Cost of product revenues (exclusive of amortization shown separately below)	\$ 2,756	\$ 2,538
Selling, general and administrative	30,846	37,459
Research and development	94	4,412
Amortization of intangible assets	8,513	1,272
Change in fair value of contingent consideration	4,443	—
Total costs and expenses	<u>\$ 46,652</u>	<u>\$ 45,681</u>

Cost of Product Revenues

Cost of product revenues were \$2.8 million for the three months ended March 31, 2017, an increase of \$0.3 million compared, to \$2.5 million for the three months ended March 31, 2016. The increase related primarily to costs of product revenues for the full quarter in 2017 from our product portfolio that we acquired as part of the Tribute merger in February 2016, as well as Blexten and Yosprala, which received regulatory approval in April 2016 and

September 2016, respectively. In addition, the first quarter of 2016 reflects costs only for products revenues from February 5, 2016 through March 31, 2016.

Selling, General and Administrative Expenses

Our selling, general and administrative expenses were \$30.8 million for the three months ended March 31, 2017, a decrease of \$6.7 million, compared to \$37.5 million for the three months ended March 31, 2016. The decrease in SG&A expenses was primarily driven by costs related to the Tribute merger in the prior year of approximately \$19.4 million, partially offset by increased costs during the first quarter of 2017 of \$5.5 million related to the build out of our U.S. sales force in 2016, and increased promotional expenses in the U.S. of \$4.2 million.

Research and Development Expenses

Research and development expenses were \$0.1 million and \$4.4 million for the three months ended March 31, 2017 and 2016, respectively. The decrease in research and development expenses for the three months ended March 31, 2017 compared to March 31, 2016 was primarily due to lower costs incurred for Yosprala, for which FDA approval was received in September 2016.

Amortization of Intangible Assets

Amortization of acquired intangible assets is recognized ratably over the estimated useful life of the related assets acquired in the Merger and the acquisitions of Zontivity and Toprol-X-1 and the AG in 2016. Amortization expense was \$8.5 million and \$1.3 million for the three months ended March 31, 2017 and 2016, respectively. The increase of \$7.2 million during the three months ended March 31, 2017 primarily related to assets acquired in the Zontivity and Toprol-XL and the AG acquisitions in September 2016 and October 2016, respectively, as well as a full quarter of amortization in 2017 for the assets acquired in the Tribute merger.

Change in Fair Value of Contingent Consideration

Change in fair value of contingent consideration was \$4.4 million during the three months ended March 31, 2017 related primarily to accretion expense from the contingent consideration recorded in connection with the Zontivity and Toprol-XL and the AG acquisitions. There was no contingent consideration recorded during the first quarter of 2016.

Interest and Other Income, net

The following table sets forth interest expense and other income, net for the periods presented:

	Three Months Ended March 31,	
	2017	2016
Interest expense	\$ (6,653)	\$ (307)
Other income, net	411	4,797
Total interest and other income, net	\$ (6,242)	\$ 4,490

Interest Expense

Interest expense for the three months ended March 31, 2017 totaled \$6.7 million and was primarily due to the October 31, 2016 drawdown of \$200.0 million under a credit facility under the Second Amended and Restated Debt Facility Agreement (the "Facility Agreement"), dated December 7, 2015, among Aralez Pharmaceuticals Inc., Pozen, Tribute (the "Credit Parties") and certain lenders party thereto with an interest rate of 12.5% and the issuance of \$75.0 million aggregate principal amount of our 2.5% senior secured convertible notes in February 2016. Interest expense for the three months ended March 31, 2016 was \$0.3 million.

Other Income, net

Other income, net for the three months ended March 31, 2017 was \$0.4 million compared to \$4.8 million for the three months ended March 31, 2016, a decrease of \$4.4 million. The decrease principally related to a \$4.6 million decrease in the fair value of the warrants liability acquired from Tribute during the prior year, offset by a \$0.3 million gain from the sale of a building during the three months ended March 31, 2017.

Liquidity and Capital Resources

Our principal sources of liquidity are cash generated from the royalty payments received from our commercialization partners for net sales of VIMOVO; the operating income of Tribute; sales of Fibracor and its authorized generic, Yosprala, Zontivity, and Toprol-XL and the AG; and the financings completed on February 5, 2016 and October 31, 2016. Our principal liquidity requirements are for working capital; operational expenses; commercialization activities for products, including Yosprala, Zontivity, Toprol-XL and the AG, and Fibracor and our Canadian portfolio, and product candidates; contractual obligations, including any royalty and milestone payments that may become due; capital expenditures; and debt service payments. As of March 31, 2017, we had approximately \$73.7 million of cash and cash equivalents which, together with cash we expect to generate from our business, we currently believe is sufficient to fund our operations for at least the next twelve months, including our principal liquidity requirements set forth above.

Our ability to become profitable and/or to generate positive cash from operations depends upon, among other things, our ability to generate revenues from sales of our products and prudently manage its expenses. New sources of product revenue have only recently been approved, in the case of Yosprala in the United States and Blexten in Canada, or acquired by the Company, in the case of Zontivity in the United States and Canada and Toprol-XL and the AG in the United States. The ability of such products to generate revenues and cash flows depends on a variety of factors, including the success of our commercialization efforts and competition in applicable markets. If we do not generate sufficient product revenues, or prudently manage our expenses, our business, financial condition, cash flows and results of operations could be materially and adversely affected.

We have begun implementing cost savings initiatives, which include a 32% reduction in our U.S. sales force and realignment of certain financial resources to support the launch of Zontivity, together with a significant decrease in marketing spend on Yosprala and other cost reductions across the business. In addition, we are actively exploring other initiatives, such as business development opportunities and refinancing options, to improve our future liquidity. There can be no assurances that these other initiatives will be available on reasonable terms, or at all. If we are not successful in any or all of these initiatives, or if our future operations fail to meet our current expectations, our projected future liquidity may be limited, which could materially and adversely affect our business, financial condition, cash flows and results of operations.

To the extent our capital resources are insufficient to meet future operating requirements or business development activities, we may need to raise additional capital, reduce planned expenditures, or incur indebtedness, among other things. If we require additional financing in the future, we cannot assure you that it will be available to us on favorable terms, or at all, particularly if the credit and financial markets are constrained at the time we require funding. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, our business, financial condition, cash flows and results of operations could be materially and adversely affected.

Borrowings and Other Liabilities

At March 31, 2017, we had \$75.0 million aggregate principal outstanding related to our 2.5% senior secured convertible notes due February 2022 (the “2022 Notes”) issued to certain lenders under the Facility Agreement in connection with the closing of the Merger and \$200.0 million outstanding under a credit facility under the Facility Agreement, due on October 31, 2022, with an interest rate of 12.5% per annum.

See Note 8, “Debt,” in the accompanying notes to consolidated financial statements for additional information.

Repurchases of Common Shares

From time to time, our Board of Directors may authorize us to repurchase our common shares, subject to compliance with our credit agreement. If and when our Board of Directors should determine to authorize any such action, it would be on terms and under market conditions that the Board of Directors determines are in the best interest of Aralez and its shareholders. Any such repurchases could deplete some of our cash resources.

Cash Flows

Operating Activities

Net cash provided by operating activities was \$10.5 million for the three months ended March 31, 2017 compared to net cash used in operating activities of \$41.3 million for the three months ended March 31, 2016. Net cash provided by operating activities was primarily related to positive working capital from our Toprol-XL acquisition, as well as non-cash adjustments for depreciation and amortization, contingent consideration accretion, and stock-based compensation.

Net cash used in operating activities for the three months ended March 31, 2016 was primarily due to expenses related to the acquisition of Tribute, including payments of transaction expenses of approximately \$12.0 million, excise tax equalization payments of \$11.4 million, and severance payments of \$2.7 million. Also contributing were pre-commercialization expenses incurred for the launch of Yosprala and costs related to the build out and support of the global corporate infrastructure.

Investing Activities

Net cash used in investing activities was \$1.7 million for the three months ended March 31, 2017 compared to net cash used by investing activities of \$18.3 million for the three months ended March 31, 2016. Net cash used in investing activities for the three months ended March 31, 2017, principally related to \$1.5 million paid for capital expenditures. Net cash used in investing activities for the three months ended March 31, 2016, primarily consisted of \$17.9 million of cash consideration used to consummate the Merger, consisting of the repayment of Tribute indebtedness, net of cash acquired.

Financing Activities

Net cash used in financing activities for the three months ended March 31, 2017 was de minimis but included \$0.1 million related to contingent consideration payments. Net cash provided by financing activities for the three months ended March 31, 2016 was \$148.6 million and included the receipt of \$75.0 million from the issuance of the 2022 Notes and \$75.0 million from the issuance of equity to certain investors, net of issuance costs of \$0.7 million.

Commitments and Contingencies

Legal Proceedings

See Note 11, "Commitments and Contingencies," in the accompanying notes to condensed consolidated financial statements.

Contractual Obligations

The table below presents a summary of our contractual obligations at March 31, 2017 (in thousands):

Contractual Obligations (1)	Payments Due By Period				
	Total	Within 1 year	1-3 Years	3-5 Years	More than 5 years
2022 Notes – principal (2)	\$ 75,000	\$ —	\$ —	\$ 75,000	\$ —
2022 Notes – interest (2)	9,565	1,875	3,750	3,940	—
Credit Facility - principal (3)	200,000	—	—	—	200,000
Credit Facility - interest (3)	145,958	25,000	50,000	50,068	20,890
Operating lease obligations (4)	19,344	1,824	6,163	4,978	6,379
Other (5)	900	150	300	300	150
Total	\$ 450,767	\$ 28,849	\$ 60,213	\$ 134,286	\$ 227,419

- (1) This table does not include potential future milestone payments, royalty or profit-share obligations to third parties under asset purchase, product development, license and other agreements to the extent that the timing and likelihood of such milestone payments are not known, and, in the case of royalty and profit-share obligations, if the amount of such obligations are not reasonably estimable, as discussed below.
- (2) The interest expense for the 2022 Notes includes the fixed-rate 2.5% per annum interest payable on the \$75.0 million principal outstanding as of March 31, 2017. The table above assumes no conversions prior to maturity.
- (3) The interest expense on the borrowings under the credit facility under the Facility Agreement includes the fixed-rate 12.5% per annum interest payable on the \$200.0 million currently outstanding.
- (4) Amounts represent lease obligations existing at March 31, 2017, primarily for office space, including lease agreements for our global headquarters in Mississauga, Ontario, Canada, for our U.S. headquarters in Princeton, New Jersey, and for our Irish headquarters in Dublin, Ireland. The table above includes lease commitments for the full term of the leases under the respective agreements. Certain of such lease agreements may be terminated before the full term, including the agreement for the Princeton, New Jersey lease, which may be terminated after seven years in consideration of an early termination penalty equal to four months of rent.
- (5) Amounts consist of non-cancelable commitments to third parties for minimum royalties payable under various license, distribution and manufacturing agreements.

We have various agreements with third-parties with contingent consideration and milestone payments that are potentially payable by or to us, as more fully described in Note 2, “Business Agreements,” in the accompanying notes to the condensed consolidated financial statements. These payments are contingent upon achieving development, regulatory and/or sales-based milestones that may or may not ever be achieved. Therefore, our requirement to make or receive such payments in the future or at all is highly uncertain. These agreements include:

- In connection with our acquisition of Toprol-XL, we are obligated to pay certain milestone payments upon the occurrence of certain milestone events based on the annual aggregate net sales of Toprol-XL and the AG and other contingent events, which in no event will exceed \$48 million in the aggregate, and royalty payments of (A) 15% of total quarterly net sales of Toprol-XL and any other authorized or owned generic version of Toprol-XL that is marketed, distributed or sold by or on behalf of, or under a license or sublicense from, Aralez (other than the AG), and (B) 15% of quarterly net sales of the AG, but for purposes of royalty payments and clause (B) only, net sales do not include the supply price paid for the AG by Aralez Ireland to AstraZeneca under the supply agreement entered into between Aralez Ireland and AstraZeneca in respect of the applicable period.
- In connection with our acquisition of Zontivity, we are obligated to pay certain milestone payments upon the occurrence of certain milestone events based on the annual aggregate net sales of Zontivity, any

combination product containing vorapaxar sulphate and one or more other active pharmaceutical ingredients or any line extension thereof, which in no event will exceed \$80 million in the aggregate and royalty payments in the low double digits based on the annual aggregate net sales of Zontivity, any combination product containing vorapaxar sulphate and one or more other active pharmaceutical ingredients or any line extension thereof.

- Under an exclusive license and supply agreement with Faes Farma, S.A. (“Faes”), a Spanish pharmaceutical company, we have the exclusive right to sell bilastine, a product for the treatment of allergic rhinitis and chronic idiopathic urticaria (hives) in Canada, which is now named Blexten. We will owe up to \$1.7 million in sales-based milestone payments to Faes if certain sales targets are met.
- Under a license agreement with Nautilus, which was acquired by Depomed, Inc. in December 2013, we have the exclusive rights to develop, register, promote, manufacture, use, market, distribute and sell Cambia in Canada. Up to \$6.0 million in sales-based milestone payments may be payable over time.
- We have a product development and profit share agreement with Actavis to develop, obtain regulatory approval of and market Bezalip SR in the United States. We may owe a milestone payment of \$5.0 million to Actavis in the event that we pursue and obtain regulatory approval to market Bezalip SR in the United States.
- In connection with our acquisition of Fibracor and its authorized generic in the United States, we may be obligated to pay up to \$4.5 million in milestone payments based on annual net sales of Fibracor and its authorized generic as well as royalties ranging from the high single digits to low double digits based on annual net sales of such products.

Off-Balance Sheet Arrangements

At March 31, 2017, we have not entered into any off-balance sheet arrangements, as defined by Item 303(a)(4) of Regulation S-K.

Critical Accounting Policies and Estimates

We prepare our consolidated financial statements in conformity with accounting principles generally accepted in the United States, or GAAP. The preparation of consolidated financial statements requires estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and related disclosure of contingent assets and liabilities. Actual results may differ from these estimates. The accounting policies that we believe are most critical to fully understand our consolidated financial statements include those relating to: revenue recognition; intangible assets; contingent consideration; income taxes; accounting for share-based compensation; and fair value measurements.

Revenue Recognition

Principal sources of revenue are (i) net revenues from sales of Zontivity, Toprol-XL and the AG, and Yosprala (ii) product sales from the product portfolio acquired with our acquisition of Tribute, and (iii) royalty revenues from sales of VIMOVO by our commercialization partners. In all instances, revenue is recognized only when the price is fixed or determinable, persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered, and collectibility of the resulting receivable is reasonably assured.

Product Sales

Revenues from the sale of products acquired with our acquisition of Tribute are distributed through Canadian wholesalers to Canadian retail pharmacies and are recorded net of discounts, wholesaler fees, chargebacks, rebates, returns and allowances, and are recognized when legal title to the goods and risk of ownership has been passed to the customer which in this case is the Canadian wholesaler. Discounts, wholesaler fees, chargebacks, rebates, returns and

allowances are not significant for these product sales and are not expected to be significant in the future given the Canadian marketplace.

Revenues from the sale of Yosprala® in the United States are recorded on a sell through method since we do not have sufficient historical data to estimate returns. As such, we defer revenue and costs of inventory for all Yosprala products shipped to wholesalers in the United States until the product is sold through to the end customer. Revenue recorded since we launched Yosprala in the United States was not significant during the first quarter of 2017. Product sales from Fibrivor® are recorded on a sell in method and were not significant during the first quarter of 2017.

All of our products have a returns policy that allows the customer to return pharmaceutical products within a specified period of time both prior to and subsequent to the product's expiration date. Our estimate of the provision for returns for those products that use a sell in method is analyzed quarterly and is based upon many factors, including historical data of actual returns and analysis of the level of inventory in the distribution channel, if any. We believe that the reserves we have established is reasonable based upon current facts and circumstances. Applying different judgments to the same facts and circumstances could result in the estimated amount for reserves to vary. If actual results vary with respect to our reserves, we may need to adjust our estimates, which could have a material effect on our results of operations in the period of adjustment.

Other Revenues

Other revenues principally include revenues from licensing arrangements with other biopharmaceutical companies (principally royalty revenues from VIMOVO), including milestones payments and royalties. Revenue from royalties is recognized when we have fulfilled the terms in accordance with contractual agreements, have no future obligation, and the amount of the royalty fee is determinable. Royalty revenue that is reasonably estimable and determinable is recognized based on estimates utilizing information reported to us by its commercialization partners.

Other revenues also include net revenues from sales of Zontivity, from its acquisition date, recognized net of related cost of product revenues and fees paid to Merck under a transition services agreement in effect through March 31, 2017. Similarly, we also include net revenues from sales of Toprol-XL and the AG from its acquisition date, recognized net of related cost of product revenues and fees paid to AstraZeneca under a transition services agreement in effect through December 31, 2017 (as extended from July 31, 2017 pursuant to an amendment to the transition services agreement). We record these revenues net of related cost since we are not the principal in the arrangements and expect to record this revenue similar to a royalty arrangement until we are deemed to be the principal in the sales and marketing of these products, at which point we will record net sales and costs of revenue separately. Effective March 31, 2017, we will record revenues of Zontivity on a sell in method, which will be classified as product sales.

Intangible Assets

Goodwill

Goodwill relates to amounts that arose in connection with the acquisitions of Tribute, Zontivity and Toprol-XL and the AG. Goodwill represents the excess of the purchase price over the fair value of the net assets acquired when accounted for using the acquisition method of accounting for business combinations. Goodwill is not amortized but is evaluated for impairment on an annual basis, in the fourth quarter, or more frequently if an event occurs or circumstances change that would more-likely-than-not reduce the fair value of our reporting unit below its carrying amount.

Other Intangible Assets, net

Other intangible assets consist of acquired technology rights. The Company amortizes its intangible assets using the straight-line method over their estimated economic lives. Costs to obtain, maintain and defend the Company's patents are expensed as incurred. We will evaluate the potential impairment of other intangible assets if events or changes in circumstances indicate that the carrying amount of the assets may not be fully recoverable or that the useful lives of these assets are no longer appropriate. Events giving rise to impairment are an inherent risk in our industry and many factors cannot be predicted. Factors that we consider in deciding when to perform an impairment review include significant

changes in our forecasted projections for the asset or asset group for reasons including, but not limited to, significant under-performance of a product in relation to expectations, significant changes or planned changes in our use of the assets, significant negative industry or economic trends, and new or competing products that enter the marketplace. The impairment test is based on a comparison of the undiscounted cash flows expected to be generated from the use of the asset group and its eventual disposition to the carrying value of the asset group. If impairment is indicated, the asset is written down by the amount by which the carrying value of the asset exceeds the related fair value of the asset with the related impairment charge recognized within the statements of operations. Such impairment charges may be material to our results. The valuation techniques utilized in performing the initial valuation of other intangible assets or subsequent quantitative impairment tests incorporate significant assumptions and judgments to estimate the fair value. The use of different valuation techniques or assumptions could result in significantly different fair value estimates.

Contingent Consideration

Certain of the our business acquisitions involve the potential for future payment of consideration that is contingent upon the achievement of operational and commercial milestones and royalty payments on future product sales. The fair value of contingent consideration liabilities is determined at the acquisition date using unobservable inputs. These inputs include the estimated amount and timing of projected cash flows, the probability of success (achievement of the contingent event) and the risk-adjusted discount rate used to present value the probability-weighted cash flows. Subsequent to the acquisition date, at each reporting period, the contingent consideration liability is remeasured at current fair value with changes recorded in the consolidated statements of operations. Changes in any of the inputs may result in a significantly different fair value adjustment.

Income Taxes

We account for income taxes using the liability method in accordance with Financial Accounting Standards Board (“FASB”) Accounting Standards Codification (“ASC”), Topic 740, “Income Taxes” (“ASC 740”). Deferred tax assets and liabilities are determined based on temporary differences between financial reporting and tax basis assets and liabilities and are measured by applying enacted rates and laws to taxable years in which differences are expected to be recovered or settled. Further, the effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that the rate changes. A valuation allowance is required when it is “more-likely-than-not” that all or a portion of deferred tax assets will not be realized. Since our inception, we have incurred substantial cumulative losses and may incur substantial and recurring losses in future periods. The utilization of the loss carryforwards to reduce future income taxes will depend on our ability to generate sufficient taxable income prior to the expiration of the loss carryforwards. In addition, the maximum annual use of net operating loss and research credit carryforwards is limited in certain situations where changes occur in stock ownership.

Aralez files federal and state income tax returns, as applicable, with the tax authorities in various jurisdictions including Canada, Ireland and the United States. Pozen is no longer subject to U.S. federal or North Carolina state income tax examinations by tax authorities for years before 2013. Tribute is no longer subject to Canadian income tax examinations by tax authorities for years before 2011. However, the loss and credit carryforwards generated by Pozen and Tribute may still be subject to change to the extent these losses and credits are utilized in a year that is subject to examination by tax authorities.

ASC 740 prescribes a comprehensive model for how a company should recognize, measure, present and disclose in its financial statements uncertain tax positions that the company has taken or expects to take on a tax return, including a decision whether to file or not file a return in a particular jurisdiction. Our financial statements reflect expected future tax consequences of such positions presuming the taxing authorities’ full knowledge of the position and all relevant facts. We recognize any interest and penalties accrued related to unrecognized tax benefits as income tax expense.

Share-Based Compensation

We expense the fair value of employee share-based compensation over the employees' service periods, which are generally the vesting period of the equity award. For awards with performance conditions granted, we recognize

compensation cost over the expected period to achieve the performance conditions, provided achievement of the performance conditions are deemed probable. Awards with market-based conditions are expensed over the service period regardless of whether achievement of the market condition is deemed probable or is ultimately achieved. Compensation expense is measured using the fair value of the award at the grant date, adjusted for estimated forfeitures.

In order to determine the fair value of option awards on the grant date, we use the Black-Scholes option pricing model. Inherent in this model are assumptions related to expected share price volatility, estimated option life, risk-free interest rate and dividend yield. Our expected share price volatility assumption is based on the historical volatility of our common shares, which is obtained from public data sources. The expected life represents the weighted average period of time that share-based awards are expected to be outstanding giving consideration to vesting schedules, historical exercise patterns and post-vesting cancellations for terminated employees that have been exhibited historically, adjusted for specific factors that may influence future exercise patterns. The risk-free interest rate is based on factual data derived from public sources. We use a dividend yield of zero as we have no intention to pay cash dividends in the foreseeable future. For performance-based awards with market conditions, the Company used a Monte Carlo simulation model to determine the fair value of awards as of the grant date.

Determining the appropriate amount to expense for performance-based awards based on the achievement of stated goals requires judgment, including forecasting future performance results. The estimate of expense is revised periodically based on the probability of achieving the required performance targets and adjustments are made as appropriate. The cumulative impact of any revisions is reflected in the period of change. If any applicable financial performance goals are not met, no compensation cost is recognized and any previously recognized compensation cost is reversed.

In the first quarter of 2017, we adopted ASU 2016-09. As a result of the adoption of ASU 2016-09, We recognize the impact of forfeitures when they occur, with no adjustment for estimated forfeitures, and recognize excess tax benefits as a reduction of income tax expense regardless of whether the benefit reduces income taxes payable. Additionally, we now recognize the cash flow impact of such excess tax benefits in operating activities in our condensed consolidated statements of cash flows. The classification of excess tax benefits on the statement of cash flows for the prior period have not been adjusted. There was no net impact on our opening accumulated deficit upon application of this guidance using the modified retrospective transition method as the total cumulative-effect adjustment for previously deferred excess tax benefits was offset by a related change in the valuation allowance.

Fair Value Measurements

The accounting standard for fair value measurements defines fair value, establishes a framework for measuring fair value in accordance with GAAP, and requires detailed disclosures about fair value measurements. Under this standard, fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The valuation techniques are based on observable and unobservable inputs. Observable inputs reflect readily obtainable data from independent sources, while unobservable inputs reflect certain market assumptions. This standard classifies these inputs into the following hierarchy:

- *Level 1 Inputs* — Quoted prices for identical instruments in active markets.
- *Level 2 Inputs* — Quoted prices for similar instruments in active markets; quoted prices for identical or similar instruments in markets that are not active; and model-derived valuations whose inputs are observable or whose significant value drivers are observable.
- *Level 3 Inputs* — Instruments with primarily unobservable value drivers.

The fair value hierarchy level is determined by asset class based on the lowest level of significant input. In periods of market inactivity, the observability of prices and inputs may be reduced for certain instruments. This condition could cause an instrument to be reclassified between levels.

The carrying amount of our cash and cash equivalents approximate its fair value due to the short-term nature of these amounts. The warrants liability and contingent consideration are our only liabilities carried at fair value, and we utilized Level 3 inputs to estimate fair value. The significant unobservable inputs used in the fair value measurement of our warrants liability, which uses a Black-Scholes valuation model, include the volatility of our common shares and the expected term. The significant unobservable inputs used in the fair value measurement of our contingent consideration liability include the estimated amount and timing of projected cash flows, the probability of success (achievement of the contingent event) and the risk-adjusted discount rate used to present value the probability-weighted cash flows. The use of different inputs could result in materially different fair value estimates.

Recent Accounting Pronouncements

See Note 1, “Organization, Basis of Presentation and Accounting Policies”, in the accompanying notes to condensed consolidated financial statements within Item 1 of Part I in this report, which is incorporated herein by reference.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our cash on hand is invested in bank deposits and money market funds that invest primarily in short-term, highly-rated investments, including U.S. government securities, commercial paper and certificates of deposit guaranteed by banks and short-term corporate fixed income obligations and U.S. government and government agency obligations. Under our current policies, we do not use interest rate derivative instruments to manage our exposure to interest rate changes. Due to the short-term maturities of our investments, we do not believe that a decrease in market rates would have a significant negative impact on the value of our investment portfolio.

Aralez will face market risks attributable to fluctuations in foreign currency exchange rates and foreign currency exposure on the translation into U.S. dollars of the financial results of our operations in Canada and Europe. Both favorable and unfavorable foreign currency impacts to our foreign currency-denominated operating expenses are mitigated to a certain extent by the natural, opposite impact on our foreign currency-denominated revenue.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures designed to ensure that we are able to collect the information we are required to disclose in the reports we file with the SEC and to process, summarize and disclose this information within the time periods specified in the rules and forms of the SEC. Based on the evaluation of our disclosure controls and procedures (as defined in the Exchange Act, Rules 13a-15(e) and 15d-15(e)) as of March 31, 2017, our Chief Executive Officer and Chief Financial Officer have concluded that such disclosure controls and procedures are effective to ensure that information required to be disclosed in our periodic reports filed under the Exchange Act is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure and is recorded, processed, summarized and reported within the time periods specified by the SEC’s rules and forms.

Changes in Internal Control over Financial Reporting

There were no changes in the our internal control over financial reporting for the quarterly period ended March 31, 2017 identified in connection with the evaluation required by Rules 13a-15(e) and 15d-15(e) of the Exchange Act that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. Other Information

ITEM 1. LEGAL PROCEEDINGS

See Note 11, “Commitments and Contingencies,” in the accompanying notes to condensed consolidated financial statements within Item 1 of Part I in this report, which is incorporated herein by reference.

ITEM 1A. RISK FACTORS

In addition to the other information set forth in this report, you should carefully consider the following risk factor as well as the risk factors discussed under the “Risk Factors” section included in our 2016 Annual Report on Form 10-K, which was filed on March 13, 2017. The following updates and supplements the risk factors previously disclosed in the Annual Report.

Our expense reduction initiatives, including our recent decision to reduce our U.S. sales force, may impact our ability to maintain or increase our sales levels or successfully commercialize our products. In addition, we may not realize the expected benefits of our initiatives to reduce costs across our operations.

Our ability to successfully commercialize our products depends in part on our sales and marketing resources, including sales personnel, dedicated to such efforts. We recently announced a number of expense reduction initiatives, including a reduction in our U.S. sales force. Each remaining sales representative will be now responsible for a larger territory than prior to the reduction in force. The sales force reduction could harm our ability to attract and retain qualified sales personnel. The sales force reduction could also result in a lack of focus and reduced productivity among our remaining sales personnel. All of the foregoing may negatively impact the sales of our products.

In addition, we have incurred restructuring charges and may incur additional restructuring charges as we implement our cost saving initiatives and we may not realize some or all of the expected benefits from such initiatives. There may also be significant disruptions in our operations now or in the future as a result of these initiatives, which may impact our business, financial condition or results of operations.

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

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

- 10.1 VA National Contract signed February 11, 2016 and effective April 29, 2016, between the United States of America and Aralez Pharmaceuticals US Inc., by novation pursuant to a Novation Agreement, entered into on February 23, 2017, between the United States of America, Aralez Pharmaceuticals US Inc. and AstraZeneca Pharmaceuticals LP. †
- 10.2 Modification of Contract, executed on April 6, 2017 and effective April 29, 2017, between the United States of America and Aralez Pharmaceuticals US Inc. (incorporated by reference to Exhibit 10.1 to Aralez Pharmaceutical Inc.'s Current Report on Form 8-K filed April 11, 2017)
- 10.3 Amendment to Employment Agreement with Adrian Adams, dated March 20, 2017 (incorporated by reference to Exhibit 10.1 to Aralez Pharmaceutical Inc.'s Current Report on Form 8-K filed March 23, 2017).
- 10.4 Amendment to Employment Agreement with Andrew Koven, dated March 20, 2017 (incorporated by reference to Exhibit 10.2 to Aralez Pharmaceutical Inc.'s Current Report on Form 8-K filed March 23, 2017).
- 31.1 Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 31.2 Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 32.1 Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 32.2 Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 101 The following materials from Aralez Pharmaceuticals Inc.'s Form 10-Q for the quarter ended March 31, 2017, formatted in eXtensible Business Reporting Language (XBRL): (i) Condensed Consolidated Balance Sheets at March 31, 2017 and December 31, 2016, (ii) Condensed Consolidated Statements of Operations for the three months ended March 31, 2017 and 2016, (iii) Condensed Consolidated Statements of Comprehensive Loss for the three months ended March 31, 2017 and 2016, (iv) Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2017 and 2016, and (v) Notes to Condensed Consolidated Financial Statements.

† Portions hereof have been omitted and filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment in accordance with Exchange Act Rule 24b-2

[***] INDICATES MATERIAL THAT WAS OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT WAS REQUESTED. ALL SUCH OMITTED MATERIAL WAS FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO THE RULES APPLICABLE TO SUCH CONFIDENTIAL TREATMENT REQUEST.

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT		BPA NO.	1. CONTRACT ID CODE	PAGE	OF PAGES
				1	1

2. AMENDMENT/MODIFICATION NUMBER P00002	3. EFFECTIVE DATE See Block 16c	4. REQUISITION/PURCHASE REQ. NUMBER	5. PROJECT NUMBER (If applicable) 1
--	------------------------------------	-------------------------------------	--

6. ISSUED BY CODE	7. ADMINISTERED BY (If other than Item 6) CODE
	Department of Veterans Affairs OA&L / National Acquisition Center Building 37 1st Avenue, One Block North of Cermak Hines IL 60141

8. NAME AND ADDRESS OF CONTRACTOR (Number, street, county, state, and ZIP Code) ARALEZ PHARMACEUTICALS US INC. 555 E LANCASTER AVE STE 540 RADNOR PA 19087 CODE 7KH89	(X)	9A. AMENDMENT OF SOLICITATION NUMBER
		9B. DATED (SEE ITEM 11)
	X	10A. MODIFICATION OF CONTRACT/ORDER NUMBER VA797P-16-C-0035
		10B. DATED (SEE ITEM 13) 02-11-2016

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers is extended, is not extended. Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or electronic communication which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by letter or electronic communication, provided each letter or electronic communication makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required)

13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS, IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

CHECK ONE	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103 (b).
	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:
X	D. OTHER (Specify type of modification and authority) FAR 52.212-4 Changes

E. IMPORTANT: Contractor is not, is required to sign this document and return 1 copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)

Designation of Agent Agreement

This modification is issued to incorporate the attached Designation of Agent into National Contract VA797P-16-C-0035 for Metoprolol SA Tablets.

This Designation of Agent Agreement consists of 5 pages and is attached herein.

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type for Print) Eric Trachtenberg, Secretary	16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print) Adrienne A. Albachiara, Contracting officer
15B. CONTRACTOR/OFFEROR _____ /s/ Eric Trachtenberg (Signature of person authorized to sign)	16B. UNITED STATES OF AMERICA BY ADRIENNE A. ALBACHIARA [***] (Signature of Contracting Officer)
15C. DATE SIGNED 3/2/17	16C. DATE SIGNED 3/2/2017

PREVIOUS EDITION NOT USABLE

STANDARD FORM 30 (REV. 11/2016)
Prescribed by GSA - FAR (48 CFR) 53.243

[***] INDICATES MATERIAL THAT WAS OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT WAS REQUESTED. ALL SUCH OMITTED MATERIAL WAS FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO THE RULES APPLICABLE TO SUCH CONFIDENTIAL TREATMENT REQUEST.

DESIGNATION OF AGENT AGREEMENT

This Designation of Agent Agreement ("Agreement") is entered effective as of February 23, 2017 by and between Aralez Pharmaceuticals US Inc. ("Contractor"), a corporation duly organized and existing under the laws of Pennsylvania with its principal office located at 400 Alexander Park, Princeton, NJ 08540, AstraZeneca Pharmaceuticals LP ("Agent"), a corporation duly organized and existing under the laws of Delaware with its principal office located at 1800 Concord Pike, Wilmington, DE 19803 and the United States Government, represented by the Department of Veterans Affairs (the "Government").

WHEREAS, effective October 31, 2016, assets, rights, and interests ("Purchased Assets") that are necessary for Contractor to sell and market the pharmaceutical product containing metoprolol succinate as the active pharmaceutical ingredient and distributed under the brand name Toprol-XL® National Drug Codes that are listed in Attachment "A" to this Agreement (the "Product") were acquired by Aralez Pharmaceuticals Trading DAC;

WHEREAS, the Government, Contractor, and Agent have entered into a Novation Agreement with an effective date of February 23, 2017, pursuant to which the Government has approved and recognized the Contractor as successor in interest to the VA National Contract No. VA797P-16-C-0035 (the "VA National Contract");

WHEREAS, under a Supply Agreement, dated as of October 31, 2016 (the "Supply Agreement") with a term of at least ten years, AstraZeneca AB, a corporate affiliate of Agent, will continue to manufacture and supply the Product that the Contractor will market and sell under the VA National Contract; and

WHEREAS, under a Transitional Services Agreement, dated as of October 31, 2016 ("TSA"), AstraZeneca AB has agreed to perform certain services for a period of time following the transfer of the Purchased Assets to facilitate the transition of the supply, sale, and distribution of the Product.

NOW THEREFORE, in consideration of the foregoing and in accordance with the mutual agreements and understandings set forth below, Contractor hereby designates Agent as a designated agent for certain limited purposes relating to the VA National Contract.

1. Designation. The Contractor hereby designates Agent to act as designated agent for the purposes of:
 - a. Supplying the Product to the Pharmaceutical Prime Vendor Contractors listed in Attachment "B" of this Agreement ("PPV Contractors") in accordance with the terms of and for the periods prescribed in the Supply Agreement; and
 - b. Processing and administering discounts and chargebacks in connection with wholesaler sales of the Product in accordance with the terms of and for the periods prescribed in the VA National Contract and the TSA.
-

[*] INDICATES MATERIAL THAT WAS OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT WAS REQUESTED. ALL SUCH OMITTED MATERIAL WAS FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO THE RULES APPLICABLE TO SUCH CONFIDENTIAL TREATMENT REQUEST.**

2. Ordering. The parties understand that the PPV Contractors are responsible for the following activities:
 - a. Receiving and filling Government orders for the purchase of the Product under the VA National Contract;
 - b. Invoicing and billing the Government for such purchases; and
 - c. Receiving payment for such purchases from the Government.
3. Construction and Order of Precedence. Nothing in this Agreement is intended to or shall be construed to add to or alter the rights and obligations set forth in the Supply Agreement and the TSA. In the event of any inconsistency between the provisions of this Agreement and the provisions of the Supply Agreement or the TSA, the provisions of the Supply Agreement or the TSA, as applicable, shall govern. In the event of any inconsistency between the provisions of this Agreement, the Supply Agreement, or the TSA and the VA National Contract, the provisions of the VA National Contract shall govern; provided, however, that the Agent's obligations will not extend beyond those specifically enumerated in the Supply Agreement or the TSA.
4. No liability to Agent. Nothing in this Agreement shall give rise to any Government liability to Agent under the VA National Contract.
5. Identity of Contractor. Contractor shall remain the contractor for all purposes under the VA National Contract, and shall ensure that Agent performs its functions as agent in a manner consistent with the terms of the VA National Contract. The Government's recognition of Agent under this Agreement shall not be construed as a waiver of any rights of the Government against Contractor under the VA National Contract.
6. Expiration of Agreement. This Agreement shall remain in effect until the Government's receipt of Contractor's or Agent's written cancellation of the designation.
7. Recognition of designation. The Government and the Contractor, by their respective authorized representatives, hereby recognize AstraZeneca Pharmaceuticals LP as designated agent for the limited purposes stated in this Agreement.

IN WITNESS WHEREOF, the parties have caused this Agreement to be duly executed by their respective authorized representatives.

[Signature Page Follows]

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ARALEZ PHARMACEUTICALS US INC., Contractor

By /s/ Eric Trachtenberg

Name Eric Trachtenberg

Title Secretary

Date 3/2/17

ASTRAZENECA PHARMACEUTICALS LP, Agent

By

Name

Title

Date

UNITED STATES GOVERNMENT

By ADRIENNE A. [***]
ALBACHIARA [***]

Name Adrienne A. Albachiara

Title Contracting Officer, Department of Veterans Affairs

Date 3/3/2017

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ARALEZ PHARMACEUTICALS US INC., Contractor

By

Name

Title

Date

ASTRAZENECA PHARMACEUTICALS LP, Agent

By /s/ Odalys Caprisecca

Name Odalys Caprisecca

Title Sr Director, Pricing Government Reporting

Date 2/1/17

UNITED STATES GOVERNMENT

By /s/ Adrienne A. Albachiara

Name Adrienne A. Albachiara

Title Contracting Officer, Department of Veterans Affairs

Date

[***] INDICATES MATERIAL THAT WAS OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT WAS REQUESTED. ALL SUCH OMITTED MATERIAL WAS FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO THE RULES APPLICABLE TO SUCH CONFIDENTIAL TREATMENT REQUEST.

ATTACHMENT "A"

Toprol-XL National Drug Codes (NDCs)

NDC 00186-1092-05
NDC 00186-1094-05
NDC 00186-1088-05
NDC 00186-1090-05
NDC 00186-1094-35
NDC 00186-1094-05
NDC 00186-1092-35
NDC 00186-1092-05
NDC 00186-1090-35
NDC 00186-1090-05
NDC 00186-1088-35
NDC 00186-1088-05

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ATTACHMENT "B"

VA PHARMACEUTICAL PRIME VENDOR (PPV) CONTRACTOR

<p>McKesson Corporation One Postal Street, 29th Floor San Francisco, CA 94101 POC: Mr. Paul Flach Vice President Government & National Accounts Phone: [***]</p>

DOD PHARMACEUTICAL PRIME VENDOR (PPV) CONTRACTORS

<p>McKesson Drug Company Attn: Lori White 1220 Senlac Drive Carrollton, TX 75006 Phone: [***] Fax: [***] Tricare Mail Order Pharmacy Program National Prime Vendor Email: [***]</p>	<p>AmeriSource-Bergen Company Attn: Dina Barton 100 Friars Blvd. Thorofare, NJ 08086 Phone: [***] Fax: [***] Email: [***]</p>
<p>Dakota Drug Company Attn: Jan McCann / Becky Gilstad 28-32 N. Main Street Minot, ND 58701 Phone: [***] Fax: [***] Email: [***]</p>	<p>DMS Pharmaceutical Group, Inc. Attn: Jean Hawkins 810 Busee Highway Park Ridge, IL 60068 Phone: [***] Fax: [***] Email: [***]</p>
<p>Cardinal Health, Inc. Attn: Lisa Parsley 5555 Glendon Court Dublin, OH 43016 Phone: [***] Fax: [***] Email: [***]</p>	

[*] INDICATES MATERIAL THAT WAS OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT WAS REQUESTED. ALL SUCH OMITTED MATERIAL WAS FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO THE RULES APPLICABLE TO SUCH CONFIDENTIAL TREATMENT REQUEST.**

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT			BPA NO	1. CONTRACT ID CODE	PAGE OF PAGES 1 1
2. AMENDMENT/MODIFICATION NUMBER P00001	3. EFFECTIVE DATE 2/23/2017	4. REQUISITION/PURCHASE REQ. NUMBER	5. PROJECT NUMBER (if applicable) 1		
6. ISSUED BY CODE		7. ADMINISTERED BY (If other Than Item 6) CODE	Department of Veterans Affairs OA&L / National Acquisition Center Building 37 1st Avenue, One Block North of Cermak Hines IL 60141		
8. NAME AND ADDRESS OF CONTRACTOR (Number, street, county, state and ZIP Code) ARALEZ PHARMACEUTICALS US INC. 400 Alexander Park Drive Princeton, NJ 08540			(X)	9A. AMENDMENT OF SOLICITATION NUMBER	
				9B. DATED (SEE ITEM 11)	
			X	10A. MODIFICATION OF CONTRACT/ORDER NUMBER VA797P-16-C-0035	
				10B. DATED (SEE ITEM 13) 02-11-2016	
CODE 7KH89	FACILITY CODE				

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

The above numbered, solicitation is amended as set forth in item 14. The hour and date specified for receipt of Offers is extended, is not extended. Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or electronic communication which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by letter or electronic communication, provided each letter or electronic communication makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If Required)

13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS, IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

CHECK ONE	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
X	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43,103 (b).
	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:
	D. OTHER (Specify type of modification and authority)

E. IMPORTANT: Contractor is not, is required to sign this document and return _____ copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)

Novation of VA797P-16-C-0035 Metoprolol SA Tablets

This modification is issued to incorporate the attached Novation Agreement which also necessitates a name change and updated point of contact and authorized Aralez Pharmaceuticals US, Inc. per letter dated January 4, 2017. This Novation Agreement covers all Metoprolol line items under Contract VA797P-16-C-0035. The changes are as follows:

From: AstraZeneca Pharmaceuticals LP 1800 Concord Pike Wilmington, DE 19803 DUNS: 87-651-6568/TIN: 23-2967016	To: Aralez Pharmaceuticals US, Inc. 400 Alexander Park Drive Princeton, NJ 08540 DUNS: 08-008-0206/TIN: 47-4626948
--	---

All other terms and conditions remain the same as previously awarded.

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print)	16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print) Adrienne A. Albachiera, Contracting officer
15B. CONTRACTOR/OFFEROR (Signature of person authorized to sign)	15C. DATE SIGNED 3/2/2017
16B. UNITED STATES OF AMERICA BY _____ /s/ Adrienne A. Albachiera (Signature of Contracting Officer)	16C. DATE SIGNED 2/23/2017

PREVIOUS EDITION NOT USABLE

STANDARD FORM 30 (REV. 11/2016)
Prescribed by GSA - FAR (48 CFR) 53.243

NOVATION AGREEMENT

AstraZeneca Pharmaceuticals LP ("Transferor"), a Delaware limited partnership and subsidiary of AstraZeneca AB; Aralez Pharmaceuticals US Inc. ("Transferee"), a company duly organized and existing under the laws of Delaware and corporate affiliate of Aralez Pharmaceuticals Trading DAC ("APTD"); and the United States of America ("Government") enter into this Agreement as of October 31, 2016.

(a) The parties agree to the following facts:

(1) The Government, represented by various Contracting Officers of Department of Veterans Affairs ("VA"), has entered into VA National Contract No. VA797P-16-C-0035 ("VA National Contract") with the Transferor. The term "the VA National Contract" as used in this Agreement, includes any and all orders under the VA National Contract made between the Government and the Transferor before the effective date of this Agreement (whether or not performance and payment have been completed and releases executed if the Government or the Transferor has any remaining rights, duties, or obligations). Included in the term "the VA National Contract" are also all modifications made under the terms and conditions of the VA National Contract between the Government and the Transferee, on or after the effective date of this Agreement.

(2) As of the date of this Agreement, all assets, rights, and interests of the Transferor required for the Transferee to market and sell Toprol XL® in the United States, including sales under the VA National Contract have been transferred to the APTD, a corporate affiliate of the Transferee, by virtue of an Asset Purchase Agreement dated October 3, 2016. The transfer of assets includes contracts, regulatory approvals, regulatory documentation, product records, domain names, promotional materials, and inventory. Under a ten-year Supply Agreement, AstraZeneca AB will continue to manufacture and supply product that the Transferee will market and sell in the United States, including sales under the VA National Contract.

(3) The Transferee has acquired rights to all the assets of the Transferor involved in performance of the VA National Contract Agreement by virtue of the above transfer and intra-company agreements between APTD and the Transferee.

(4) The Transferee has assumed all obligations and liabilities of the Transferor under the VA National Contract by virtue of the above transfer and an intra-company agreements between APTD and the Transferee.

- (5) The Transferee is in a position to fully perform all obligations that may exist under the VA National Contract.
- (6) It is consistent with the Government's interest to recognize the Transferee as the successor party to the VA National Contract.
- (7) Evidence of the above transfer has been filed with the Government.

(b) In consideration of these facts, the parties agree that by this Agreement—

(1) The Transferor confirms the transfer to the Transferee, and waives any claims and rights against the Government that it now has or may have in the future in connection with the VA National Contract.

(2) The Transferee agrees to be bound by and to perform the VA National Contract in accordance with the conditions contained in the VA National Contract. The Transferee also assumes all obligations and liabilities of, and all claims against, the Transferor under the VA National Contract as if the Transferee were the original party to the VA National Contract.

(3) The Transferee ratifies all previous actions taken by the Transferor with respect to the VA National Contract, with the same force and effect as if the action had been taken by the Transferee.

(4) The Government recognizes the Transferee as the Transferor's successor in interest in and to the VA National Contract. The Transferee by this Agreement becomes entitled to all rights, titles, and interests of the Transferor in and to the VA National Contract as if the Transferee were the original party to the VA National Contract. Following the effective date of this Agreement, the term "Contractor," as used in the VA National Contract, shall refer to the Transferee.

(5) Except as expressly provided in this Agreement, nothing in it shall be construed as a waiver of any rights of the VA against the Transferor.

(6) All payments and reimbursements previously made by the Government to the Transferor, and all other previous actions taken by the under the VA National Contract, shall be considered to have discharged those parts of the Government's obligations under the VA National Contract. All payments and reimbursements made by the Government after the date of this Agreement in the name of or to the Transferor shall have the same force and effect as if

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Confidential / Exempt From Disclosure Under FOIA

made to the Transferee, and shall constitute a complete discharge of the Government's obligations under the VA National Contract, to the extent of the amounts paid or reimbursed.

(7) The Transferor and the Transferee agree that the Government is not obligated to pay or reimburse either of them for, or otherwise give effect to, any costs, taxes, or other expenses, or any related increases, directly or indirectly arising out of or resulting from the transfer of this Agreement, other than those that the Government in the absence of this transfer or Agreement would have been obligated to pay or reimburse under the terms of the contracts.

(8) The Transferor guarantees payment of all liabilities and the performance of all obligations that the Transferee—

(i) Assumes under this Agreement; or

(ii) May undertake in the future should the VA National Contract be modified under their terms and conditions. The Transferor waives notice of, and consents to, any such future modifications.

(9) The VA National Contract shall remain in full force and effect, except as modified by this Agreement. Each party has executed this Agreement as of the day and year first above written.

[Signature Page Follows]

[*] INDICATES MATERIAL THAT WAS OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT WAS REQUESTED. ALL SUCH OMITTED MATERIAL WAS FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO THE RULES APPLICABLE TO SUCH CONFIDENTIAL TREATMENT REQUEST.**

Confidential / Exempt From Disclosure Under FOIA

UNITED STATES OF AMERICA,

By /s/ Adrienne A. Albachiara
Name Adrienne A. Albachiara
Title Contracting Officer, VANAC

ASTRAZENECA PHARMACEUTICALS LP,

By _____
Name _____
Title _____

ARALEZ PHARMACEUTICALS US INC.

By /s/ ANDREW I KOVEN
Name ANDREW I KOVEN
Title PRESIDENT

[*] INDICATES MATERIAL THAT WAS OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT WAS REQUESTED. ALL SUCH OMITTED MATERIAL WAS FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO THE RULES APPLICABLE TO SUCH CONFIDENTIAL TREATMENT REQUEST.**

UNITED STATES OF AMERICA,

By _____
Name _____
Title _____

ASTRAZENECA PHARMACEUTICALS LP,

By /s/ Odalys Caprisecca
Name Odalys Caprisecca
Title Sr. Director, Pricing & Government Reporting

ARALEZ PHARMACEUTICALS US INC.

By _____
Name _____
Title _____

[*] INDICATES MATERIAL THAT WAS OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT WAS REQUESTED. ALL SUCH OMITTED MATERIAL WAS FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO THE RULES APPLICABLE TO SUCH CONFIDENTIAL TREATMENT REQUEST.**

SOLICITATION/CONTRACT/ORDER FOR COMMERCIAL ITEMS OFFEROR TO COMPLETE BLOCKS 12, 17, 23, 24, & 30				1. REQUISITION NO.		PAGE 1 OF 66	
2. CONTRACT NO. VA797P-16-C-0035_		3. AWARD/EFFECTIVE DATE 4/29/2016		4. ORDER NO.		5. SOLICITATION NUMBER VA797P-16-R-0011	
7. FOR SOLICITATION INFORMATION CALL:		a. NAME Diana Martinez [***]		b. TELEPHONE NO. (No Collect Calls) 708-786-5160		8. OFFER DUE DATE/LOCAL TIME 11-23-2015 2:30PM (CST)	
9. ISSUED BY Department of Veterans Affairs OA&L / National Acquisition Center Building 37, NCS (003A4C4) 1st Avenue, One Block North of Cermak Hines IL 60141		CODE		10. THIS ACQUISITION IS <input type="checkbox"/> SMALL BUSINESS <input type="checkbox"/> HUBZONE SMALL BUSINESS <input type="checkbox"/> SERVICE-DISABLED VETERAN-OWNED SMALL BUSINESS		<input checked="" type="checkbox"/> UNRESTRICTED OR <input type="checkbox"/> SET ASIDE: _____ % FOR: <input type="checkbox"/> WOMEN-OWNED SMALL BUSINESS (WOSB) ELIGIBLE UNDER THE WOMEN-OWNED SMALL BUSINESS PROGRAM NAICS: 325412 <input type="checkbox"/> EDWOSB <input type="checkbox"/> 8(A) SIZE STANDARD: 750 Employees	
11. DELIVERY FOR FOB DESTINATION UNLESS BLOCK IS MARKED <input type="checkbox"/> SEE SCHEDULE		12. DISCOUNT TERMS N/A		<input type="checkbox"/> 13a. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)		13b. RATING N/A	
15. DELIVER TO VA & DOD Pharmaceutical Prime Vendors Refer to Attachments A & B		CODE		16. ADMINISTERED BY Department of Veterans Affairs OA&L / National Acquisition Center Building 37, NCS (003A4C4) 1st Avenue, One Block North of Cermak Hines IL 60141		CODE	
17a. CONTRACTOR/OFFEROR Astrazeneca Pharmaceuticals LP 1800 Concord Pike Wilmington, DE, 19803 1-302-886-0054 DUNS: 876516568 TELEPHONE NO.		CODE		FACILITY CODE		18a. PAYMENT WILL BE MADE BY VA & DOD Pharmaceutical Prime Vendors Refer to Attachments A & B	
Cage Code: 36WK2 DUNS: DUNS+4:		PHONE:		FAX:			
<input type="checkbox"/> 17b. CHECK IF REMITTANCE IS DIFFERENT AND PUT SUCH ADDRESS IN OFFER				18b. SUBMIT INVOICES TO ADDRESS SHOWN IN BLOCK 18a UNLESS BLOCK BELOW IS CHECKED <input type="checkbox"/> SEE ADDENDUM			
19. ITEM NO.		20. SCHEDULE OF SUPPLIES/SERVICES		21. QUANTITY	22. UNIT	23. UNIT PRICE	24. AMOUNT
		Metoprolol SA Succinate Tablets Award will be made in the aggregate for the base year and all four option years for line items 1, 2a or 2b, 3, 4a or 4b, 5, 6a or 6b, 7, and 8a or 8b. To be considered for award, offerors must submit a price for the base year and all four option years for line items 1, 2a or 2b, 3, 4a or 4b, 5, 6a or 6b, 7, and 8a or 8b. Prices offered shall not exceed two decimal places. Offered prices must include the Cost Recovery Fee of [***], as outlined in Scope of Contract. Offerors must list an 11 digit NDC number for each offered drug that is unique to the offeror's company as outlined in Scope of Contract. If the offeror is a distributor, the NDC number must be unique to the distributor. (Use Reverse and/or Attach Additional Sheet as Necessary)					
25. ACCOUNTING AND APPROPRIATION DATA				26. TOTAL AWARD AMOUNT (For Govt. Use Only) [***]			
<input type="checkbox"/> 27a. solicitation incorporates by reference FAR 52.212-1, 52.212-4, Far 52.212-3 and 52.212-5 ARE attached. Addenda <input checked="" type="checkbox"/> are <input type="checkbox"/> are not attached. <input type="checkbox"/> 27b. contract/purchase order incorporates by reference FAR 52.212-4, FAR 52.212-5 is attached. Addenda <input type="checkbox"/> are <input type="checkbox"/> are not attached.							
<input checked="" type="checkbox"/> 28. CONTRACTOR IS REQUIRED TO SIGN THIS DOCUMENT AND RETURN 1 scan COPIES TO ISSUING OFFICE. CONTRACTOR AGREES TO FURNISH AND DELIVER ALL ITEMS SET FORTH OR OTHERWISE IDENTIFIED ABOVE AND ON ANY ADDITIONAL SHEETS SUBJECT TO THE TERMS AND CONDITIONS SPECIFIED				<input checked="" type="checkbox"/> 29. AWARD OF CONTRACT: REF. <u>AstraZeneca Pharmaceuticals LP</u> OFFER DATED 12/8/15 and FPR dated 1/11/16. YOUR OFFER ON SOLICITATION (BLOCK 5), INCLUDING ANY ADDITIONS OR CHANGES WHICH ARE SET FORTH HEREIN IS ACCEPTED AS TO ITEMS: 1, 2b, 3, 4b, 5, 6b, 7, and 8b			
30a. SIGNATURE OF OFFEROR/CONTRACTOR Paul A. Maillet /s/ Paul A. Maillet Senior Director, Contract Operations				31a. UNITED STATES OF AMERICA (SIGNATURE OF CONTRACTING OFFICER) /s/ Erika Moreno [***]			
30b. NAME AND TITLE OF SIGNER (TYPE OR PRINT)		30c. DATE SIGNED 12-8-15		31b. NAME OF CONTRACTING OFFICER (TYPE OR PRINT) Erika Moreno, Contracting Officer		31c. DATE SIGNED 2/11/2016	

AUTHORIZED FOR LOCAL REPRODUCTION
PREVIOUS EDITION IS NOT USABLE

STANDARD FORM 1449 (REV. 2/2012)
prescribed by GSA - FAR (48 CFR) 53.212

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19.ITEM NO.	20. SCHEDULE OF SUPPLIES/SERVICES	21. QUANTITY	22. UNIT	23. UNIT PRICE		24. AMOUNT
METOPROLOL SA SUCCINATE TABLETS						
<p>To be considered for award, offerors are required to submit a price for all line items (1, 2a or 2b, 3, 4a or 4b, 5, 6a or 6b, 7, and 8a or 8b) for the base year and all four option years. Award will be made in the aggregate for all line items (1, 2a or 2b, 3, 4a or 4b, 5, 6a or 6b, 7, and 8a or 8b). Line items 2a or 2b, 4a or 4b, 6a or 6b, and 8a or 8b are for bulk requirement and will be accepted in their bottles of 500s or 1000s. Offerors must submit prices for either 500s or 1000s. If both subline items are offered, only the lower priced product (i.e. based on a per tablet price) will be included in the calculation of the lowest total aggregate price for evaluation of award.</p>						
<p>1. METOPROLOL SUCCINATE 100MG TAB,SA 100s NDC #: 00186-1092-05</p>						
	Base Year	24,291	Bottles	\$ 40.80	\$	991,072.80
	[***]					
} A						
<p>2a. METOPROLOL SUCCINATE 100MG TAB,SA 500s NDC #: _____</p>						
	Base Year	43,024	Bottles	\$ _____	\$ _____	
	[***]					
or						
<p>2b. METOPROLOL SUCCINATE 100MG TAB,SA 1000s NDC #: Pending NDC Availability (AZ will fill with 100 count bottles for 1st half of 2016 if awarded)</p>						
	Base Year	21,512	Bottles	\$ 408.00	\$	8,776,896.00
	[***]					
} A						
<p>3. METOPROLOL SUCCINATE 200MG TAB,SA 100s NDC #: 00186-1094-05</p>						
	Base Year	31,663	Bottles	\$ 61.20	\$	1,937,775.60
	[***]					
} A						
<p>4a. METOPROLOL SUCCINATE 200MG TAB,SA 500s NDC #: _____</p>						
	Base Year	11,262	Bottles	\$ _____	\$ _____	
	[***]					



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19.ITEM NO.	20. SCHEDULE OF SUPPLIES/SERVICES	21. QUANTITY	22. UNIT	23. UNIT PRICE	24. AMOUNT
or					
4b. METOPROLOL SUCCINATE 200MG TAB,SA 1000s					
NDC #: Pending NDC Availability (AZ will fill with 100 count bottles for 1st half of 2016 if awarded)					
00186-1094-35 (Per FPR dated 1/11/2016)					
	Base Year	5,631	Bottles	\$ 612.00	\$ 3,446,172.00
	[***]				
} A					
5. METOPROLOL SUCCINATE 25MG TAB,SA 100s					
NDC #: 00186-1088-05					
	Base Year	30,548	Bottles	\$ 25.50	\$ 778,974.00
	[***]				
} A					
6a. METOPROLOL SUCCINATE 25MG TAB,SA 500s					
NDC #: _____					
	Base Year	53,562	Bottles	\$ _____	\$ _____
	[***]				
or					
6b. METOPROLOL SUCCINATE 25MG TAB,SA 1000s					
NDC #: Pending NDC Availability (AZ will fill with 100 count bottles for 1st half of 2016 if awarded)					
00186-1094-35 (Per FPR dated 1/11/2016)					
	Base Year	26,781	Bottles	\$ 255.00	\$ 6,829,155.00
	[***]				
} A					
7. METOPROLOL SUCCINATE 50MG TAB,SA 100s					
NDC #: 00186-1090-05					
	Base Year	34,571	Bottles	\$ 25.50	\$ 881,560.50
	[***]				
} A					



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19. ITEM NO.	20. SCHEDULE OF SUPPLIES/SERVICES	21. QUANTITY	22. UNIT	23. UNIT PRICE		24. AMOUNT
8a.	METOPROLOL SUCCINATE 50MG TAB,SA 500s NDC #: _____	Base Year 66,940 ***	Bottles	\$ _____ \$ _____	\$ _____ \$ _____] A
or						
8b.	METOPROLOL SUCCINATE 50MG TAB,SA 1000s NDC #: Pending NDC Availability (AZ will fill with 100 count bottles for 1st half of 2016 if awarded)	Base Year 33,470 ***	Bottles	\$ 255.00	\$ 8,534,850.00] A
00186-1094-35 (Per FPR dated 1/11/2016)						

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SECTION B - CONTINUATION OF SF 1449 BLOCKS

CONTINUATION OF STANDARD FORM 1449: SCHEDULE OF SUPPLIES/SERVICES

Please be advised the following are included in the solicitation and are highlighted here.

Proposals may be delivered to Department of Veterans Affairs, National Acquisition Center, National Contract Service (003A4C), 1st Avenue, 1 Block North of Cermak Road, Building 37, Hines, IL 60141. Proposals will also be accepted in Microsoft Word or PDF form via e-mail to [***] with either a scanned (pdf) copy of the signed SF1449 or a digitally signed copy of the SF 1449. Offerors are not required to submit an original proposal if an electronic proposal was received; however a hard copy of the SF 1449 (only) with an original signature is required no later than 10 days after the posted due date and time if an electronic proposal is submitted. Please note that faxed proposals are not acceptable and will be rejected. Reference FAR 52.212-1(f) regarding timeliness of submission of offers.

If the offeror is not the manufacturer of the offered items, the offeror shall submit either: (1) A letter of commitment from the manufacturer to the offeror which will assure the offeror of a source of supply sufficient to satisfy the Government's requirements for the contract period, **OR** (2) evidence that the offeror will have an uninterrupted source of supply from which to satisfy the Government's requirements for the contract period. "Manufacturer" is defined as the entity that measures, mixes, weighs, and compounds the active and inactive ingredients into a capsule or tablet. This requirement shall be met before contract award. Offers that fail to meet this requirement before contract award shall be rejected and shall receive no further consideration. (See Addendum 52.212-1– Instruction to Offerors.

Award will be made in the aggregate for all line items for the base year, including all four option years. To be considered for award, offerors must propose a price for line items 1, 2a or 2b, 3, 4a or 4b, 5, 6a or 6b, 7, and 8a or 8b for the base year and each option year. Proposals that fail to include a price for the base year and each of the four option years for line items 1, 2a or 2b, 3, 4a or 4b, 5, 6a or 6b, 7, and 8a or 8b shall be rejected and shall receive no further consideration.

(Refer to Schedule of Supplies for package size details and estimates)

Offered prices shall include a [***] Cost Recovery Fee (See Scope of Contract, paragraph 12).

The Government reserves the right not to award a contract on this solicitation should offered prices match or exceed current Federal Supply Schedule prices.

Offers for pharmaceuticals sourced from countries not covered by the Trade Agreement Act (TAA) may be given consideration pursuant to Federal Acquisition Regulation (FAR) Part 25.

Acknowledgement of Amendments. The following amendments are acknowledged as part of this solicitation. *(Please complete if applicable)*

Amendment Number	Date Acknowledged by Offeror

The System for Award Management (SAM) is an online system that replaces CCR/Fed Reg, ORCA, and EPLS. Contractors should now go to www.sam.gov to find their information. Training tools are available

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on the SAM website at www.sam.gov for familiarization with the SAM system . Prospective contractors shall maintain a current and accurate record in the SAM database. SAM updates are required, as necessary, but at least annually. (see 52.212-4(t) and 52.212-1(k)).

Subcontracting Plan Requirements: Pursuant to the requirements of Public Law 95-507, all large business concerns are required to have an approved subcontracting plan for contracts valued over \$700,000 before the Government can award a contract (see FAR 52.219-9 for details). Offerers must submit a currently approved commercial plan or a new plan for review and approval. Attachment "D" includes all of the elements required to be addressed and is included to facilitate the submission of a subcontracting plan.

As prescribed in FAR Part 42.15, the VA evaluates contractor performance on all contracts that exceed \$150,000, and shares those evaluations with other federal government agencies. The FAR requires that the contractor be provided an opportunity to comment on past performance evaluations prior to each report closing. To fulfill this requirement, VA will be using an online database, the Contractor Performance Assessment Reporting System (CPARS). Annual reporting of past performance will be completed at <http://www.cpars.gov> and uploaded to PPIRS (Past Performance Information Retrieval System).

SCOPE OF CONTRACT

1. INTRODUCTION

1.1 Background. All Ordering Activities under the Department of Veterans Affairs and all Ordering Activities under the Department of Defense (DOD) acquire their pharmaceutical requirements through their respective Pharmaceutical Prime Vendor Programs (PPV), hereafter referred to as the VA PPV Program and DOD PPV Program or jointly as PPV Programs. The PPV Programs are separate contracts which establish the fees for the distribution of pharmaceutical products that are distributed through the PPV Programs on Federal Government (i.e., Federal Supply Schedules, National Standardization) contracts. A contract resulting from this solicitation establishes the VA National Contract prices for the products listed in the schedule of supplies that will be distributed through the PPV Programs. Section 2.1, "Government Participants" lists the PPV Program participants that will be authorized users of the contract resulting from this solicitation. The successful contractor shall be required to be compliant with Pedigree Laws in any of the 50 United States and territories.

1.2 Purpose and Objectives. The purpose of this solicitation is to establish a supply source that will provide the drugs listed in the schedule for purchase through the PPV Programs. The total annual estimated usage for VA, Federal Health Care Center (FHCC), State Veterans Homes - Option 2 (SVH), DOD, Indian Health Service (IHS), and Bureau of Prisons (BOP) appears on the Schedule of Supplies section of this Solicitation. The objective of such a contract is to ensure availability and consistency of product for nationwide usage and to obtain volume-based, committed use pricing.

1.3 Government Purchase Compliance. VA, FHCC, SVH (Option 2), DOD, IHS, and BOP will purchase their requirements for the strengths of the drugs listed in the schedule through the PPV Programs except when: (1) the contracted items is/are unavailable to meet the needs of the Government, or (2) an alternate is requested by the prescribing healthcare provider. In the event that either 1 or 2 applies, these instances will be considered exceptions to section C.2 – 52.216-21, Requirements. VA's PPV contract has ordering lock-out procedures in place to support VA contract compliance and to prevent purchases of non-contract products. DOD manages compliance through individual facility tracking reports.

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1.4 Contract Effective Date. The contract effective date shall be 120 days (or sooner upon mutual agreement) after the date of contract award. Before the contract effective date, the PPVs will begin placing orders with the contractor for delivery to multiple PPV distribution centers for distribution to the Government participants under this contract. The contractor shall ensure that sufficient inventory of contract items awarded under this solicitation is available, and that chargeback agreements with the PPVs have been executed sufficiently in advance of the contract effective date to permit the PPVs to begin timely distribution of Government orders by the contract effective date. The current PPVs are listed as attachments "A" and "B" of this solicitation. The current PPVs may change and the contractor will be notified of any changes in PPV contractors during the term of the contract resulting from this solicitation. Payment terms, time and place of delivery to PPV distribution centers and other business-to-business agreement terms shall be agreed upon between the PPV contractors and the contractor awarded a contract from this solicitation. Within 15 days from receipt of award, the Contracting Officer shall be notified by the contractor awarded a contract from this solicitation if any business-to-business agreements cannot be reached with the PPVs. Failure or refusal to reach agreement with the PPVs shall constitute sufficient cause for terminating the contract under Federal Acquisition Regulation Part 52.212-4(m), Contract Terms and Conditions-Commercial Items, Termination for Cause.

1.5 Contract Duration. The contract(s) resulting hereunder will be in effect for one (1) year with four (4) one-year pre-priced option periods that may be exercised by the Government unilaterally.

2. EXTENT OF OBLIGATION

2.1 Government Participants. The contractor shall provide the products specified in the schedule at the prices awarded herein for the facilities/agencies below:

- All Department of Veterans Affairs (VA) facilities
- All Ordering Activities under the Department of Defense (DOD) Pharmaceutical Prime Vendor Program
- Indian Health Service (IHS) facilities
- All Bureau of Prisons (BOP) facilities
- Federal Health Care Center (FHCC)
- All Option 2 State Veteran Homes (See paragraph 2.2 State Veteran Homes)

A database of all facilities authorized to use the VA PPV Program may be downloaded from the National Acquisition Center's web site at <http://www.va.gov/oal/business/nc/ppv.asp>. The database identifies each state veteran home as option 1 or 2. A database for all facilities authorized to use the DOD PPV Program may be downloaded from the DOD's website at <https://www.medical.dla.mil/Portal/PrimeVendor/PvPharm/PharmPvOverview.aspx>.

2.2 State Veteran Homes (SVH's). There are numerous State Veteran Homes (SVHs) that have entered into sharing agreements with VA Medical Centers (VAMCs). The SVHs with sharing agreements that participate in the VA PPV Program are identified as being one of two types: Option 1 or Option 2.

Option 1: The SVH orders pharmaceuticals directly from the VA PPV and pays the VA PPV for all items purchased. An Option 1 SVH is not eligible for national contract prices awarded under this solicitation unless it is specifically named in the scope of contract or added after award by mutual agreement.

Option 2: The VAMC authorizes the SVH's order, and the VAMC makes payment to the VA PPV for all pharmaceuticals ordered by the SVH. An Option 2 SVH is eligible for the national contract prices awarded under this solicitation.

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2.3 Consolidated Mail Out Patient Pharmacies (CMOPs) (VA ONLY). Many drugs are prescribed and mailed directly to patients' homes in three-month or 90-day supply and VA CMOPs may place an initial order with the VA PPV contractor for up to 30% of the estimated annual contract quantities immediately upon the contract effective date. An initial order of up to 30% of the estimated annual contract quantities may be placed by the VA PPV contractor with the contractor awarded a contract under this solicitation to fulfill the CMOP 30% initial order requirements.

2.4 Estimated Quantities. The quantities in the schedule reflect the combined usage of all VA (inclusive of FHCC and SVH), DOD, IHS, and BOP activities currently participating in the PPV Programs. These estimated annual requirements do not include those of any other Government agency, including those currently participating in the VA PPV Program (e.g. ICE, Option 1 State Veteran's Homes). The estimated usage cited in the Schedule is the Government's total estimated usage for the strengths listed. There is no expressed or implied guarantee that the estimated quantity will be purchased under this contract. Actual quantities purchased may exceed or be less than those represented.

3. PRODUCT REGISTRATION

Product information pertaining to all items offered under this solicitation, including the offeror's unique National Drug Code(s) (NDC), must be submitted to First Data Bank, RxNorm, and Medispan prior to the effective date of contract performance. A New Product Submission Form can be obtained by contacting First Data Bank at (800) 633-3453, extension 566, or via email at <http://www.fdbhealth.com/solutions/manufacturing-relations/>. RxNorm information can be obtained at <http://www.nlm.nih.gov/research/umls/rxnorm/>. Medispan information can be obtained at <http://www.medispan.com/drug-information-products/>.

4. NATIONAL CONTRACT ITEM BACKORDERS

A contract awarded under this solicitation will be the Government's primary source of supply. **(See FAR 52.216-21 Requirements)** The Government's ability to provide quality healthcare to its patient population is severely impaired when a national contract product is not available due to backorders. The purpose of this clause is to provide guidance to the awarded contractor regarding a temporary solution to national contract item backorders that may be implemented in lieu of the Government terminating the contract for cause. However, consideration of this clause shall not waive any of the Government's rights to terminate the contract for cause in accordance with FAR 52.212-4(m). For purposes of this contract, a backorder occurs when the PPVs issue an order with the contractor awarded a contract for the products in this solicitation, and the complete order quantity is not delivered to the PPVs within 15 days after receipt of order. This includes initial CMOP orders (see section 2.3). If a national contract item is backordered by the PPVs, the VA National Acquisition Center (VANAC) contracting officer will investigate the backorder to determine if the national contract contractor bears responsibility for the backorder. The awarded contractor shall inform the VANAC contracting officer within 4 calendar days after a backorder occurs. In addition to informing the contracting officer of the backorder, the contractor shall provide an estimated date when the backorder will be shipped, and may propose a solution to satisfy the Government's needs for the contract items until the backorder is resolved. The Government reserves the right to accept or reject any possible solutions that the contractor may propose to alleviate a national contract backorder situation. If the contracting officer determines that the contractor bears responsibility for the backorder, and the contractor is not able to provide a solution that is acceptable to the Government, (i.e., acceptable solution to the backorder, in lieu of Termination for Cause), the parties agree that the Government may buy against the contractor by acquiring the same or similar items from another source and billing the contractor for any excess procurement costs. In other words, if the government must purchase product from another vendor because of a national contract backorder, the contractor will issue credit or

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reimburse the Government for the difference between the purchase price and the contract price. After a backorder incident occurs for which the Contractor is responsible, the Government's decision to enter into a buy-against agreement described above will not deprive the Government of its right under Clause 52.212-4 (m) to terminate the contract for a breach of the buy-against agreement, for a subsequent contractor-caused backorder, or for any other sufficient cause.

5. PACKAGING REQUIREMENTS

Offerors must state the exact name of the drug being supplied as it will appear on the label. Offerors shall also provide a unique 11-digit NDC number for all items offered; the NDC number must be specific to the offering company and to the drug being supplied. All bottles of 100 tablets or less must have a child resistant closure. All tablets/capsules must be compatible with automated dispensing units (Baxter ATC Canisters, Opitfill, etc.) Glass bottles are not acceptable. Items are identified in the Schedule of Supplies and in Attachment C.

6. BAR CODING

All pharmaceutical products provided under this contract shall include bar code labeling at the unit-of use package level. The bar code labeling must be in a linear format that conforms to all GS1-128 (formerly EAN.UCC) or Health Industry Business Communication Council (HIBCC) Health Industry Bar Code (HIBC) supplier labeling standards. The bar code symbology must comply with all GSI or HIBCC parameters including, but not limited to: symbology type or encoded pattern, bar and space dimensions and tolerances, and allowable ratio of wide to narrow elements.

The bar code may be any linear bar code symbology such as GS1-128 (formerly EAN.UCC), GSI DataBar (formerly RSS), or Universal Product Code (if the UPC contains the National Drug Code or NDC). The bar code must encode the NDC, either alone or within the GS1 data structure (Global Trade Item Number (GTIN)).

The bar code printing must be American National Standards Institute (ANSI)/International Organization for Standardization (ISO)/IEC Quality Grade C or better. Manufacturers and packagers must ensure that production runs include an initial verification check, as well as routine audits to ensure the bar code is printed clearly and consistently to meet the quality standard of Grade C or better. Contractors shall be responsible for ensuring that bar code labels meet the quality requirements specified in this clause prior to shipping pharmaceutical products to any Government Prime Vendor under this contract.

The bar code must be on the outside container or wrapper of the medication as well as on the immediate container, unless the bar code is readily visible *and* machine-readable through the outside container or wrapper. When the bar code is not easily machine-readable through the over wrap, the over wrap should contain the bar code.

If applicable, the bar code must go on each cell of a blister pack. Furthermore, the bar code must remain intact under normal conditions of use; thus it should not be printed across the perforations of a blister pack.

When applicable to the symbology used, bar codes shall be surrounded by sufficient quiet zone so that the bar code can be scanned correctly. Bar code placement shall minimize curvature of the bar code. For example, bar codes should be placed in "ladder orientation" on vials or bottles to minimize curvature of the bar code. Bar code labeling shall not be placed solely on outer packaging.

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It is recommended that bar code labeling also include the lot number and expiration date. If two separate distinctive bar codes are used, one for NDC and the other for lot number/expiration date; the lot number and expiration date bar code must not be in close proximity to the NDC barcode or in a format that may be confused with the NDC bar code. When applicable, all Healthcare Distribution Management Association (HDMA) guidelines shall be followed.

7. THERAPEUTIC EQUIVALENCE

Only products that have received under the Federal Food, Drug and Cosmetic Act a therapeutic equivalence code of "A" by the Food and Drug Administration will be considered, unless all drugs in the family group are "B" rated. In that case, no award will be made other than to the innovator unless the non-innovator vendor submits acceptable data demonstrating bioequivalence.

8. NATIONAL DRUG CODES

Offerors shall provide a separate and distinct eleven-digit National Drug Code (NDC) Number unique to the offeror (e.g., 00012-3456-78) for each product proposed, in the space provided following each item in block 20 of the SF1449, "Schedule of Supplies and Prices" of the solicitation. The first five numbers of the eleven-digit NDC number for each product proposed shall identify the offeror. Offers that fail to provide the information required by this clause by the solicitation closing date shall be rejected and shall receive no further consideration.

9. DRUG APPLICATION

By signing this solicitation, the offeror certifies that it has on file (if any of the following are required by FDA for the offered drugs) an FDA approved New Drug Application (NDA), an approved abbreviated NDA (ANDA), or a Biologic License approval, as appropriate for the items offered in response to the solicitation.

10. RECALLS

If a drug recall is initiated for any drug provided under this contract, regardless of whether it is a voluntary recall by the manufacturer or a recall required by the U.S. Food and Drug Administration (FDA); or, if FDA withdraws their approval to manufacture any drug that is included on this contract, the following action shall immediately be taken by the contractor:

Forward two copies of the recall notification along with any pertinent information to:

Chief, Pharmaceutical Division (003A4C4)
VA National Acquisition Center
National Contract Service
1st Ave., 1 Block North of Cermak Rd., Bldg. 37
P.O. Box 76, Hines, IL 60141
Fax Number [***]

Deputy Chief Consultant (M/S119D)
VHA Pharmacy Benefits Management Services
1st Ave., 1 Block North of Cermak Rd., Bldg. 37, Rm 139
Hines, IL 60141
Fax Number [***]

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Manager, Product Recall Office
National Center for Patient Safety
Veterans Health Administration
24 Frank Lloyd Wright Drive, Lobby M
Ann Arbor, MI 48106
[***]
Phone Number: [***]

All Government Prime Vendors that were sent shipments of the affected product(s).

11. COVERED DRUGS

Should a covered drug be proposed and awarded as a result of this solicitation, the awarded prices shall meet the requirements of Public Law 102-585, Section 603, the Veterans Healthcare Act of 1992, (38 U.S.C. 8126) and shall apply to all Government participants listed in section 2.1 of the Scope of Contract, regardless of whether the participant is covered under the law. Therefore, prices for the base year and all option years shall not exceed the annually established Federal Ceiling Price (FCP) plus the [***] Cost Recovery Fee (CRF).

Attention is directed to the fact that although Public Law 102-585, Section 603 applies to covered drugs, competitively negotiated and awarded prices for the base year and any option years exercised by the government will govern *unless the annually established FCP results in a price lower than competitively awarded contract prices*. In this instance, the contract will be modified bilaterally to reflect the lower annually established FCP plus the [***] CRF.

Both parties understand the VA National Contract Service will obtain FCPs from the VA Pharmacy Benefits Management (PBM). The parties agree the FCP will be calculated pursuant to the requirements of Public Law 102-585, Section 603, which includes the contractor's Master Agreement, and Pharmaceutical Pricing Agreement, and any relevant VA Dear Manufacturer Letters.

Contractors submitting a proposal for a covered drug are required to complete the following clause:

MASTER AGREEMENTS AND PHARMACEUTICAL PRICING AGREEMENTS

In compliance with Public Law 102-585, Section 603, The Veterans Healthcare Act of 1992, offerors of covered drug products (including biologics) must state below whether they currently have a Master Agreement (MA) and a Pharmaceutical Pricing Agreement (PPA) in place with the Department of Veterans Affairs (VA).

YES, Offeror has a MA and PPA in place with the VA NO, Offeror does not have a MA and PPA in place with the VA.

If the answer to the above is "No" and if the prospective contractor is offering covered drug products (including biologics that fall within 21 CFR 600.3), contractor must submit and execute a MA and PPA with its offer. No offer of covered drugs submitted by a manufacturer will be considered for award unless and until the manufacturer has on file with VA's National Acquisition Center an executed MA and PPA.

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12. COST RECOVERY FEE AND SUBMISSION OF QUARTERLY SALES REPORTS

(a) Quarterly Sales Reports. The Contractor shall report all contract sales under this contract and submit collected Cost Recovery Fees as follows:

(1) The Contractor shall accurately report the dollar value, in U.S. dollars and rounded to the nearest whole dollar, of all sales made under this contract by calendar quarter (January 1-March 31, April 1-June 30, July 1-September 30, and October 1-December 31). Reported sales must include all sales made to all authorized contract users, whether shipped directly to the users or through Prime Vendor contractors. The report shall reflect sales by contract line item and shall segment sales by the Department of Veterans Affairs (VA) and Other Government Agencies (OGA). A Cost Recovery Fee equivalent to [***] shall be collected from all contract users. The [***] Cost Recovery Fee shall be imbedded in the awarded contract prices, and offers submitted in response to this solicitation shall include the Cost Recovery Fee in every line item price offered. The reported contract sales shall include the cost recovery fee and each quarterly report shall show the total cost recovery fee amount collected on the reported sales. The Contractor shall maintain a consistent accounting method of sales reporting, based on the Contractor's established commercial accounting practice.

(2) Contract sales reports are due to the VA contracting officer within 60 calendar days following the completion of each reporting quarter or completion of the contract, whichever occurs first. A report is required even when no billings or invoices are issued or no orders are received during the contract period.

(3) The sales report signed by an authorized representative of the contractor shall be sent by mail or email to the Contracting Officer. Mailed reports shall be sent to the address listed below. Emailed reports shall be sent to [***].

Department of Veterans Affairs
National Acquisition Center (049A1N2)
P.O. Box 76
First Avenue, 1 Block North of Cermak, Bldg. 37
Hines, IL 60141

(4) In addition to the submission of quarterly sales reports due to the contracting officer within 60 days after the end of each reporting quarter, contractors shall provide copies of sales reports simultaneously with contractor's cost recovery fee payment submissions via facsimile, to the attention of C.R. Agent Cashier, fax: [***].

(b) Cost Recovery Fee. The [***] Cost Recovery Fee amount collected and due shall be paid either electronically or by check, and shall be addressed to the "Department of Veterans Affairs". When the Contractor has multiple national contracts, the fee may be consolidated into one check. Consolidated payments for multiple contracts shall identify each contract number included, dollar amount remitted for each contract number, and reporting quarter.

To ensure that the payment is credited properly, the contractor shall identify the check or electronic transmission as a "Cost Recovery Fee" and include a copy of the applicable Sales Report. The Cost Recovery Fee payment is due to the Fiscal Division at the same time the sales report is due to the

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contracting officer, i.e., within 60 calendar days following the completion of each reporting quarter or completion of the contract.

Cost Recovery Fee payments shall not be combined with any Industrial Fund Fee payments. Contractors shall remit separately any Industrial Fund Fee payments in support of any of the Contractor's Federal Supply Schedule contracts.

Cost recovery fee payments made electronically shall include the following information:

Receiving Bank Name: [***]
Receiving Bank Contact: [***]
Contact Phone: [***]
Receiving Bank City, State: [***]
Receiving Bank Routing/Transit Number: [***]
Receiving Bank Capability: [***]
Receiving Account Number: [***]
820 ACH Format used by Receiving Bank: [***]

Contract Number(s): *(Contractor shall insert the contract number, which will be assigned by the VA contracting officer at time of award.)*

Cost recovery fee payments made in check form shall be made to the attention of "Department of Veterans Affairs" and mailed to the following address:

Fiscal Division (901A)
Attn: C.R. Agent Cashier
P.O. Box 7005
Hines, IL 60141

(c) The Government reserves the right to inspect without further notice, such records of the Contractor as pertain to sales under any contract resulting from this solicitation. Willful failure or refusal to furnish the required reports, or falsification thereof, shall constitute sufficient cause for terminating the contract under FAR 52.212-4(m), Contract Terms and Conditions - Commercial Items, Termination for Cause.

(d) Failure to remit the full amount of the Cost Recovery Fee within 60 calendar days after the end of the applicable reporting period constitutes a contract debt to the United States Government under the terms of Federal Acquisition Regulation (FAR) Subpart 32.6. The Government may exercise all rights under the Debt Collection Improvement Act of 1996, including withholding or setting off payments and interest on the debt (see FAR clause 52.232-17, Interest). Should the Contractor fail to submit the required sales reports, falsify them, or fail to timely pay the Cost Recovery Fee, the Government shall have, in addition to the rights and remedies described in this clause, all other rights and remedies permitted by Federal law and statutes.

13. MANUFACTURING FACILITIES/PLACE OF PERFORMANCE

1. The U.S. Food and Drug Administration (FDA) is the Government agency responsible for providing and enforcing pharmaceutical current Good Manufacturing Practices (GMP) standards for human drugs, pharmaceutical products, biologicals, medical devices, chemical products, medical cylinder oxygen, reagents, diagnostics, test kits and sets included in this solicitation. Only offers from companies that have an acceptable GMP status on record with the FDA for the facilities identified by the offeror in Paragraph 8 below will be considered for award. The FDA will evaluate a prospective offeror for VA procurements only if the offeror has had a qualifying GMP inspection within the previous two years. Before a contract can be awarded, any successful offeror's manufacturing facilities shall have a current acceptable GMP status with FDA, or shall have had an acceptable report from the last FDA facility inspection on record. In the absence of a current GMP evaluation, an offeror is required to include with its proposal documentation on the acceptable outcome of a FDA facility inspection that occurred more than two years prior to submission of the offer.
2. For any Nutritional/Dietary Supplements offered, documentation of clinical studies that were performed on the offered products pertaining to the therapeutic treatment of patients may be required by the Department of Veterans Affairs National Acquisition Center (VANAC) as a quality assurance measurement. Offerors of Nutritional/Dietary Supplements will be required to adhere to published FDA GMP standards after January 1, 2008.
3. If at any time during the life of the contract, the contractor's facility or the source from which the contractor obtains any of the products offered on this contract is informed in a FDA "warning letter" that it fails to meet FDA current Good Manufacturing Practices (GMPs) (21 CFR Part 210 and 211), and/or a facility's unacceptable FDA GMP status is communicated to the VANAC, the Contracting Officer will apply the procedures outlined in Paragraph 4 of this clause.
4. The VANAC Contracting officer will review the contractor's (or its source's) unacceptable GMP status with appropriate VHA clinical staff and will either: 1) instruct the contractor to stop the shipment of products listed on this contract that were manufactured and/or packaged in a facility with unacceptable GMP status, or 2) authorize the contractor to continue to supply such contract products for 90 days from the date when unacceptable GMP status was communicated to VANAC, provided that the products have not been subjected to a consumer-level recall. An additional 90 days may be authorized at the discretion of the VANAC Contracting Officer. Contractors are cautioned that products that were manufactured and /or packaged in a facility with unacceptable GMP status and then shipped without written authorization from the VANAC Contracting Officer shall be returned to the contractor at the contractor's risk and expense. The contractor shall have corrected all significant GMP deficiencies or have an acceptable plan with the FDA for the correction of such deficiencies which led to unacceptable status by the end of the 90-day authorization period and any extensions of such period granted by the VANAC Contracting Officer. Additionally, the contractor is responsible for keeping the VANAC Contracting Officer informed of all corrections made and shall provide the VANAC Contracting Officer with: 1) written documentation of the correction plan, 2) Notification from FDA of acceptance of plan, and 3) a copy of any reinspection requests and subsequent reinspection reports, when they are available. If FDA's evaluation of contractor's (or its source's) compliance efforts and/or re-inspection of the non-compliant facility does not result in an acceptable rating by FDA within 90 days from the date when unacceptable GMP status was communicated to VANAC, or by the end of a VANAC Contracting

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Officer's authorization period (whichever is the greater period of time), the contract may be terminated for cause in accordance with FAR Clause 52.212-4(m). The contractor's (or its source's) failure to correct the GMP deficiencies in a timely manner shall not constitute or give rise to any "excusable delays" pursuant to FAR Clause 52.212-4(f). (Nothing in this clause shall be read as limiting the recognized grounds upon which a Contracting Officer may terminate this contract or delete products pursuant to the applicable clause contained in the contract.)

5. The contractor shall use only the FDA-inspected manufacturing facilities provided in Paragraph 8, below, for the duration of the contract, unless substitution of manufacturing facilities is approved by the VANAC Contracting Officer. In case of any manufacturing facility relocation or substitution of manufacturing facilities, the contractor shall notify the VANAC Contracting Officer of the change, and the contractor shall request approval from the VANAC Contracting Officer to supply the contracted products from the new location. If the change is approved by the VANAC Contracting Officer after an inquiry to FDA for GMP status of the new location, approval will be provided by means of a formal contract modification.

6. If the products are to be manufactured at more than one location, each manufacturing facility and each facility address shall be listed along with the products manufactured at the facility. Subcontractors (i.e., packagers, labelers, etc.) that participate in the production of the products offered on this solicitation shall also be listed along with their addresses. All facilities described in this paragraph and listed below shall be substantially in compliance with applicable FDA GMP standards prior to contract award.

7. Offeror shall identify below or by attachment (if additional space is needed), the products offered on this solicitation (products shall be identified by product name and by solicitation item number); whether the offeror manufactures the products; and/or whether the offeror is a distributor of the products offered. "Manufacturer" is defined as the entity that measures, mixes, weighs, and compounds the active and inactive ingredients into a capsule or tablet.

8. If the finished products to be offered are of foreign manufacture, the complete name and address of the manufacturer shall be provided below. The offeror is also required to check the box below that is applicable to its offer. Please note that the information required below must be the name and address of the manufacturing facility, rather than the address of the foreign headquarters, distributor or agent.

OFFEROR IS THE MANUFACTURER (AT THE FOLLOWING LOCATIONS) OF THE PRODUCTS OFFERED ON THIS SOLICITATION.

OFFEROR IS A DISTRIBUTOR OF THE PRODUCTS OFFERED ON THIS SOLICITATION.

THE PRODUCTS WILL BE MANUFACTURED BY THE FOLLOWING COMPANY AT THE FOLLOWING LOCATIONS:

[***]
(Name of Manufacturing Company)

[***]
(Street Address) (Post Office Address Not Acceptable)

[***]
(U.S.A. Point of Contact, e-Mail Address and U.S.A Telephone Number)

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PHARMACEUTICALS - PARENTERALS

Solicitation Item # & Product Name	Location and Owner of Facility where ingredients are measured, weighed, mixed and compounded (Facility Owner Name, Address, City, County, State and Zip Code)	Point of Contact including Phone #
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

PHARMACEUTICALS - PARENTERALS, STERILIZATION

Solicitation Item # & Product Name	Sterilization and Owner Location (Facility Owner Name, Address, City, County, State and Zip Code)	Point of Contact Including Phone #
_____	_____	_____
_____	_____	_____
_____	_____	_____
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TABLETS, CAPSULES AND PILLS

Solicitation Item # & Product Name	Location and Owner of Facility where Ingredients are measured, weighed, mixed and compounded (Facility Owner Name, Address, City, County, State and Zip Code)	Point of Contact Including Phone #
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
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OTHER PHARMACEUTICAL PRODUCTS

(Solutions, syrups, mixtures, powders, ointments, pastes, creams, etc.)

Solicitation Item # & Product Name	Location and Owner of Facility where Ingredients are measured, weighed, mixed and compounded (Facility Owner Name, Address, City, County, State and Zip Code)	Point of Contact Including Phone #
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

PACKAGING

Solicitation Item # & Product Name	Location of Facilities where Intermediate containers will be filled and labeled (Facility Name, Location, City, County, State and Zip Code)	Point of Contact Including Phone #
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]

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PACKING

Solicitation Item # &
Product Name

Location of Facilities where products will be
packed and prepared for shipment (Facility
Name, Location, City, County, State and Zip
Code)

Point of Contact Including Phone #

[***]

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14. INCORPORATION OF DOCUMENTS

The following documents are hereby incorporated by reference and made a part of this solicitation. The designation "USP" and "NF" shall be considered interchangeable when monographs for ingredients or preparations are transferred from one official compendium to the other. For ingredients or preparations which no longer appear in the latest revision of the USP or NF, the previous volume shall apply. Ingredients or preparations for which monographs appear for the first time in the Official Compendia shall comply with the applicable monographs unless the word "modified" appears as part of the item name. The requirements that an item or ingredient comply with test standards and requirements of the USP or the NF does not delete any other applicable portions of the compendia, such as, but not limited to, General Notices. Thus, for USP/NF items, alternative test methods are permitted.

AMERICAN CHEMICAL SOCIETY (ACS), Reagent Chemicals, American Chemical Society Specifications. (Copies are available from Applies Publications, American Chemical Society, Washington, DC 20036).

U.S. DEPARTMENT OF HEALTH, EDUCATION AND WELFARE, FOOD AND DRUG ADMINISTRATION (FDA). Federal Food, Drug, and Cosmetic Act and Regulations promulgated thereunder. (Copies are available from Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20204).

U.S. PHARMACOPOEIAL CONVENTION, INC. (USP/NF). Pharmacopoeia of the United States. (Copies are available from Mack Publishing Company, Easton, PA 18042).

SECTION C - CONTRACT CLAUSES

C.1 52.212-4 CONTRACT TERMS AND CONDITIONS—COMMERCIAL ITEMS (MAY 2015) (MAY 5, 2011 DEVIATION)

(a) Inspection/Acceptance (TAILORED). Products will be ordered by the Government through Government Prime Vendor contracts. The Government's inspection rights become effective upon receipt at the Government ordering facility. The Government reserves the right to inspect or test any supplies or services that have been tendered for acceptance, at the Government's discretion. The contractor shall tender for acceptance only those items that conform to the requirements of this contract. 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) (DEVIATION) Reserved.

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

(d) Disputes (DEVIATION). This contract is subject to the Contract Disputes Act of 1978, as amended (41

U.S.C. 601-613). 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. The Civilian Board of Contract Appeals has jurisdiction over any disputes arising under this contract. Also, a dispute arising between a Contractor and any authorized Government Prime Vendor(s) does not give rise to a "claim" under the Disputes Clause, FAR 52.233-1.

(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) (DEVIATION) Reserved.

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(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 (DEVIATION). Payment for the items awarded on this contract will be made by the Government at the awarded prices directly to the Government Prime Vendor Contractors upon delivery by the Prime Vendor Contractors to Government ordering facilities.

(j) Risk of loss (TAILORED). 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 delivery of supplies to the Government facility. Risk of loss does not pass to the Government upon delivery by the contractor to any Government contracted VA Prime Vendor contractor.

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

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(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. 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, and Compliance with Laws Unique to Government Contracts 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) System for Award Management (SAM).

(1) Unless exempted by an addendum to this contract, the Contractor is responsible during performance and through final payment of any contract for the accuracy and completeness of the data within the SAM database, and for any liability resulting from the Government's reliance on inaccurate or incomplete data. To remain registered in the SAM database after the initial registration, the Contractor is required to review and update on an annual basis from the date of initial registration or subsequent updates its information in the SAM database to ensure it is current, accurate and complete. Updating information in the SAM does not alter the terms and conditions of this contract and is not a substitute for a properly executed contractual document.

(2)(i) If a Contractor has legally changed its business name, "doing business as" name, or division name (whichever is shown on the contract), or has transferred the assets used in performing the contract, but has not completed the necessary requirements regarding novation and change-of-name agreements in FAR subpart 42.12, the Contractor shall provide the responsible Contracting Officer a minimum of one business day's written notification of its intention to (A) change the name in the SAM database; (B) comply with the requirements of subpart 42.12; and (C) agree in writing to the timeline and procedures specified by the responsible Contracting Officer. The Contractor must provide with the notification sufficient documentation to support the legally changed name.

(ii) If the Contractor fails to comply with the requirements of paragraph (t)(2)(i) of this clause, or fails to perform the agreement at paragraph (t)(2)(i)(C) of this clause, and, in the absence of a properly executed novation or change-of-name agreement, the SAM information that shows the Contractor to be other than the Contractor indicated in the contract will be considered to be incorrect information within the meaning of the "Suspension of Payment" paragraph of the electronic funds transfer (EFT) clause of this contract.

(3) The Contractor shall not change the name or address for EFT payments or manual payments, as appropriate, in the SAM record to reflect an assignee for the purpose of assignment of claims (see Subpart 32.8, Assignment of Claims). Assignees shall be separately registered in the SAM database. Information provided to the Contractor's SAM record that indicates payments, including those made by

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EFT, to an ultimate recipient other than that Contractor will be considered to be incorrect information within the meaning of the "Suspension of payment" paragraph of the EFT clause of this contract.

(4) Offerors and Contractors may obtain information on registration and annual confirmation requirements via SAM accessed through <https://www.acquisition.gov>.

(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 User 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 certifications, including those completed electronically via the System for Award Management (SAM), are incorporated by reference into the contract.

ADDENDUM to FAR 52.212-4 CONTRACT TERMS AND CONDITIONS--COMMERCIAL ITEMS

Clauses that are incorporated by reference (by Citation Number, Title, and Date), have the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available.

The following clauses are incorporated into 52.212-4 as an addendum to this contract :

1. Ordering. This solicitation provides for award(s) of contract(s) in support of VA's standardization program. Products awarded on the resultant contract(s) will be distributed through Government Prime Vendor contract (s). Order placement for supplies awarded will be made by Government Prime Vendor contractor(s) to the awarded contractor(s) and, any supplies to be furnished under this contract shall be ordered by issuance of delivery orders by the individuals or facilities directly to Prime Vendor contractor(s). Government Prime Vendor contractor(s) will accept orders and payment for the contracted item(s) on behalf of the contractor. Such orders may be issued from the effective date of the contract through the expiration date of the final option period exercised. All delivery orders are subject to the terms and conditions of this contract. In the event of conflict between a delivery order or task order and this contract, the contract shall control.

2. Delivery. Delivery order requirements such as product quantities, time and place of delivery, and method of delivery for product(s) awarded on resultant contract(s) will be determined between the awarded contractor(s) and Government Prime Vendor contractors.

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3. Chargeback Arrangements. Chargeback arrangements/agreements shall be coordinated between the Government Prime Vendor contractors and the successful contractor(s). The government will not become involved in this area nor will the Government assume any responsibility for any monies involved with such arrangements.

C.2 52.203-99 PROHIBITION ON CONTRACTING WITH ENTITIES THAT REQUIRE CERTAIN INTERNAL CONFIDENTIALITY AGREEMENTS (DEVIATION) (FEB 2015)

(a) The Contractor shall not require employees or contractors seeking to report fraud, waste, or abuse to sign or comply with internal confidentiality agreements or statements prohibiting or otherwise restricting such employees or subcontractors from lawfully reporting such waste, fraud, or abuse to a designated investigative or law enforcement representative of a Federal department or agency authorized to receive such information.

(b) The contractor shall notify employees that the prohibitions and restrictions of any internal confidentiality agreements covered by this clause are no longer in effect.

(c) The prohibition in paragraph (a) of this clause does not contravene requirements applicable to Standard Form 312, Form 4414, or any other form issued by a Federal department or agency governing the nondisclosure of classified information.

(d)(1) In accordance with section 743 of Division E, Title VII, of the Consolidated and Further Continuing Resolution Appropriations Act, 2015 (Pub. L. 113-235), use of funds appropriated (or otherwise made available) under that or any other Act may be prohibited, if the Government determines that the Contractor is not in compliance with the provisions of this clause.

(2) The Government may seek any available remedies in the event the contractor fails to comply with the provisions of this clause.

C.3 52.204-18 COMMERCIAL AND GOVERNMENT ENTITY CODE MAINTENANCE (JUL 2015)

(a) Definition. As used in this clause-
"Commercial and Government Entity (CAGE) code" means-

- (1) An identifier assigned to entities located in the United States or its outlying areas by the Defense Logistics Agency (DLA) Contractor and Government Entity (CAGE) Branch to identify a commercial or government entity, or
- (2) An identifier assigned by a member of the North Atlantic Treaty Organization (NATO) or by the NATO Support Agency (NSPA) to entities located outside the United States and its outlying areas that the DLA Contractor and Government Entity (CAGE) Branch records and maintains in the CAGE master file. This type of code is known as an NCAGE code.

(b) Contractors shall ensure that the CAGE code is maintained throughout the life of the contract. For contractors registered in the System for Award Management (SAM), the DLA Contractor and Government Entity (CAGE) Branch shall only modify data received from SAM in the CAGE master file if the contractor initiates those changes via update of its SAM registration. Contractors undergoing a novation or change-of-name agreement shall notify the contracting officer in accordance with [subpart 42.12](#). The contractor shall communicate any change to the CAGE code to the contracting officer within 30 days after the change, so that a modification can be issued to update the CAGE code on the contract.

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(c) Contractors located in the United States or its outlying areas that are not registered in SAM shall submit written change requests to the DLA Contractor and Government Entity (CAGE) Branch. Requests for changes shall be provided on a DD Form 2051, Request for Assignment of a Commercial and Government Entity (CAGE) Code, to the address shown on the back of the DD Form 2051. Change requests to the CAGE master file are accepted from the entity identified by the code.

(d) Contractors located outside the United States and its outlying areas that are not registered in SAM shall contact the appropriate National Codification Bureau or NSPA to request CAGE changes. Points of contact for National Codification Bureaus and NSPA, as well as additional information on obtaining NCAGE codes, are available at <http://www.dlis.dla.mil/nato/ObtainCAGE.asp>.

(e) Additional guidance for maintaining CAGE codes is available at http://www.dlis.dla.mil/cage_welcome.asp.

C.4 52.216-21 REQUIREMENTS (OCT 1995) (MAY 5, 2011 DEVIATION)

(a) This is a requirements contract for the supplies or services specified and effective for the period stated, in the Schedule. The quantities of supplies or services specified in the Schedule are estimates only and are not purchased by this contract. Except as this contract may otherwise provide, if the Government's requirements do not result in orders in the quantities described as "estimated" or "maximum" in the Schedule, that fact shall not constitute the basis for an equitable price adjustment.

(b) Delivery or performance shall be made only as authorized by orders issued through Prime Vendor contract(s) in accordance with the Ordering clause. Subject to any limitations specified in this contract, the Contractor shall deliver to the Prime Vendor contractor(s) the supplies specified in the Schedule and called for by orders issued by the Prime Vendor(s) in accordance with the Ordering clause. Prime Vendor contractor(s) may issue orders requiring delivery to multiple Prime Vendor contractor distribution centers.

(c) Except as this contract otherwise provides, the Government shall order from the Contractor through the Prime Vendor contractor(s) all the supplies or services specified in the Schedule that are required to be purchased by the Department of Veterans Affairs and other Government agencies as specified in the Schedule.

(d) The Government is not required to purchase from the Contractor requirements in excess of any limit on total orders under this contract.

(e) If the Government urgently requires delivery of any quantity of an item that the Prime Vendor contractor(s) do not have available for delivery as required by the Prime Vendor contract terms, the Government may acquire the urgently required item(s) from any other available source.

(f) Any order(s) issued by the Prime Vendor contractor(s) during the effective period of this contract and not completed within the effective period shall be completed by the Contractor within the time specified in the Prime Vendor contractor issued order. This contract shall govern the rights and obligations between the Contractor(s) of this contract, the Prime Vendor contractor(s) and the Government with respect to the order(s) to the same extent as if the order(s) were completed during the contract period, provided that, the Contractor shall not be required to make any deliveries under this contract after 15 days from the expiration date of the contract.

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C.5 52.217-9 OPTION TO EXTEND THE TERM OF THE CONTRACT (MAR 2000)

(a) The Government may extend the term of this contract by written notice to the Contractor within 30 days; provided that the Government gives the Contractor a preliminary written notice of its intent to extend at least 60 days before the contract expires. The preliminary notice does not commit the Government to an extension.

(b) If the Government exercises this option, the extended contract shall be considered to include this option clause.

(c) The total duration of this contract, including the exercise of any options under this clause, shall not exceed five (5) years.

C.6 52.252-2 CLAUSES INCORPORATED BY REFERENCE (FEB 1998)

This contract incorporates one or more clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this/these address(es):

- <http://www.acquisition.gov/far/index.html>
- <http://www.va.gov/oal/library/vaar/>

FAR Number	Title	Date
52.203-17	CONTRACTOR EMPLOYEE WHISTLEBLOWER RIGHTS AND REQUIREMENT TO INFORM EMPLOYEES OF WHISTLEBLOWER RIGHTS	APR 2014

C.7 VAAR 852.203-70 COMMERCIAL ADVERTISING (JAN 2008)

The bidder or offeror agrees that if a contract is awarded to him/her, as a result of this solicitation, he/she will not advertise the award of the contract in his/her commercial advertising in such a manner as to state or imply that the Department of Veterans Affairs endorses a product, project or commercial line of endeavor.

C.8 VAAR 852.203-71 DISPLAY OF DEPARTMENT OF VETERAN AFFAIRS HOTLINE POSTER (DEC 1992)

(a) Except as provided in paragraph (c) below, the Contractor shall display prominently, in common work areas within business segments performing work under VA contracts, Department of Veterans Affairs Hotline posters prepared by the VA Office of Inspector General.

(b) Department of Veterans Affairs Hotline posters may be obtained from the VA Office of Inspector General (53E), P.O. Box 34647, Washington, DC 20043-4647.

(c) The Contractor need not comply with paragraph (a) above if the Contractor has established a mechanism, such as a hotline, by which employees may report suspected instances of improper conduct, and instructions that encourage employees to make such reports.

C.9 VAAR 852.219-9 VA SMALL BUSINESS SUBCONTRACTING PLAN MINIMUM REQUIREMENTS (DEC 2009)

- (a) This clause does not apply to small business concerns.
- (b) If the offeror is required to submit an individual subcontracting plan, the minimum goals for award of subcontracts to service-disabled veteran-owned small business concerns and veteran-owned small business concerns shall be at least commensurate with the Department's annual servicedisabled veteran-owned small business and veteran-owned small business prime contracting goals for the total dollars planned to be subcontracted.
- (c) For a commercial plan, the minimum goals for award of subcontracts to service-disabled veteranowned small business concerns and veteran-owned small businesses shall be at least commensurate with the Department's annual service-disabled veteran-owned small business and veteran-owned small business prime contracting goals for the total value of projected subcontracts to support the sales for the commercial plan.
- (d) To be credited toward goal achievements, businesses must be verified as eligible in the Vendor Information Pages database. The contractor shall annually submit a listing of service-disabled veteran-owned small businesses and veteran-owned small businesses for which credit toward goal achievement is to be applied for the review of personnel in the Office of Small and Disadvantaged Business Utilization.
- (e) The contractor may appeal any businesses determined not eligible for crediting toward goal achievements by following the procedures contained in 819.407.

C.10 SUBCONTRACTING PLAN – MONITORING AND COMPLIANCE

This solicitation includes FAR 52.219-9, Small Business Subcontracting Plan, and VAAR 852.219-9, VA Small Business Subcontracting Plan Minimum Requirement. Accordingly, any contract resulting from this solicitation will include these clauses. The contractor is advised in performing contract administration functions, the CO may use the services of a support contractor(s) to assist in assessing the contractor's compliance with the plan, including reviewing the contractor's accomplishments in achieving the subcontracting goals in the plan. To that end, the support contractor(s) may require access to the contractor's business records or other proprietary data to review such business records regarding the contractor's compliance with this requirement. All support contractors conducting this review on behalf of VA will be required to sign an "Information Protection and Non-Disclosure and Disclosure of Conflicts of Interest Agreement" to ensure the contractor's business records or other proprietary data reviewed or obtained in the course of assisting the CO in assessing the contractor for compliance are protected to ensure information or data is not improperly disclosed or other impropriety occurs. Furthermore, if VA determines any services the support contractor(s) will perform in assessing compliance are advisory and assistance services as defined in FAR 2.101, Definitions, the support contractor(s) must also enter into an agreement with the contractor to protect proprietary information as required by FAR 9.505-4, Obtaining access to proprietary information, paragraph (b). The contractor is required to cooperate fully and make available any records as may be required to enable the CO to assess the contractor compliance with the subcontracting plan.

C.11 52.212-5 CONTRACT TERMS AND CONDITIONS REQUIRED TO IMPLEMENT STATUTES OR EXECUTIVE ORDERS--COMMERCIAL ITEMS (NOV 2015)

(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) 52.209-10, Prohibition on Contracting with Inverted Domestic Corporations (Nov 2015)
- (2) 52.233-3, Protest After Award (AUG 1996) (31 U.S.C. 3553).
- (3) 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:

[Contracting Officer check as appropriate.]

- X (1) 52.203-6, Restrictions on Subcontractor Sales to the Government (Sept 2006), with Alternate I (Oct 1995) (41 U.S.C. 4704 and 10 U.S.C. 2402).
- X (2) 52.203-13, Contractor Code of Business Ethics and Conduct (Oct 2015) (41 U.S.C. 3509).
- ___ (3) 52.203-15, Whistleblower Protections under the American Recovery and Reinvestment Act of 2009 (June 2010) (Section 1553 of Pub. L. 111-5). (Applies to contracts funded by the American Recovery and Reinvestment Act of 2009.)
- X (4) 52.204-10, Reporting Executive Compensation and First-Tier Subcontract Awards (Oct 2015) (Pub. L. 109-282) (31 U.S.C. 6101 note).
- ___ (5) [Reserved].
- ___ (6) 52.204-14, Service Contract Reporting Requirements (Jan 2014) (Pub. L. 111-117, section 743 of Div. C).
- ___ (7) 52.204-15, Service Contract Reporting Requirements for Indefinite-Delivery Contracts (Jan 2014) (Pub. L. 111-117, section 743 of Div. C).
- X (8) 52.209-6, Protecting the Government's Interest When Subcontracting with Contractors Debarred, Suspended, or Proposed for Debarment. (Oct 2015) (31 U.S.C. 6101 note).
- X (9) 52.209-9, Updates of Publicly Available Information Regarding Responsibility Matters (Jul 2013) (41 U.S.C. 2313).
- ___ (10) [Reserved].
- ___ (11)(i) 52.219-3, Notice of HUBZone Set-Aside or Sole-Source Award (Nov 2011) (15 U.S.C. 657a).
- ___ (ii) Alternate I (Nov 2011) of 52.219-3.
- X (12)(i) 52.219-4, Notice of Price Evaluation Preference for HUBZone Small Business Concerns (OCT 2014) (if the offeror elects to waive the preference, it shall so indicate in its offer) (15 U.S.C. 657a).
- ___ (ii) Alternate I (JAN 2011) of 52.219-4.
- ___ (13) [Reserved]
- ___ (14)(i) 52.219-6, Notice of Total Small Business Set-Aside (Nov 2011) (15 U.S.C. 644).
- ___ (ii) Alternate I (Nov 2011).
- ___ (iii) Alternate II (Nov 2011).
- ___ (15)(i) 52.219-7, Notice of Partial Small Business Set-Aside (June 2003) (15 U.S.C. 644).
- ___ (ii) Alternate I (Oct 1995) of 52.219-7.
- ___ (iii) Alternate II (Mar 2004) of 52.219-7.
- X (16) 52.219-8, Utilization of Small Business Concerns (Oct 2014) (15 U.S.C. 637(d)(2) and (3)).
- ___ (17)(i) 52.219-9, Small Business Subcontracting Plan (Oct 2015) (15 U.S.C. 637(d)(4)).
- ___ (ii) Alternate I (Oct 2001) of 52.219-9.
- X (iii) Alternate II (Oct 2001) of 52.219-9.
- ___ (iv) Alternate III (Oct 2015) of 52.219-9.
- ___ (18) 52.219-13, Notice of Set-Aside of Orders (Nov 2011) (15 U.S.C. 644(r)).

- ___ (19) [52.219-14](#), Limitations on Subcontracting (Nov 2011) ([15 U.S.C. 637\(a\)\(14\)](#)).
- X (20) [52.219-16](#), Liquidated Damages-Subcontracting Plan (Jan 1999) ([15 U.S.C. 637\(d\)\(4\)\(E\)\(i\)](#)).
- ___ (21) [52.219-27](#), Notice of Service-Disabled Veteran-Owned Small Business Set-Aside (Nov 2011) ([15 U.S.C. 657 f](#)).
- X (22) [52.219-28](#), Post Award Small Business Program Rerepresentation (Jul 2013) ([15 U.S.C. 632\(a\)\(2\)](#)).
- ___ (23) [52.219-29](#), Notice of Set-Aside for Economically Disadvantaged Women-Owned Small Business (EDWOSB) Concerns (Jul 2013) ([15 U.S.C. 637\(m\)](#)).
- ___ (24) [52.219-30](#), Notice of Set-Aside for Women-Owned Small Business (WOSB) Concerns Eligible Under the WOSB Program (Jul 2013) ([15 U.S.C. 637\(m\)](#)).
- X (25) [52.222-3](#), Convict Labor (June 2003) (E.O. 11755).
- X (26) [52.222-19](#), Child Labor-Cooperation with Authorities and Remedies (Jan 2014) (E.O. 13126).
- X (27) [52.222-21](#), Prohibition of Segregated Facilities (Apr 2015).
- X (28) [52.222-26](#), Equal Opportunity (Apr 2015) (E.O. 11246).
- X (29) [52.222-35](#), Equal Opportunity for Veterans (Oct 2015)([38 U.S.C. 4212](#)).
- X (30) [52.222-36](#), Equal Opportunity for Workers with Disabilities (Jul 2014) ([29 U.S.C. 793](#)).
- X (31) [52.222-37](#), Employment Reports on Veterans (OCT 2015) (38 U.S.C. 4212).
- X (32) [52.222-40](#), Notification of Employee Rights Under the National Labor Relations Act (Dec 2010) (E.O. 13496).
- X (33)(i) [52.222-50](#), Combating Trafficking in Persons (Mar 2015) ([22 U.S.C. chapter 78](#) and E.O. 13627).
 - ___ (ii) Alternate I (Mar 2015) of [52.222-50](#) ([22 U.S.C. chapter 78](#) and E.O. 13627).
- ___ (34) [52.222-54](#), Employment Eligibility Verification (OCT 2015). (Executive Order 12989). (Not applicable to the acquisition of commercially available off-the-shelf items or certain other types of commercial items as prescribed in [22.1803](#).)
- ___ (35)(i) [52.223-9](#), Estimate of Percentage of Recovered Material Content for EPA-Designated Items (May 2008) ([42 U.S.C. 6962\(c\)\(3\)\(A\)\(ii\)](#)). (Not applicable to the acquisition of commercially available off-the-shelf items.)
 - ___ (ii) Alternate I (May 2008) of [52.223-9](#) ([42 U.S.C. 6962\(i\)\(2\)\(C\)](#)). (Not applicable to the acquisition of commercially available off-the-shelf items.)
- ___ (36)(i) [52.223-13](#), Acquisition of EPEAT®-Registered Imaging Equipment (JUN 2014) (E.O.s 13423 and 13514).
 - ___ (ii) Alternate I (Oct 2015) of [52.223-13](#).
- ___ (37)(i) [52.223-14](#), Acquisition of EPEAT®-Registered Televisions (JUN 2014) (E.O.s 13423 and 13514).
 - ___ (ii) Alternate I (Jun 2014) of [52.223-14](#).
- ___ (38) [52.223-15](#), Energy Efficiency in Energy-Consuming Products (DEC 2007) ([42 U.S.C. 8259b](#)).
- ___ (39)(i) [52.223-16](#), Acquisition of EPEAT®-Registered Personal Computer Products (OCT 2015) (E.O.s 13423 and 13514).
 - ___ (ii) Alternate I (Jun 2014) of [52.223-16](#).
- X (40) [52.223-18](#), Encouraging Contractor Policies to Ban Text Messaging While Driving (AUG 2011) (E.O. 13513).
- ___ (41) [52.225-1](#), Buy American-Supplies (May 2014) ([41 U.S.C. chapter 83](#)).
- ___ (42)(i) [52.225-3](#), Buy American-Free Trade Agreements-Israeli Trade Act (May 2014) ([41 U.S.C. chapter 83](#), [19 U.S.C. 3301](#) note, [19 U.S.C. 2112](#) note, [19 U.S.C. 3805](#) note, [19 U.S.C. 4001](#) note, Pub. L. 103-182, 108-77, 108-78, 108-286, 108-302, 109-53, 109-169, 109-283, 110-138, 112-41, 112-42, and 112-43).
 - ___ (ii) Alternate I (May 2014) of [52.225-3](#).
 - ___ (iii) Alternate II (May 2014) of [52.225-3](#).
 - ___ (iv) Alternate III (May 2014) of [52.225-3](#).
- X (43) [52.225-5](#), Trade Agreements (Nov 2013) ([19 U.S.C. 2501](#), et seq., [19 U.S.C. 3301](#) note).
- X (44) [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).

- ___ (45) [52.225-26](#), Contractors Performing Private Security Functions Outside the United States (Jul 2013) (Section 862, as amended, of the National Defense Authorization Act for Fiscal Year 2008; [10 U.S.C. 2302 Note](#)).
- ___ (46) [52.226-4](#), Notice of Disaster or Emergency Area Set-Aside (Nov 2007) ([42 U.S.C. 5150](#)).
- ___ (47) [52.226-5](#), Restrictions on Subcontracting Outside Disaster or Emergency Area (Nov 2007) ([42 U.S.C. 5150](#)).
- ___ (48) [52.232-29](#), Terms for Financing of Purchases of Commercial Items (Feb 2002) ([41 U.S.C. 4505](#), [10 U.S.C. 2307\(f\)](#)).
- ___ (49) [52.232-30](#), Installment Payments for Commercial Items (Oct 1995) ([41 U.S.C. 4505](#), [10 U.S.C. 2307\(f\)](#)).
- ___ (50) [52.232-33](#), Payment by Electronic Funds Transfer-System for Award Management (Jul 2013) ([31 U.S.C. 3332](#)).
- ___ (51) [52.232-34](#), Payment by Electronic Funds Transfer-Other than System for Award Management (Jul 2013) ([31 U.S.C. 3332](#)).
- ___ (52) [52.232-36](#), Payment by Third Party (May 2014) ([31 U.S.C. 3332](#)).
- ___ (53) [52.239-1](#), Privacy or Security Safeguards (Aug 1996) ([5 U.S.C. 552a](#)).
- ___ (54)(i) [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](#)).
- ___ (ii) Alternate I (Apr 2003) of [52.247-64](#).

(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:

[Contracting Officer check as appropriate.]

- ___ (1) [52.222-17](#), Nondisplacement of Qualified Workers (May 2014)(E.O. 13495).
- ___ (2) [52.222-41](#), Service Contract Labor Standards (May 2014) ([41 U.S.C. chapter 67](#)).
- ___ (3) [52.222-42](#), Statement of Equivalent Rates for Federal Hires (May 2014) ([29 U.S.C. 206](#) and [41 U.S.C. chapter 67](#)).
- ___ (4) [52.222-43](#), Fair Labor Standards Act and Service Contract Labor Standards-Price Adjustment (Multiple Year and Option Contracts) (May 2014) ([29 U.S.C. 206](#) and [41 U.S.C. chapter 67](#)).
- ___ (5) [52.222-44](#), Fair Labor Standards Act and Service Contract Labor Standards-Price Adjustment (May 2014) ([29 U.S.C. 206](#) and [41 U.S.C. chapter 67](#)).
- ___ (6) [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](#)).
- ___ (7) [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](#)).
- ___ (8) [52.222-55](#), Minimum Wages Under Executive Order 13658 (Dec 2014)(E.O. 13658).
- ___ (9) [52.226-6](#), Promoting Excess Food Donation to Nonprofit Organizations (May 2014) ([42 U.S.C. 1792](#)).
- ___ (10) [52.237-11](#), Accepting and Dispensing of \$1 Coin (Sept 2008) ([31 U.S.C. 5112\(p\)\(1\)](#)).

(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, 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

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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 (Oct 2015) ([41 U.S.C. 3509](#)).

(ii) [52.219-8](#), Utilization of Small Business Concerns (Oct 2014) ([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 \$700,000 (\$1.5 million for construction of any public facility), the subcontractor must include [52.219-8](#) in lower tier subcontracts that offer subcontracting opportunities.

(iii) [52.222-17](#), Nondisplacement of Qualified Workers (May 2014) (E.O. 13495). Flow down required in accordance with paragraph (l) of FAR clause [52.222-17](#).

(iv) [52.222-21](#), Prohibition of Segregated Facilities (Apr 2015)

(v) [52.222-26](#), Equal Opportunity (Apr 2015) (E.O. 11246).

(vi) [52.222-35](#), Equal Opportunity for Veterans (Oct 2015) ([38 U.S.C. 4212](#)).

(vii) [52.222-36](#), Equal Opportunity for Workers with Disabilities (Jul 2014) ([29 U.S.C. 793](#)).

(viii) [52.222-37](#), Employment Reports on Veterans (Oct 2015) ([38 U.S.C. 4212](#))

(ix) [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](#).

(x) [52.222-41](#), Service Contract Labor Standards (May 2014) ([41 U.S.C. chapter 67](#)).

(xi)

___ (A) [52.222-50](#), Combating Trafficking in Persons (Mar 2015) ([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).

(xii) [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](#)).

(xiii) [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](#)).

(xiv) [52.222-54](#), Employment Eligibility Verification (OCT 2015) (E.O. 12989).

(xv) [52.222-55](#), Minimum Wages Under Executive Order 13658 (Dec 2014) (Executive Order 13658).

(xvi) [52.225-26](#), Contractors Performing Private Security Functions Outside the United States (Jul 2013) (Section 862, as amended, of the National Defense Authorization Act for Fiscal Year 2008; [10 U.S.C. 2302 Note](#)).

(xvii) [52.226-6](#), Promoting Excess Food Donation to Nonprofit Organizations (May 2014) ([42 U.S.C. 1792](#)). Flow down required in accordance with paragraph (e) of FAR clause [52.226-6](#).

(xviii) [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.

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C.12 MANDATORY WRITTEN DISCLOSURES

Mandatory written disclosures required by FAR clause 52.203-13 to the Department of Veterans Affairs, Office of Inspector General (OIG) must be made electronically through the VA OIG Hotline at <http://www.va.gov/oig/contacts/hotline.asp> and clicking on "FAR clause 52.203-13 Reporting". If you experience difficulty accessing the website, call the Hotline at 1-800-488-8244 for further instructions.

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PURSUANT TO THE RULES APPLICABLE TO SUCH CONFIDENTIAL TREATMENT REQUEST.

SECTION D - CONTRACT DOCUMENTS, EXHIBITS, OR ATTACHMENTS

D.1 ATTACHMENT "A"

VA PHARMACEUTICAL PRIME VENDOR CONTRACTOR

McKesson Corporation
One Postal Street, 29th Floor
San Francisco, CA 94101
POC: Mr. Paul Flach
Vice President Government & National Accounts
Phone: [***]

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D.2 ATTACHMENT "B"

DOD PHARMACEUTICAL PRIME VENDOR (PPV) CONTRACTORS

<p>McKesson Drug Company Attn: Lori White 1220 Senlac Drive Carrollton, TX 75006 Phone: [***] Fax: [***] Tricare Mail Order Pharmacy Program National Prime Vendor Email: [***]</p>	<p>AmeriSource-Bergen Company Attn: Dina Barton 100 Friars Blvd. Thorofare, NJ 08086 Phone: [***] Fax: [***] Email: [***]</p>
<p>Dakota Drug Company Attn: Jan McCann / Becky Gilstad 28-32 N. Main Street Minot, ND 58701 Phone: [***] Fax: [***] Email: [***]</p>	<p>DMS Pharmaceutical Group, Inc. Attn: Jean Hawkins 810 Busee Highway Park Ridge, IL 60068 Phone: [***] Fax: [***] Email: [***]</p>
<p>Cardinal Health, Inc. Attn: Lisa Parsley 5555 Glendon Court Dublin, OH 43016 Phone: [***] Fax: [***] Email: [***]</p>	

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D.3 ATTACHMENT "C"

[***]

[***] INDICATES MATERIAL THAT WAS OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT WAS REQUESTED. ALL SUCH OMITTED MATERIAL WAS FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO THE RULES APPLICABLE TO SUCH CONFIDENTIAL TREATMENT REQUEST.

D.4 ATTACHMENT "D"

SMALL BUSINESS SUBCONTRACTING PLAN

(Model Outline*)

Please see the attached document labeled Attachment D that represents AstraZeneca's current Subcontracting Plan

SUBCONTRACTING PLAN PERIOD: _____

Individual plans should cover the entire period of performance, and commercial plans should coincide with the company's fiscal year. In the event your company's fiscal year is for a period that will end before the contract periods of any federal contracts you hold which include the requirement to have a small business subcontracting plan, **you will be required to submit a new subcontracting plan for approval thirty (30) days prior to expiration of the existing subcontracting plan.** In the event an acceptable plan cannot be negotiated prior to expiration of the existing subcontracting plan, your contract(s) may be terminated.

DATE SUBMITTED: _____

NAME OF PLANHOLDER: _____

SUBSIDIARIES INCLUDED: _____

ADDRESS: _____

ITEM/SERVICE: _____

1. TYPE OF PLAN

List the total estimated dollar value of all planned subcontracting (to all types of business concerns, both **large and small**). Select only one of the following:

a) **Individual Plan** (This Contract Only) Contract #/Solicitation # _____

Total value of projected subcontracts (both **large and small** businesses) \$ _____

Total Contract Value (including options) \$ _____

*Separate goals **must** be included for each option period

b) **Commercial Division-wide Plan**

Total projected sales \$ _____

Total value of projected subcontracts (both **large and small** businesses) \$ _____

(Subcontracts Represent _____% of Total Annual Sales)

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c) **Commercial Company-wide Plan**

Total projected sales \$ _____

Total value of projected subcontracts (both **large and small** businesses) \$ _____

(Subcontracts Represent _____% of Total Annual Sales)

* *Federal Acquisition Regulation (FAR), paragraph 19.708(b)(1), prescribes the use of the clause at FAR 52.219-9 entitled "Small Business Subcontracting Plan." The following is a **suggested** model for use when formulating such subcontracting plan. While this model plan has been designed to be consistent with FAR 52.219-9, other formats of a subcontracting plan may be acceptable. However, failure to include the essential information as exemplified in this model may be cause for either a delay in acceptance or the rejection of an offer where the clause is applicable. Further, the use of this model is not intended to waive other requirements that may be applicable under FAR 52.219-9 or that may appear in the Government's solicitation. "SUBCONTRACT," as used in this clause, means any agreement (other than one involving an employer-employee relationship) entered into by a federal government prime contractor or subcontractor calling for supplies or services required for performance of the contract or subcontract.*

2. GOALS

State separate dollar and percentage goals, expressed in terms of **percentages of the total available subcontracting dollars** listed in the previous section.

a) Total estimated dollar value and percent of planned subcontracting with **small businesses (SB)** (including ANCs and Indian tribes), veteran-owned small, service-disabled veteran-owned small, HUBZone small, small disadvantaged (including ANCs and Indian tribes), and women-owned small business concerns:

\$ _____ and _____%

b) Total estimated dollar value and percent of planned subcontracting with **veteran-owned small businesses (VO)**:

\$ _____ and _____%

c) Total estimated dollar value and percent of planned subcontracting with **service-disabled veteran-owned small businesses (SDVO)** (Note: This is a subset of veteran-owned):

\$ _____ and _____%

d) Total estimated dollar value and percent of planned subcontracting with **small disadvantaged businesses (SDB)** (including ANCs and Indian tribes):

\$ _____ and _____%

e) Total estimated dollar value and percent of planned subcontracting with **women-owned small businesses (WO)**:

\$ _____ and _____%

f) Total estimated dollar value and percent of planned subcontracting with **HUBZone small businesses (HUB)**:

\$ _____ and _____%

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3. PRODUCTS AND/OR SERVICES

The types of products and/or services to be subcontracted are:

- LB: _____
- SB: _____
- VO: _____
- SDVO: _____
- SDB: _____
- WO: _____
- HUB: _____

4. GOAL DEVELOPMENT

The following method was used in developing the subcontracting goals:

5. IDENTIFYING POTENTIAL SOURCES

The following methods were used to identify potential sources for solicitation purposes (See FAR 52.219-9(d)(5) for examples of methods that may be used.):

6. INDIRECT COSTS

Indirect costs have have not been included in the dollar and percentage subcontracting goals stated above. (Check one.)

If "have been" is checked (and you are proposing an individual plan), explain the method used in determining the proportionate share of indirect costs to be incurred with small business (including Alaska Native Corporations and Indian tribes), veteran-owned small business, service-disabled veteran-owned small business, small disadvantaged business (including ANCs and Indian tribes), women-owned small business, and HUBZone small business concerns. *Note: Commercial planholders who choose to include indirect costs will not need to provide the aforementioned explanation because the costs will be applied at 100%.*

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7. PROGRAM ADMINISTRATOR

The following individual will administer the subcontracting program:

NAME: _____
TITLE: _____
ADDRESS: _____

TELEPHONE: _____
E-MAIL: _____

This individual's specific duties, as they relate to the firm's subcontracting program, are as follows:

8. EQUITABLE OPPORTUNITY

The following good faith efforts (internal and external) will be taken to assure that small business, veteran-owned small business, service-disabled veteran-owned small business, small disadvantaged business, women-owned small business, and HUBZone small business concerns will have an equitable opportunity to compete for subcontracts:

9. FLOW-DOWN CLAUSE

The offeror agrees that the FAR clause of this contract entitled "Utilization of Small Business Concerns" (52.219-8) will be included in all subcontracts which offer further subcontracting opportunities, and all subcontractors (except small business concerns) that receive subcontracts in excess of \$650,000 ++(Effective 1 Oct 2015 new threshold is \$700,000) with further subcontracting possibilities will be required to adopt a subcontracting plan that complies with the requirements of this clause.

NOTE: See exceptions listed in FAR 52.219-9(j).

10. REPORTING & COOPERATION

The offeror agrees to

- (i) Cooperate in any studies or surveys as may be required;
- (ii) Submit periodic reports so that the Government can determine the extent of compliance by the offeror with the subcontracting plan;
- (iii) Submit the Individual Subcontracting Report (ISR) and/or the Summary Subcontract Report (SSR), in accordance with the paragraph (l) of this clause using the Electronic Subcontracting Reporting System (eSRS) at <http://www.esrs.gov>. The reports shall provide information on subcontract awards to small business concerns (including ANCs and Indian tribes that are not small businesses), veteran-owned small business concerns, service-disabled veteran-owned small business concerns, HUBZone small business concerns, small disadvantaged business concerns (including ANCs and Indian tribes that have not been certified by the Small Business Administration as small disadvantaged businesses), women-owned small business concerns, and Historically Black Colleges and Universities and Minority Institutions. Reporting shall be in accordance with this clause, or as provided in agency regulations;
- (iv) Ensure that its subcontractors with subcontracting plans agree to submit the ISR and/or the SSR using eSRS;
- (v) Provide its prime contract number, its DUNS number, and the e-mail address of the offeror's official responsible for acknowledging receipt of or rejecting the ISRs, to all firsttier subcontractors with subcontracting plans so they can enter this information into the eSRS when submitting their ISRs; and
- (vi) Require that each subcontractor with a subcontracting plan provide the prime contract number, its own DUNS number, and the e-mail address of the subcontractor's official responsible for acknowledging receipt of or rejecting the ISRs, to its subcontractors with subcontracting plans.

11. RECORDKEEPING

The following is a description of the types of records that will be maintained concerning procedures that have been adopted to comply with the requirements and goals in the plan, including establishing source lists; and a description of the offeror's efforts to locate small business, veteranowned small business, service-disabled veteran-owned small business, HUBZone small business, small disadvantaged business, and women-owned small business concerns and award subcontracts to them. The records shall include at least the following (on a plant-wide or company-wide basis, unless otherwise indicated):

- (i) Source lists (e.g., SAM), guides, and other data that identify small business, veteran-owned small business, service-disabled veteran-owned small business, HUBZone small business, small disadvantaged business, and women-owned small business concerns.
- (ii) Organizations contacted in an attempt to locate sources that are small business, veteranowned small business, service-disabled veteran-owned small business, HUBZone small business, small disadvantaged business, or women-owned small business concerns.
- (iii) Records on each subcontract solicitation resulting in an award of more than \$150,000, indicating --

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- (A) Whether small business concerns were solicited and if not, why not;
 - (B) Whether veteran-owned small business concerns were solicited and, if not, why not;
 - (C) Whether service-disabled veteran-owned small business concerns were solicited and, if not, why not;
 - (D) Whether HUBZone small business concerns were solicited and, if not, why not;
 - (E) Whether small disadvantaged business concerns were solicited and if not, why not;
 - (F) Whether women-owned small business concerns were solicited and if not, why not; and
 - (G) If applicable, the reason award was not made to a small business concern.
- (iv) Records of any outreach efforts to contact -
- (A) Trade associations;
 - (B) Business development organizations;
 - (C) Conferences and trade fairs to locate small, HUBZone small, small disadvantaged, and women-owned small business sources; and
 - (D) Veterans service organizations.
- (v) Records of internal guidance and encouragement provided to buyers through -
- (A) Workshops, seminars, training, etc., and
 - (B) Monitoring performance to evaluate compliance with the program's requirements.
- (vi) On a contract-by-contract basis, records to support award data submitted by the offeror to the Government, including the name, address, and business size of each subcontractor. Contractors having commercial plans need not comply with this requirement.

Signed: _____ **Date Signed:** _____
Typed Name: _____ **Title:** _____
Plan Approved by (Government official): _____ **Date Approved:** _____
Typed Name: _____
Contracting Officer

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	Prior Year Goals	Prior Year Achievements*	Current Goals
Total Subcontracting Dollars +	\$ _____	\$ _____	\$ _____
Small Business Dollars	\$ _____	\$ _____	\$ _____
Small Business Percent	_____ %	_____ %	_____ %
Small Veteran-owned Dollars	\$ _____	\$ _____	\$ _____
Small Veteran-owned Percent	_____ %	_____ %	_____ %
Service-Disabled Veteran-Owned Dollars	\$ _____	\$ _____	\$ _____
Service-Disabled Veteran-Owned Percent	_____ %	_____ %	_____ %
Small Disadvantaged Dollars	\$ _____	\$ _____	\$ _____
Small Disadvantaged Percent	_____ %	_____ %	_____ %
Small Women-owned Dollars	\$ _____	\$ _____	\$ _____
Small Women-owned Percent	_____ %	_____ %	_____ %
HUBZone Small Business Dollars	\$ _____	\$ _____	\$ _____
HUBZone Small Business Percent	_____ %	_____ %	_____ %

Round percentages to two decimal places and dollar figures to the nearest whole dollar.

* If total prior year contract achievements are not available, use actual figures and estimate/prorate balance. Achievements based on Government's Fiscal Year while Goals are based on Company's Fiscal Year.

+ Including subcontracting dollars for small and large businesses

++ Effective OCT 1, 2015 subcontracting plans are required for contracts expected to exceed \$700,000 (increased from \$650,000).

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Contractors shall submit new commercial plans to the contracting officer 30 working days prior to the end of the contractor's fiscal year, IAW FAR 19.704(d).

***Individual Plans must list and justify goals for each option period separately. This page is for individual plans ONLY. Individual plans for VA FSS should only complete the columns for base period, option period 1, and total periods.**

	Base Period	Option Period 1	Option Period 2	Total Periods
1.a. Total Contract	\$ _____	\$ _____	\$ _____	\$ _____
1.b. Total Subcontracted	_____ %	_____ %	_____ %	_____ %
2.a. To SB Dollars	\$ _____	\$ _____	\$ _____	\$ _____
Percent of Line 1.a.	_____ %	_____ %	_____ %	_____ %
2.b. To VOSB Dollars	\$ _____	\$ _____	\$ _____	\$ _____
Percent of Line 1.b.	_____ %	_____ %	_____ %	_____ %
2.c. To SDVOSB Dollars	\$ _____	\$ _____	\$ _____	\$ _____
Percent of Line 1.b.	_____ %	_____ %	_____ %	_____ %
2.d. To SDB Dollars	\$ _____	\$ _____	\$ _____	\$ _____
Percent of Line 1.b.	_____ %	_____ %	_____ %	_____ %
2.e. To WOSB Dollars	\$ _____	\$ _____	\$ _____	\$ _____
Percent of Line 1.b.	_____ %	_____ %	_____ %	_____ %
2.f. To HUBZone Dollars	\$ _____	\$ _____	\$ _____	\$ _____
Percent of Line 1.b.	_____ %	_____ %	_____ %	_____ %

Complete additional option year sheets for contracts with more option periods.

SECTION 302 CERTIFICATION

I, Adrian Adams, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Aralez Pharmaceuticals 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 those entities, particularly during the period in which this report is being prepared;
 - (b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 9, 2017

/s/ Adrian Adams

Adrian Adams
Chief Executive Officer
(Principal Executive Officer)

SECTION 302 CERTIFICATION

I, Scott J. Charles, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Aralez Pharmaceuticals 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 those entities, particularly during the period in which this report is being prepared;
 - (b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 9, 2017

/s/ Scott J. Charles

Scott J. Charles
Chief Financial Officer
(Principal Financial Officer)

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

In connection with the Quarterly Report of Aralez Pharmaceuticals Inc. (“Aralez”) on Form 10-Q for the period ending March 31, 2017, as filed with the Securities and Exchange Commission (the “SEC”) on the date hereof (the “Report”), I, Adrian Adams, Chief Executive Officer of Aralez, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

- (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 Aralez.

Date: May 9, 2017

/s/ Adrian Adams

Adrian Adams

Chief Executive Officer

This certification is being furnished to the Securities and Exchange Commission pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not be deemed filed by Aralez for purposes of Section 18 of the Securities Exchange Act of 1934, or otherwise subject to liability of that Section. This certification will not be deemed incorporated by reference into any filing under the Securities Act of 1933 or the Securities Exchange Act of 1934, except to the extent Aralez specifically incorporates it by reference.

A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 has been provided to Aralez and shall be furnished to the Securities and Exchange Commission or its staff upon request.

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

In connection with the Quarterly Report of Aralez Pharmaceuticals Inc. (“Aralez”) on Form 10-Q for the period ending March 31, 2017, as filed with the Securities and Exchange Commission (the “SEC”) on the date hereof (the “Report”), I, Scott J. Charles, Chief Financial Officer of Aralez, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

- (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 Aralez.

Date: May 9, 2017

/s/ Scott J. Charles

Scott J. Charles
Chief Financial Officer

This certification is being furnished to the Securities and Exchange Commission pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not be deemed filed by Aralez for purposes of Section 18 of the Securities Exchange Act of 1934, or otherwise subject to liability of that Section. This certification will not be deemed incorporated by reference into any filing under the Securities Act of 1933 or the Securities Exchange Act of 1934, except to the extent Aralez specifically incorporates it by reference.

A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 has been provided to Aralez and shall be furnished to the Securities and Exchange Commission or its staff upon request.
