

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

**FORM 10-Q**

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

For the quarterly period ended September 30, 2016

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number **001-36646**

**Asterias Biotherapeutics, Inc.**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of incorporation or organization)

**46-1047971**

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

**6300 Dumbarton Circle  
Fremont, California 94555**

(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code  
**(510) 456-3800**

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 website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).  Yes  No

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

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

(Do not check if a smaller reporting company)

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

APPLICABLE ONLY TO CORPORATE ISSUERS:

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date: 46,422,452 shares of Series A Common Stock, \$0.0001 par value, as of November 10, 2016.

## PART 1—FINANCIAL INFORMATION

*Statements made in this Report that are not historical facts may constitute forward-looking statements that are subject to risks and uncertainties that could cause actual results to differ materially from those discussed. Such risks and uncertainties include but are not limited to those discussed in this Report under Item 1 of the Notes to Financial Statements, and under Risk Factors in this Report. Words such as “expects,” “may,” “will,” “anticipates,” “intends,” “plans,” “believes,” “seeks,” “estimates,” and similar expressions identify forward-looking statements.*

*References to “Asterias,” “our” or “we” means Asterias Biotherapeutics, Inc.*

*The description or discussion, in this Form 10-Q, of any contract or agreement is a summary only and is qualified in all respects by reference to the full text of the applicable contract or agreement.*

Item 1. Financial Statements

**ASTERIAS BIOTHERAPEUTICS, INC.**  
**CONDENSED BALANCE SHEETS**  
**(IN THOUSANDS EXCEPT PAR VALUE AMOUNTS)**

	September 30, 2016 <u>(Unaudited)</u>	December 31, 2015
<b>ASSETS</b>		
<b>CURRENT ASSETS</b>		
Cash and cash equivalents	\$ 17,926	\$ 11,183
Available-for-sale securities, at fair value	15,999	17,006
Landlord receivable	-	567
Prepaid expenses and other current assets	1,989	1,033
<b>Total current assets</b>	<b>35,914</b>	<b>29,789</b>
<b>NONCURRENT ASSETS</b>		
Intangible assets, net	18,802	20,816
Property, plant and equipment, net	5,212	5,756
Investment in affiliates	-	416
Deferred tax asset	9,956	9,744
Other assets	419	457
<b>TOTAL ASSETS</b>	<b>\$ 70,303</b>	<b>\$ 66,978</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES</b>		
Amount due to BioTime, Inc. (Notes 1 and 10)	\$ 463	\$ 530
Accounts payable	640	747
Accrued expenses and other current liabilities	981	1,183
Capital lease liability	7	7
Deferred grant income	1,392	2,513
Deferred tax liabilities, current portion	5,393	5,274
<b>Total current liabilities</b>	<b>8,876</b>	<b>10,254</b>
<b>LONG-TERM LIABILITIES</b>		
Capital lease liability	21	26
Warrant liability	8,376	-
Deferred tax liabilities, net of current portion	5,963	7,020
Deferred rent liability	251	179
Lease liability	4,090	4,400
<b>TOTAL LIABILITIES</b>	<b>27,577</b>	<b>21,879</b>
Commitments and contingencies (see Note 9)		
<b>STOCKHOLDERS' EQUITY</b>		
Preferred Stock, \$0.0001 par value, authorized 5,000 shares; none issued and outstanding	-	-
Common Stock, \$0.0001 par value, authorized 75,000 Series A Common Stock and 75,000 Series B Common Stock; 45,857 and 38,228 shares Series A Common Stock issued and outstanding at September 30, 2016 and December 31, 2015, respectively; no Series B Common Stock issued and outstanding at September 30, 2016 and December 31, 2015	5	4
Additional paid-in capital	117,452	92,900
Accumulated other comprehensive income (loss) on available-for-sale investments, net	(348)	434
Accumulated deficit	(74,383)	(48,239)
<b>Total stockholders' equity</b>	<b>42,726</b>	<b>45,099</b>
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<b>\$ 70,303</b>	<b>\$ 66,978</b>

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

**ASTERIAS BIOTHERAPEUTICS, INC.**  
**CONDENSED STATEMENTS OF OPERATIONS**  
**(IN THOUSANDS, EXCEPT PER SHARE DATA)**  
**(UNAUDITED)**

	<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
	<b>September 30,</b>		<b>September 30,</b>	
	<b>2016</b>	<b>2015</b>	<b>2016</b>	<b>2015</b>
<b>REVENUE</b>				
Royalties from product sales	\$ 218	\$ 353	\$ 337	\$ 528
Sale of cell lines	-	-	-	40
Grant income	1,858	1,070	4,865	2,406
Total revenue	2,076	1,423	5,202	2,974
Cost of sales	(59)	(176)	(118)	(265)
Total gross profit	2,017	1,247	5,084	2,709
<b>EXPENSES</b>				
Research and development	(5,232)	(4,629)	(17,594)	(11,918)
General and administrative	(4,210)	(1,554)	(13,081)	(5,071)
Total operating expenses	(9,442)	(6,183)	(30,675)	(16,989)
Loss from operations	(7,425)	(4,936)	(25,591)	(14,280)
<b>OTHER INCOME/(EXPENSE)</b>				
Change in fair value on warrant liability	(3,995)	-	(2,368)	-
Interest expense, net	(128)	(126)	(413)	(197)
Other expense, net	(2)	(6)	(27)	(7)
Total other expense, net	(4,125)	(132)	(2,808)	(204)
Loss before income tax benefit	(11,550)	(5,068)	(28,399)	(14,484)
Deferred income tax benefit	902	1,561	2,255	4,386
<b>NET LOSS</b>	<b>\$ (10,648)</b>	<b>\$ (3,507)</b>	<b>\$ (26,144)</b>	<b>\$ (10,098)</b>
<b>BASIC AND DILUTED NET LOSS PER COMMON SHARE</b>	<b>\$ (0.24)</b>	<b>\$ (0.09)</b>	<b>\$ (0.63)</b>	<b>\$ (0.29)</b>
<b>WEIGHTED AVERAGE COMMON SHARES OUTSTANDING: BASIC AND DILUTED</b>	<b>45,193</b>	<b>37,602</b>	<b>41,588</b>	<b>34,643</b>

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

**ASTERIAS BIOTHERAPEUTICS, INC.**  
**CONDENSED STATEMENTS OF COMPREHENSIVE LOSS**  
**(IN THOUSANDS)**  
**(UNAUDITED)**

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2016</b>	<b>2015</b>	<b>2016</b>	<b>2015</b>
<b>NET LOSS</b>	\$ (10,648)	\$ (3,507)	\$ (26,144)	\$ (10,098)
Other comprehensive loss, net of tax:	-	-	-	-
Unrealized gain (loss) on available-for-sale securities, net of taxes	4,715	(1,579)	(782)	(1,829)
<b>COMPREHENSIVE LOSS</b>	<b>\$ (5,933)</b>	<b>\$ (5,086)</b>	<b>\$ (26,926)</b>	<b>\$ (11,927)</b>

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

**ASTERIAS BIOTHERAPEUTICS, INC.**  
**CONDENSED STATEMENTS OF CASH FLOWS**  
**(IN THOUSANDS)**  
**(UNAUDITED)**

	<b>Nine Months Ended</b>	
	<b>September 30,</b>	
	<b>2016</b>	<b>2015</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$ (26,144)	\$ (10,098)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	909	396
Stock-based compensation	3,648	2,118
Amortization of intangible assets	2,014	2,015
Amortization of prepaid rent	-	63
Deferred income tax benefit	(2,255)	(4,386)
Common stock issued for services in lieu of cash	644	-
Change in fair value on warrant liability	2,368	-
Distribution of Asterias warrants to shareholders other than BioTime	5,285	-
Changes in operating assets and liabilities:		
Grant receivable	-	118
Prepaid expenses and other current assets	(955)	(455)
Other long term assets	8	(98)
Accounts payable	(107)	(313)
Accrued expenses and other current liabilities	625	740
Deferred rent liability	73	1
Deferred grant income	(1,121)	1,869
Other current liability	166	-
Amount due to BioTime, Inc.	(233)	(351)
Net cash used in operating activities	<u>(15,075)</u>	<u>(8,381)</u>
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Purchase of property, plant and equipment, including tenant improvements	(643)	(194)
Payments on construction in progress	-	(3,830)
Payment of security deposits	-	(1)
Reimbursement of security deposit	31	-
Net cash used in investing activities	<u>(612)</u>	<u>(4,025)</u>
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from sale of common shares	2,149	8,286
Proceeds from sale of common stock and warrants	20,199	-
Proceeds from exercise of warrants	-	11,700
Financing costs	(1,969)	(598)
Proceeds from exercise of stock options	1,933	23
Repayment of lease liability and capital lease obligation	(315)	-
Shares withheld and retired to pay employee taxes	(134)	-
Reimbursement from landlord on construction in progress	567	2,564
Net cash provided by financing activities	<u>22,430</u>	<u>21,975</u>
<b>NET INCREASE IN CASH AND CASH EQUIVALENTS:</b>	<b>6,743</b>	<b>9,569</b>
<b>CASH AND CASH EQUIVALENTS:</b>		
At beginning of period	11,183	3,076
At end of period	<u>\$ 17,926</u>	<u>\$ 12,645</u>

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

**ASTERIAS BIOTHERAPEUTICS, INC.**  
**NOTES TO CONDENSED FINANCIAL STATEMENTS**  
**(UNAUDITED)**

**1. Organization, Basis of Presentation and Liquidity**

Asterias Biotherapeutics, Inc. (“Asterias”) was incorporated in Delaware on September 24, 2012. Prior to May 13, 2016, Asterias was a majority-owned and controlled subsidiary of BioTime, Inc. (“BioTime”). As further discussed below, on May 13, 2016, BioTime deconsolidated Asterias’ financial statements due to BioTime’s loss of control of Asterias as defined by generally accepted accounting principles.

Asterias is a biotechnology company focused on the emerging fields of cell therapy and regenerative medicine. Asterias has two core technology platforms. The first is a type of stem cell capable of becoming all of the cell types in the human body, a property called pluripotency. The second is the use of a cell type called “dendritic cells” to teach cancer patients’ immune systems to attack their tumors. Asterias currently has three clinical stage programs based on these platforms: AST-OPC1 is a therapy derived from pluripotent stem cells that is currently in a Phase 1/2a clinical trial for spinal cord injuries; AST-VAC1 is a patient-specific cancer immunotherapy being evaluated by Asterias in Acute Myeloid Leukemia (AML); and AST-VAC 2 is a non-patient specific cancer immunotherapy for which the initiation of a Phase 1/2a clinical trial in non-small cell lung cancer is planned for the first half of 2017.

The financial statements presented herein, and discussed below, have been prepared on a stand-alone basis. The accompanying unaudited condensed financial statements have been prepared in accordance with accounting principles generally accepted in the United States (“GAAP”) for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X of the Securities Exchange Commission. In accordance with those rules and regulations certain information and footnote disclosures normally included in comprehensive financial statements have been condensed or omitted pursuant to such rules and regulations. The balance sheet as of December 31, 2015 was derived from the audited financial statements at that date, but does not include all the information and footnotes required by GAAP. These financial statements should be read in conjunction with the audited financial statements and notes thereto included in Asterias’ Annual Report on Form 10-K for the year ended December 31, 2015.

The accompanying interim condensed financial statements, in the opinion of management, include all adjustments, consisting only of normal recurring adjustments, necessary for a fair presentation of Asterias’ financial condition and results of operations. The condensed results of operations are not necessarily indicative of the results to be expected for any future interim period or for the entire year.

Prior to May 13, 2016, BioTime consolidated the results of Asterias into BioTime’s consolidated results based on BioTime’s ability to control Asterias’ operating and financial decisions and policies through a majority ownership of Asterias common stock. On May 13, 2016, Asterias completed the sale and the underwriters’ exercise of the overallotment for 5,147,059 shares of its common stock and warrants to purchase 2,959,559 shares of its common stock, through an underwritten public offering (the “Asterias Offering”) (see Note 7). BioTime did not participate in the Asterias Offering. As a result of the sale of Asterias common stock in the Asterias Offering and the issuance of 708,333 shares of Asterias common stock upon the exercise of certain stock options by a former Asterias executive, as of May 13, 2016, BioTime’s percentage ownership of the outstanding common stock of Asterias declined to less than 50%. Under generally accepted accounting principles, loss of control of a subsidiary is deemed to have occurred when, among other things, a parent company owns less than a majority of the outstanding shares of common stock of the subsidiary, lacks a controlling financial interest in the subsidiary, and is unable to unilaterally control the subsidiary through other means such as having, or having the ability to obtain, a majority of the subsidiary’s Board of Directors. BioTime determined that all of these loss of controls factors were present for BioTime as of May 13, 2016. Accordingly, BioTime deconsolidated Asterias’ financial statements and results of operations from those of BioTime, effective May 13, 2016, in accordance with ASC, 810-10-40-4(c), *Consolidation*.

BioTime continues to allocate expenses such as salaries and payroll related expenses incurred and paid on behalf of Asterias based on the amount of time that particular employees of BioTime devote to Asterias affairs. Other expenses such as legal, accounting, travel, and entertainment expenses are allocated to Asterias to the extent that those expenses are incurred by or on behalf of Asterias. BioTime also allocates certain overhead expenses such as insurance, internet, and telephone expenses based on a percentage determined by management. These allocations are made based upon activity-based allocation drivers such as time spent, percentage of square feet of office or laboratory space used, if applicable, and percentage of personnel devoted to Asterias operations or management. Due to BioTime’s deconsolidation of Asterias effective May 13, 2016, these allocated and overhead expenses are expected to decrease as Asterias continues to hire its operations and management personnel. Management evaluates the appropriateness of the percentage allocations on a quarterly basis and believes that this basis for allocation is reasonable.

In connection with the services performed by employees of BioTime, or employees of other BioTime commonly controlled and consolidated subsidiaries within the BioTime group of affiliated entities, Asterias has in the past and may in the future grant stock options to those performing services for Asterias, for which Asterias records stock-based compensation expense in its statements of operations for such services performed in the relevant periods (see Note 7).

*Liquidity* – Since inception, Asterias has incurred operating losses and has funded its operations primarily through the support from BioTime, issuance of equity securities, warrants, payments from research grants, and royalties from product sales. At September 30, 2016, Asterias had an accumulated deficit of \$74.4 million, working capital of \$27 million and stockholders' equity of \$42.7 million. Asterias has evaluated its projected cash flows and believes that its cash and cash equivalents of \$17.9 million and available for sale securities of \$16.0 million as of September 30, 2016, will be sufficient to fund Asterias' operations through the third quarter of 2017. Some of the clinical trials being conducted by Asterias will continue to be funded in part with funds from the \$14.3 million grant awarded in 2014 by the California Institute for Regenerative Medicine ("CIRM"), (\$4 million of which are still subject to meeting certain milestones as of September 30, 2016), and not from cash on hand and the value of our available for sale securities is subject to market risk. If Asterias were to lose its grant funding, the value of its available for sale securities decreases, or it is unable to obtain future adequate financing for its clinical trials, it may be required to delay, postpone, or cancel its clinical trials or limit the number of clinical trial sites, or otherwise reduce or curtail its operations. Future financings, if necessary, may not be available to Asterias at acceptable terms, or if at all. Sales of additional equity securities would result in the dilution of interests of current shareholders.

## 2. Summary of Significant Accounting Policies

*Basic and diluted net loss per share* – The computations of basic and diluted net loss per share are as follows (in thousands, except per share data):

	Three Months Ended September 30, (Unaudited)		Nine Months Ended September 30, (Unaudited)	
	2016	2015	2016	2015
Net loss	\$ (10,648)	\$ (3,507)	\$ (26,144)	\$ (10,098)
Weighted average common shares outstanding – basic and diluted	45,193	37,602	41,588	34,643
Net loss per share – basic and diluted	\$ (0.24)	\$ (0.09)	\$ (0.63)	\$ (0.29)

The following common stock equivalents were excluded from the computation of diluted net loss per share of common stock for the periods presented because including them would have been antidilutive (in thousands):

	Nine Months Ended September 30, (Unaudited)	
	2016	2015
Stock options and restricted stock units	6,349	4,609
Warrants	6,699	3,500

*Recently Issued Accounting Pronouncements* – There have been no recent accounting pronouncements since the recently issued pronouncements included in Asterias' Form 10-Q for the three months ended March 31, 2016 and June 30, 2016.

On January 5, 2016, the FASB issued Accounting Standards Update 2016-01, "Financial Instruments—Overall: Recognition and Measurement of Financial Assets and Financial Liabilities" (ASU No. 2016-01). Changes to the current GAAP model primarily affects the accounting for equity investments, financial liabilities under the fair value option, and the presentation and disclosure requirements for financial instruments. In addition, ASU No. 2016-01 clarified guidance related to the valuation allowance assessment when recognizing deferred tax assets resulting from unrealized losses on available-for-sale debt securities. The accounting for other financial instruments, such as loans, investments in debt securities, and financial liabilities is largely unchanged. The more significant amendments are to equity investments in unconsolidated entities.

In accordance with ASU No. 2016-01, all equity investments in unconsolidated entities (other than those accounted for using the equity method of accounting) will generally be measured at fair value through earnings. There will no longer be an available-for-sale classification (changes in fair value reported in other comprehensive income) for equity securities with readily determinable fair values. The classification and measurement guidance will be effective for public business entities in fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. ASU No. 2016-01, when adopted, could have a material impact on Asterias' financial statements based on the current accounting of available-for-sale securities Asterias holds as discussed in Note 4.

In August 2014, the FASB issued 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". ASU No. 2014-15 defines management's responsibility to assess an entity's ability to continue as a going concern, and to provide related footnote disclosures in certain circumstances. In connection with preparing financial statements for each annual and interim reporting period, ASU 2014-15 requires that an entity's management evaluate whether there are conditions or events, considered in the aggregate, that 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 (or within one year after the date that the financial statements are available to be issued when applicable). ASU No. 2014-15 is effective for annual and interim reporting periods ending after December 15, 2016. Early adoption is permitted. Asterias has not elected early adoption and believes the impact of the adoption of ASU No. 2014-15 could have a material adverse impact on its financial statements.

### 3. Balance Sheet Components

#### *Property, plant and equipment, net*

As of September 30, 2016 and December 31, 2015, property, plant and equipment consisted of the following (in thousands):

	<b>September 30 2016 (Unaudited)</b>	<b>December 31, 2015</b>
Leasehold improvements	\$ 5,331	\$ 4,998
Equipment and furniture	2,106	2,074
Accumulated depreciation	(2,225)	(1,316)
Property, plant and equipment, net	<u>\$ 5,212</u>	<u>\$ 5,756</u>

Depreciation expense for the nine months ended September 30, 2016 and 2015 was \$909,000 and \$396,000, respectively.

### 4. Investments in BioTime and OncoCyte

#### *Investment in BioTime*

BioTime common shares (traded on NYSE: MKT under the symbol "BTX") are included at fair value in current assets on the balance sheet as the shares are available for use and could be sold at fair value for working capital purposes. As of September 30, 2016 and December 31, 2015, Asterias held 3,852,880 BioTime shares which are valued at \$15.0 million and \$15.8 million based on the closing price on that date, respectively.

#### *Investment in OncoCyte*

On December 31, 2015, in connection with BioTime's distribution of OncoCyte common stock to BioTime shareholders, on a pro rata basis, Asterias received 192,644 shares of OncoCyte common stock from BioTime as a dividend in kind. On this date, BioTime shareholders, including Asterias, received one share of OncoCyte common stock for every twenty shares of BioTime common stock held. Asterias recorded the fair value of the OncoCyte common stock as contributed capital from BioTime.

The OncoCyte shares are included in available-for-sale securities at fair value in current assets in Asterias' balance sheet as the shares are traded on NYSE: MKT (symbol "OCX") and available for working capital purposes. As of September 30, 2016 and December 31, 2015, the OncoCyte shares are valued at \$1.0 million and \$1.2 million based on the OncoCyte closing prices on those respective dates.

## 5. Cross-License and Share Transfer with BioTime and Subsidiaries

On February 16, 2016, Asterias entered into a Cross-License Agreement (the “Cross-License”) with BioTime and BioTime's wholly owned subsidiary ES Cell International Pte Ltd (“ESI”). Under the terms of the Cross-License, Asterias received a fully-paid, non-royalty-bearing, world-wide, non-exclusive, sub-licensable license under certain BioTime patents and related patent rights and ESI patents and related patent rights specified in the Cross-License, for all purposes in the Asterias Licensed Field, as defined in the Cross-License agreement, during the term of the license.

Under the terms of the Cross-License, BioTime and ESI received a fully-paid, non-royalty-bearing, world-wide, non-exclusive, sub-licensable license in, to, and under the certain Asterias patents and related patent rights for all purposes in the BioTime/ESI Licensed Field, as defined in the Cross-License agreement, during the term of the license.

On February 16, 2016, Asterias also entered into a Share Transfer Agreement (“Share Transfer”) with BioTime and ESI pursuant to which (a) Asterias transferred to BioTime 2,100,000 shares of common stock of OrthoCyte Corporation (“OrthoCyte”) and 21,925 ordinary shares of Cell Cure Neurosciences Ltd (“Cell Cure”), each a majority-owned subsidiary of BioTime, with an aggregate carrying value at the time of the transaction of approximately \$416,000 and (b) BioTime transferred to Asterias 75,771 shares of Series A Common Stock of Asterias with a carrying value at the time of the transaction of approximately \$197,000 and warrants to purchase 3,150,000 Series A common stock of Asterias at an exercise price of \$5.00 per share, with a carrying value at the time of the transaction of approximately \$2.0 million, as additional consideration for the license of patents and patent rights from Asterias under the Cross License. On March 20, 2016, the warrants to purchase 3,150,000 shares of Series A common stock were retired by Asterias.

The Cross-License and Share Transfer transaction was accounted for as transfer of assets between entities under common control and recorded at carrying value, with the resulting gain on transfer of approximately \$1.8 million recorded by Asterias in equity as contributed capital to BioTime in accordance with, and pursuant to ASC 805-50, *Transactions Between Entities Under Common Control*. The transfer of assets was also a taxable transaction to Asterias generating a taxable gain of approximately \$3.1 million as further discussed in Note 11.

## 6. Intangible assets

Intangible assets net of accumulated amortization at September 30, 2016 and December 31, 2015 are shown in the following table (in thousands):

	September 30, 2016 (Unaudited)	December 31, 2015
Intangible assets	\$ 26,860	\$ 26,860
Accumulated amortization	(8,058)	(6,044)
Intangible assets, net	<u>\$ 18,802</u>	<u>\$ 20,816</u>

Asterias recognized \$2.0 million in amortization expense of intangible assets during each of the nine months ended September 30, 2016 and 2015.

## 7. Common Stock and Warrants

As of September 30, 2016 and December 31, 2015, Asterias had outstanding 45,857,448 and 38,228,120 Series A Shares and no Series B Shares, respectively.

### *Common Stock Issuance*

In April and January 2016, pursuant to a services agreement with Cell Therapy Catapult Services Limited, Asterias issued 63,887 and 78,133 shares of Asterias Series A common stock with a fair value of \$319,000 and \$325,000, respectively (see Note 12).

On May 13, 2016, Asterias completed the sale of 5,147,059 shares of its common stock and warrants to purchase 2,959,559 shares of its common stock, through an underwritten public offering (Asterias Offering), for \$3.40 per unit, or net proceeds to Asterias of \$16.0 million after discounts and expenses. In connection with the Asterias Offering on May 23, 2016, Asterias issued an additional 742,421 shares of its common stock upon the full exercise of the over-allotment option by the underwriters for net proceeds of \$2.2 million, after deducting underwriting discounts. Total financing costs were approximately \$1.8 million, of which \$1.2 million were allocated to the Asterias common stock (see *Warrants classified as liability* below).

On April 10, 2015, Asterias entered into an at-the-market issuance sales agreement (the “ATM”) with MLV & Co. LLC (“MLV”), pursuant to which Asterias may sell up to a maximum of \$20.0 million of its common stock from time to time through MLV under Asterias’ previously filed and currently effective shelf registration statement on Form S-3 (File No. 333-200745). During the three months ended September 30, 2016, Asterias raised approximately \$2.1 million in net proceeds under the ATM from the sale of 468,686 shares of its common stock at a weighted average price of \$4.59 per share. As of September 30, 2016, up to approximately \$13.0 million of shares of Asterias common stock are available for issuance and sale pursuant to the terms of the ATM.

#### *Warrants classified as a liability*

On May 13, 2016, included in the Asterias Offering, Asterias issued warrants to purchase 2,959,559 shares of its common stock (“Asterias Offering Warrants”). The Asterias Offering Warrants have an exercise price \$4.37 per share and expire in five years of the issuance date, or May 13, 2021. The Asterias Offering Warrants also contain certain provisions in the event of a Fundamental Transaction, as defined in the warrant agreement governing the Asterias Offering Warrants (“Warrant Agreement”), that Asterias or any successor entity will be required to purchase, at a holder’s option, exercisable at any time concurrently with or within thirty days after the consummation of the fundamental transaction, the Asterias Offering Warrants for cash. This cash settlement will be in an amount equal to the value of the unexercised portion of such holder’s warrants, determined in accordance with the Black Scholes option pricing model as specified in the Warrant Agreement.

In accordance with ASC 815-40, *Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company’s Own Stock*, contracts that require or may require the issuer to settle the contract for cash are liabilities recorded at fair value, irrespective of the likelihood of the transaction occurring that triggers the net cash settlement feature. Changes to the fair value of those liabilities are recorded in the statements of operations. Accordingly, since Asterias may be required to net cash settle the Asterias Offering Warrants in the event of a Fundamental Transaction, the Asterias Offering Warrants are classified as noncurrent liabilities at fair value, with changes in fair value recorded in other income or expense, net, in the statements of operations.

The fair value of the Asterias Offering Warrants at the time of issuance was determined by using a combination of the Binomial Lattice and Black-Scholes option pricing models under various probability-weighted outcomes which take into account consideration the probability of the fundamental transaction and net cash settlement occurring, using the contractual term of the warrants. In applying these models, the fair value is determined by applying Level 3 inputs, as defined by ASC 820, *Fair Value Measurements and Disclosures*; these inputs have included assumptions around the estimated future stock price of Asterias common stock, volatility and the timing of, and varying probabilities, that certain events will occur. The Asterias Offering Warrants are revalued each reporting period using the same methodology described above. Changes in any of the key assumptions used to value the Asterias Offering Warrants could materially impact the fair value of the warrants and Asterias’ financial statements.

On May 13, 2016, the fair value of the Asterias Offering Warrants was approximately \$6.0 million. Because the Asterias Offering Warrants are accounted for as liabilities, the total proceeds from the Asterias Offering were allocated first entirely to the Asterias Offering Warrants’ fair value and the remaining residual proceeds to the Asterias common stock. In addition, of the total \$1.8 million of the Asterias Offering discounts and expenses incurred, \$0.6 million were allocated to the Asterias Offering Warrants, based on the full fair value of the Asterias Offering Warrants and total gross proceeds, and immediately expensed as general and administrative expenses.

At September 30, 2016, based on a revaluation performed by Asterias Offering Warrants using the methodology described above, the fair value of the Asterias Offering Warrants liability was \$8.4 million, resulting in Asterias recording an unrealized loss of \$4.0 million and \$2.4 million for the three and nine months ended September 30, 2016, respectively, included in other income and expenses, net, in the statements of operations.

#### *Warrants classified as equity*

On March 30, 2016, Asterias’ board of directors declared a distribution of Asterias common stock purchase warrants to all Asterias shareholders other than BioTime, in the ratio of one warrant for every five shares of Asterias common stock owned of record as of the close of business on April 11, 2016. On April 25, 2016, Asterias distributed 3,331,229 warrants. The distribution of the warrants was treated as a disproportionate distribution since, in accordance with the terms of the Share Transfer with BioTime (see Note 5), no warrants were distributed to BioTime. The warrants are classified as equity, have an exercise price of \$5.00 per share, and were set to expire on September 30, 2016. Asterias recorded the warrants at a fair value of approximately \$3.1 million with a noncash charge to shareholder expense included in general and administrative expenses and a corresponding increase to equity as of March 30, 2016 as the warrants were deemed to be issued for accounting purposes on that date. On September 19, 2016, Asterias extended the expiration date of these warrants to February 15, 2017, no other terms were changed. As a result of the extension of the expiration date of these warrants, for the quarter ended September 30, 2016, Asterias recorded a \$2.0 million noncash charge to shareholder expense included in general and administrative expenses and a corresponding increase to equity.

In connection with the warrant distribution to shareholders discussed above, 350,000 warrants with an exercise price of \$5.00 per share were adjusted to become exercisable into 409,152 shares at an exercise price of \$4.28 per share. These warrants had an original expiration date of September 30, 2016. On September 19, 2016, Asterias extended the expiration date of these warrants to February 15, 2017, no other terms were changed. As a result of the extension of the expiration date of these warrants, for the quarter ended September 30, 2016, Asterias recorded a \$0.2 million noncash charge to shareholder expense included in general and administrative expenses and a corresponding increase to equity.

## 8. Equity Incentive Plan

### *Stock Options and Restricted Stock Units*

A summary of Asterias' 2013 Equity Incentive Plan activity and related information follows (in thousands, except per share amounts):

	<u>Shares Available for Grant</u>	<u>Number of Options and Restricted Stock Units Outstanding</u>	<u>Weighted Average Exercise/ Grant Price</u>
December 31, 2015	2,067	5,178	\$ 3.17
Additional shares approved on June 9, 2016	3,000	-	-
Options granted	(3,100)	3,100	3.53
Restricted stock and RSUs granted *	(1,030)	515	3.76
Options exercised	-	(788)	2.45
Options forfeited/cancelled	1,347	(1,347)	3.68
RSUs forfeited	3	(1)	3.53
Shares issued – RSUs vested	-	(308)	-
September 30, 2016	<u>2,287</u>	<u>6,349</u>	<u>\$ 3.15</u>

\*Restricted stock and RSUs granted from the 2013 Equity Incentive Plan reduce the shares available for grant by 2 to 1.

### *Stock-Based Compensation Expense*

The fair value of each option award is estimated on the date of grant using a Black-Scholes option valuation model applying the weighted-average assumptions noted in the following table:

	<u>September 30, (Unaudited)</u>	
	<u>2016</u>	<u>2015</u>
Expected life (in years)	5.76	\$ 5.62
Risk-free interest rates	1.38%	1.58%
Volatility	74.99%	78.74%
Dividend yield	0%	0%

The risk-free rate is based on the rates in effect at the time of grant for zero coupon U.S. Treasury notes with maturities approximately equal to each grant's expected life. A dividend yield of zero is applied since Asterias has not historically paid dividends and does not expect to pay dividends in the foreseeable future. The expected volatility is based upon the volatility of Asterias' own trading stock and of a group of publicly traded industry peer companies. The expected term of options granted is derived from using the simplified method under SEC *Staff Accounting Bulletin* Topic 14.

Stock-based compensation expense is recognized based on awards that are ultimately expected to vest, and as a result, the amount has been reduced by estimated forfeitures. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Forfeitures are estimated based on Asterias' historical experience and future expectations.

The determination of stock-based compensation is inherently uncertain and subjective and involves the application of valuation models and assumptions requiring the use of judgment. If Asterias had made different assumptions, its stock-based compensation expense, and net loss for the nine months ended September 30, 2016 and 2015, may have been significantly different.

Asterias does not recognize deferred income taxes for incentive stock option compensation expense, and records a tax deduction only when a disqualifying disposition has occurred.

Operating expenses include stock-based compensation expense as follows (in thousands):

	Three Months Ended September 30, (Unaudited)		Nine Months Ended September 30, (Unaudited)	
	2016	2015	2016	2015
Research and development	\$ 638	\$ 449	\$ 1,994	\$ 1,137
General and administrative	534	168	1,654	981
Total stock-based compensation expense	\$ 1,172	\$ 617	\$ 3,648	\$ 2,118

## 9. Commitments and Contingencies

### *Development and Manufacturing Services Agreement*

On August 3, 2016, Asterias entered into a Development and Manufacturing Services Agreement (the "Services Agreement") with Cognate BioServices, Inc. ("Cognate"), a fully-integrated contract bioservices organization providing development and cGMP manufacturing services to companies and institutions engaged in the development of cell-based products.

Under the Services Agreement, Cognate will perform under an Initial Statement of Work process development studies in support of Asterias' clinical and commercial development activities of AST-VAC1 and production and manufacturing services of AST-VAC1 under cGMP under the Second Statement of Work. In consideration for the process development services set forth in the Initial Statement of Work, Asterias agreed to make aggregate payments of up to approximately \$1.7 million in fees over the term of the Initial Statement of Work and pay for additional pass through costs for materials and equipment estimated by management to be approximately \$0.5 million. In consideration of the production and manufacturing services set forth in the Second Statement of Work, once the services under the Initial Statement of Work are completed and Asterias has received FDA concurrence on the clinical protocol for an AST-VAC1 trial, Asterias will make an initial start-up payment, a monthly payment for dedicated manufacturing capacity, and certain other manufacturing fees.

The Services Agreement will expire on the later of (a) August 3, 2019; or (b) the completion of all services contracted for by the parties in the Statements of Work under the Services Agreement prior to August 3, 2019. The term of the Services Agreement and any then pending Statements of Work thereunder may be extended by Asterias continuously for additional two-year periods upon written notice to Cognate at least thirty days prior to the expiration of the then-current term.

The Services Agreement provides certain termination rights to each party and customary provisions relating to indemnity, confidentiality and other matters. As of September 30, 2016, Asterias had prepaid \$100,000 to Cognate pursuant to the Services Agreement.

### *Fremont Lease*

On December 30, 2013, Asterias entered into a lease for an office and research facility located in Fremont, California, consisting of an existing building with approximately 44,000 square feet of space. The building is being used by Asterias as a combined office, laboratory and production facility that can be used to produce human embryonic stem cells and related products under current good manufacturing procedures. Asterias completed the tenant improvements in November 2015, which cost approximately \$4.9 million, of which the maximum of \$4.4 million was paid to Asterias by the landlord. Asterias placed the asset into service in November 2015 and is amortizing the leasehold improvements and the landlord liability over the remaining lease term through September 30, 2022.

As of September 30, 2016 and December 31, 2015, the landlord liability was \$4.1 million and \$4.4 million and the deferred rent liability was \$251,000 and \$179,000, respectively.

Beginning on January 1, 2016, base rent increased to \$105,000 per month and will increase by approximately 3% annually on every October 1 thereafter.

#### *Litigation – General*

Asterias is subject to various claims and contingencies in the ordinary course of its business, including those related to litigation, business transactions, employee-related matters, and others. When Asterias is aware of a claim or potential claim, it assesses the likelihood of any loss or exposure. If it is probable that a loss will result and the amount of the loss can be reasonably estimated, Asterias will record a liability for the loss. If the loss is not probable or the amount of the loss cannot be reasonably estimated, Asterias discloses the claim if the likelihood of a potential loss is reasonably possible and the amount involved could be material. Asterias is not aware of any claims likely to have a material adverse effect on its financial condition or results of operations.

#### *Employment Contracts*

Asterias has entered into employment contracts with certain executive officers. Under the provisions of the contracts, Asterias may be required to incur severance obligations for matters relating to changes in control, as defined, and involuntary terminations.

#### *Indemnification*

In the normal course of business, Asterias may provide indemnifications of varying scope under Asterias' agreements with other companies or consultants, typically Asterias' clinical research organizations, investigators, clinical sites, suppliers and others. Pursuant to these agreements, Asterias will generally agree to indemnify, hold harmless, and reimburse the indemnified parties for losses and expenses suffered or incurred by the indemnified parties arising from claims of third parties in connection with the use or testing of Asterias' products and services. Indemnification provisions could also cover third party infringement claims with respect to patent rights, copyrights, or other intellectual property pertaining to Asterias products and services. The term of these indemnification agreements will generally continue in effect after the termination or expiration of the particular research, development, services, or license agreement to which they relate. The potential future payments Asterias could be required to make under these indemnification agreements will generally not be subject to any specified maximum amount. Historically, Asterias has not been subject to any claims or demands for indemnification. Asterias also maintains various liability insurance policies that limit Asterias' exposure. As a result, Asterias believes the fair value of these indemnification agreements is minimal. Accordingly, Asterias has not recorded any liabilities for these agreements as of September 30, 2016 and December 31, 2015.

### **10. Shared Facilities and Services Agreement**

On April 1, 2013, Asterias and BioTime executed a Shared Facilities and Services Agreement (“Shared Services Agreement”). Under the terms of the Shared Services Agreement, Asterias has the right to use BioTime's premises and equipment located at Alameda, California, for the sole purpose of conducting Asterias' business. BioTime also provides basic accounting, billing, bookkeeping, payroll, treasury, collection of accounts receivable (excluding the institution of legal proceedings or taking of any other action to collect accounts receivable), payment of accounts payable, and other similar administrative services to Asterias. BioTime may also provide the services of attorneys, accountants, and other professionals who may also provide professional services to BioTime and its other subsidiaries. BioTime also provides Asterias with the services of its laboratory and research personnel, including BioTime employees and contractors, for the performance of research and development work for Asterias at the premise.

BioTime charges Asterias a fee for the services and usage of facilities, equipment, and supplies aforementioned. For each billing period, BioTime equitably prorates and allocates its employee costs, equipment costs, insurance costs, lease costs, professional costs, software costs, supply costs, and utilities costs, between BioTime and Asterias based upon actual documented use and cost by or for Asterias or upon proportionate usage by BioTime and Asterias, as reasonably estimated by BioTime. Asterias pays 105% of the allocated costs (the “Use Fee”). The allocated cost of BioTime employees and contractors who provide services is based upon records maintained of the number of hours of such personnel devoted to the performance of services.

The Use Fee will be determined and invoiced to Asterias on a quarterly basis for each calendar quarter of each calendar year. If the Shared Services Agreement terminates prior to the last day of a billing period, the Use Fee will be determined for the number of days in the billing period elapsed prior to the termination of the Shared Services Agreement. Each invoice will be payable in full by Asterias within 30 days after receipt. Any invoice or portion thereof not paid in full when due will bear interest at the rate of 15% per annum until paid, unless the failure to make a payment is due to any inaction or delay in making a payment by BioTime employees from Asterias funds available for such purpose, rather than from the unavailability of sufficient funds legally available for payment or from an act, omission, or delay by any employee or agent of Asterias.

In addition to the Use Fees, Asterias reimburses BioTime for any out of pocket costs incurred by BioTime for the purchase of office supplies, laboratory supplies, and other goods and materials and services for the account or use of Asterias, provided that invoices documenting such costs are delivered to Asterias with each invoice for the Use Fee. Furthermore, BioTime has no obligation to purchase or acquire any office supplies or other goods and materials or any services for Asterias, and if any such supplies, goods, materials or services are obtained for Asterias, BioTime may arrange for the suppliers thereof to invoice Asterias directly.

Asterias in turn may charge BioTime or any Other Subsidiary for similar services provided by Asterias at the same rate and terms as aforementioned. "Other Subsidiary" means a subsidiary of BioTime other than a subsidiary of Asterias.

The Shared Services Agreement terminates on December 31, 2016, provided that, unless otherwise terminated under another provision of the Shared Services Agreement, the term of the Shared Services Agreement will automatically be renewed and the termination date will be extended for an additional year each year, unless either party gives the other party written notice stating that the Shared Services Agreement will terminate on December 31 of that year.

BioTime allocated \$683,000 and \$731,000, of general overhead expenses to Asterias during the nine months ended September 30, 2016, and 2015, respectively. At September 30, 2016, Asterias had \$463,000 payable to BioTime under the Shared Services Agreement.

## **11. Income Taxes**

The provision for income taxes is determined using an estimated annual effective tax rate. The effective tax rate may be subject to fluctuations during the year as new information is obtained, which may affect the assumptions used to estimate the annual effective tax rate, including factors such as valuation allowances against deferred tax assets, the recognition or de-recognition of tax benefits related to uncertain tax positions, if any, and changes in or the interpretation of tax laws in jurisdictions where Asterias conducts business.

A deferred income tax benefit of approximately \$0.9 million and \$2.2 million was recorded for the three and nine months ended September 30, 2016, respectively. A deferred income tax benefit of approximately \$4.4 million was recorded for the nine months ended September 30, 2015, of which approximately \$4.5 million was related to federal offset by an adjustment of \$100,000 related to a provision for state taxes. Asterias established deferred tax liabilities primarily related to its acquisition of certain intellectual property and available for sale securities held in BioTime and OncoCyte common stock. As of December 31, 2015, these deferred tax liabilities exceeded Asterias' deferred tax assets. Accordingly, management believes that it is more likely than not that the federal deferred tax assets are realizable since the income tax benefits are expected to be available to offset such deferred tax liabilities, and a valuation allowance was not required for the federal deferred tax assets as of December 31, 2015. For the California deferred tax assets, Asterias had a full valuation allowance at December 31, 2015 and expects to have a full valuation allowance for the year ending December 31, 2016.

Management believes that the Asterias net operating losses generated during the nine months ended September 30, 2016, and expected to be generated for the year ending December 31, 2016, will result in no income tax benefits in the current year due to the full valuation allowance expected on those federal deferred tax assets for the year ending December 31, 2016. Accordingly, the income tax benefits recorded during the three and nine months ended September 30, 2016, are principally due to the reversal of the deferred tax liabilities from the beginning of the year.

As discussed in Note 5, in connection with the Cross-License and Share Transfer transaction completed on February 16, 2016, the transfer of assets was a taxable transaction to Asterias generating a taxable gain of approximately \$3.1 million. Asterias has sufficient current year losses from operations to offset the entire gain resulting in no income taxes due. As the transfer of assets and the resulting taxable gain is due to a direct effect of transactions between the former parent company, BioTime, and its former subsidiary, Asterias recorded the tax effect of this gain through equity in accordance with ASC 740-20-45-11(g).

## 12. License and Royalty Obligations

### *Services Agreement with Cell Therapy Catapult Services Limited*

In October 2015, Asterias entered into a Services Agreement (the “Services Agreement”) with Cell Therapy Catapult Services Limited (“Catapult”), a research organization specializing in the development of technologies which speed the growth of the cell and gene therapy industry. Under the Services Agreement, Catapult will license to Asterias, certain background intellectual property and will develop a scalable manufacturing and differentiation process for Asterias’ human embryonic stem cell derived dendritic cell cancer vaccine development program. In consideration for the license and Catapult’s performance of services, at the time of the Services Agreement Asterias agreed to make aggregate payments of up to GBP £4,350,000 over the next five years (approximately \$5.7 million based on the foreign currency exchange rate on September 30, 2016). At the option of Asterias, up to GBP £3,600,000 (approximately \$4.7 million based on the foreign currency exchange rate on September 30, 2016) of such payments may be settled in shares of Asterias Series A Common Stock instead of cash. If Asterias elects to pay for the services in stock and Catapult is unable to sell the stock in the market within 60 days of issuance, after reasonable and diligent efforts through its broker, Catapult may request that the unsold portion of the stock payment, if any, be paid by Asterias in cash at a value equal to approximately 91% of the total amount that was issued in stock. This right by Catapult to put the unsold shares back to Asterias for cash expires the earlier to occur of the sale of the stock in the market or after 60 days of issuance.

Advance payments for research and development services to be performed by Catapult are deferred and recognized as research and development expense ratably as the services are performed. Advance payments related to licenses will be expensed when paid due to the experimental nature of the project. Pursuant to the Services Agreement, if there are any issued, but unsold Asterias stock, to Catapult for payment of services and the 60-day put right has not expired as of the period end being reported on, Asterias will present that amount as “temporary” equity in accordance with ASC 480-10-S99. Once the put right expires or the shares are sold by Catapult, the temporary equity amount will be reclassified by Asterias to permanent equity without adjustment to the carrying value of the stock.

In April 2016, January 2016 and December 2015, pursuant to the Services Agreement, Asterias issued 63,887, 78,133 and 96,479 shares of Asterias Series A Common Stock with a fair market values of \$319,000, \$325,000 and \$486,000 at the time of issuance which Asterias reclassified into permanent equity since all of these shares were sold in the market by Catapult as of September 30, 2016, and December 31, 2015, respectively. For the nine months ended September 30, 2016, in connection with payments under the Services Agreement, Asterias expensed as stock-based compensation for services in lieu of cash of \$644,000.

## 13. Clinical Trial and Option Agreement and CIRM Grant Award

On October 16, 2014 Asterias signed a Notice of Grant Award (“NGA”) with CIRM, effective October 1, 2014, with respect to a \$14.3 million grant award for clinical development of Asterias’ product, AST-OPC1. The NGA was subsequently amended effective November 26, 2014 and March 2, 2016. The NGA includes the terms under which CIRM will release grant funds to Asterias. Under the NGA as amended on March 2, 2016, CIRM will disburse the grant funds to Asterias based on Asterias’ attainment of certain progress milestones.

Asterias received \$6.6 million under the NGA through December 31, 2015. During the nine months ended September 30, 2016, Asterias received an additional \$3.7 million under the NGA grant with approximately \$4.0 million expected upon further clinical milestone achievements. There can be no assurance Asterias will receive this remaining amount or that the milestones will be met. Revenues pursuant to the NGA recognized during the three months ended September 30, 2016 and 2015 were \$1.9 million and \$1.1 million, respectively. The NGA recognized during the nine months ended September 30, 2016 and 2015 were \$4.9 and \$2.4 million, respectively. Although the cash payments from CIRM are dependent on achieving certain milestones pursuant to the contract with CIRM, Asterias recognizes grant income as related research expenses are incurred. Deferred revenues relating to the CIRM grant were \$1.4 million and \$2.5 million at September 30, 2016 and December 31, 2015, respectively.

## Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

*The matters addressed in this Item 2 that are not historical information constitute "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, including statements about any of the following: any projections of earnings, revenue, gross profit, cash, effective tax rate, use of net operating losses, or any other financial items; the plans, strategies and objectives of management for future operations or prospects for achieving such plans, and any statements of assumptions underlying any of the foregoing. Any statements contained herein that are not statements of historical fact may be deemed to be forward-looking statements. Without limiting the foregoing, the words "believes," "anticipates," "plans," "expects," "seeks," "estimates," and similar expressions are intended to identify forward-looking statements. While Asterias may elect to update forward-looking statements in the future, it specifically disclaims any obligation to do so, even if the Asterias' estimates change and readers should not rely on those forward-looking statements as representing Asterias' views as of any date subsequent to the date of the filing of this Quarterly Report. Although we believe that the expectations reflected in these forward-looking statements are reasonable, such statements are inherently subject to risks and Asterias can give no assurances that its expectations will prove to be correct. Actual results could differ materially from those described in this report because of numerous factors, many of which are beyond the control of Asterias. A number of important factors could cause the results of the company to differ materially from those indicated by such forward-looking statements, including those detailed under the heading "Risk Factors" in Part I, Item 1A of Asterias' Form 10-K for the year ended December 31, 2015 and the heading "Risk Factors" in Part II, Item 1A of Asterias' Form 10-Q for the quarter ended March 31, 2016.*

The following discussion should be read in conjunction with Asterias' interim condensed financial statements and the related notes provided under "Item 1 - Financial Statements" above.

### Company Overview

Asterias is a biotechnology company focused on the emerging fields of cell therapy and regenerative medicine. Asterias has two core technology platforms. The first is a type of stem cell capable of becoming all of the cell types in the human body, a property called pluripotency. The second is the use of a cell type called "dendritic cells" to teach cancer patients' immune systems to attack their tumors. Asterias currently has three clinical stage programs based on these platforms: AST-OPC1 is a therapy derived from pluripotent stem cells that is currently in a Phase 1/2a clinical trial for spinal cord injuries; AST-VAC1 is a patient-specific cancer immunotherapy using dendritic cells being evaluated by Asterias in Acute Myeloid Leukemia (AML); and AST-VAC2 is a non-patient specific cancer immunotherapy using dendritic cells for which the initiation of a Phase 1/2a clinical trial in non-small cell lung cancer is planned for the first half of 2017.

In November 2016, Asterias successfully administered the first AIS-A patient with the highest dose of 20 million cells of AST-OPC1 as part of the SCiStar clinical trial. Dosing of this patient triggers an additional \$2.5 million grant payment from the California Institute for Regenerative Medicine under the existing \$14.3 million grant, which Asterias expects to receive in the fourth quarter of 2016.

### Critical Accounting Policies

This Management's Discussion and Analysis of Financial Condition and Results of Operations discusses and analyzes data in our unaudited Condensed Financial Statements, which we have prepared in accordance with U.S. generally accepted accounting principles. Preparation of these financial statements requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue and expenses, and related disclosure of contingent assets and liabilities. Management bases its estimates on historical experience and on various other assumptions that it believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Senior management has discussed the development, selection and disclosure of these estimates with the Audit Committee of our Board of Directors. Actual conditions may differ from our assumptions and actual results may differ from our estimates.

An accounting policy is deemed critical if it requires an accounting estimate to be made based on assumptions about matters that are highly uncertain at the time the estimate is made, if different estimates reasonably could have been used, or if changes in the estimate that are reasonably likely to occur could materially impact the financial statements. Management believes that there have been no significant changes during the nine months ended September 30, 2016 to the items that we disclosed as our critical accounting policies and estimates in Management's Discussion and Analysis of Financial Condition and Results of Operations in our Annual Report on Form 10-K for the year ended December 31, 2015, except as follows.

As fully discussed in Note 7 to the unaudited condensed financial statements, in accordance with ASC 815-40, *Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock*, contracts that require or may require the issuer to settle the contract for cash are liabilities recorded at fair value, irrespective of the likelihood of the transaction occurring that triggers the net cash settlement feature. Changes to the fair value of those liabilities are recorded in the statements of operations. Accordingly, since Asterias may be required to net cash settle the Asterias Offering Warrants in the event of a Fundamental Transaction, the Asterias Offering Warrants are classified as noncurrent liabilities at fair value, with changes in fair value recorded in other income or expense, net.

The fair value of the Asterias Offering Warrants is determined by using a combination of the Binomial Lattice and Black-Scholes option pricing models under various probability-weighted outcomes which take into consideration the probability of the fundamental transaction and the net cash settlement occurring, using the contractual term of the warrants. In applying these models, the fair value is determined by applying Level 3 inputs, as defined by ASC 820, *Fair Value Measurements and Disclosures*; these inputs have included assumptions around the estimated future stock price of Asterias common stock, volatility and the timing of, and varying probabilities, that certain events will occur. The Asterias Offering Warrants are revalued each reporting period using the same methodology described above. Changes in any of the key assumptions used to value the Asterias Offering Warrants could materially impact the fair value of the warrants and Asterias' financial statements.

## Results of Operations

### Comparison of three and nine months ended September 30, 2016 and 2015

For the three months ended September 30, 2016 and 2015 we recorded net loss of \$10.6 million and \$3.5 million, respectively. For the nine months ended September 30, 2016 and 2015 we recorded net losses of \$26.1 million and \$10.1 million, respectively.

### Revenues

The following table shows certain information about our revenues for the three and nine months ended September 30, 2016 and 2015 (in thousands, except for percentages):

	Three Months Ended September 30,		\$ Increase (Decrease)	% Increase (Decrease)
	2016	2015		
Royalties from product sales	\$ 218	\$ 353	\$ -135	-38%
Grant income	1,858	1,070	+788	+74%
Total revenues	2,076	1,423	+653	+46%
Cost of sales	(59)	(176)	+117	-66%
Total gross profit	\$ 2,017	\$ 1,247	\$ +770	+62%

  

	Nine Months Ended September 30,		\$ Increase (Decrease)	% Increase (Decrease)
	2016	2015		
Royalties from product sales	\$ 337	\$ 528	\$ -191	-36%
Sale of cell lines	-	40	-40	-100%
Grant income	4,865	2,406	+2,459	+102%
Total revenues	5,202	2,974	+2,228	+75%
Cost of sales	(118)	(265)	+147	-55%
Total gross profit	\$ 5,084	\$ 2,709	\$ +2,375	+88%

Our royalty revenues from product sales is entirely from non-exclusive license agreements with Stem Cell Technologies, Inc., Coming Life Science, Life Tech, and Millipore which we assumed as part of consideration received from Geron under the 2013 Asset Contribution Agreement.

Grant income in 2016 is entirely from CIRM which awarded us a \$14.3 million grant for clinical development of AST-OPC1. We received our first payment from CIRM in the amount of \$917,000 during October 2014 and had received \$6.6 million through December 31, 2015. For the nine months ended September 30, 2016, we received \$3.7 million under the CIRM grant with approximately \$4.0 million expected upon further clinical milestone achievements. Revenues recognized under the CIRM grant during the nine months ended September 30, 2016 and 2015 were \$4.9 and \$2.4 million, respectively.

## Operating Expenses

The following table shows our operating expenses for the three and nine months ended September 30, 2016 and 2015 (in thousands, except for percentages):

	Three Months Ended September 30,		\$ Increase	% Increase
	2016	2015		
Research and development expenses	\$ 5,232	\$ 4,629	\$ + 603	+13%
General and administrative expenses	4,210	1,554	+ 2,656	+ 171%

  

	Nine Months Ended September 30,		\$ Increase	% Increase
	2016	2015		
Research and development expenses	\$ 17,594	\$ 11,918	\$ + 5,676	+ 48%
General and administrative expenses	13,081	5,071	+8,010	+ 158%

*Research and development expenses* – Research and development expenses increased by approximately \$0.6 million to \$5.2 million for the three months ended September 30, 2016 compared to \$4.6 million for the three months ended September 30, 2015. The increases in research and development expenses during 2016 are attributable to the following: an increase in salaries/stock based compensation of \$710,000 due to an increase in headcount related to hiring personnel to support our AST-OPC1 program, an increase in AST-OPC1 clinical recruitment costs of \$223,000, an increase in scientific consulting services of \$158,000, and an increase in depreciation expense of \$134,000. These increases were offset by a decrease in Catapult fees of \$478,000 and a decrease in deferred rent of \$159,000.

Research and development expenses increased by approximately \$5.7 million to \$17.6 million for the nine months ended September 30, 2016 compared to \$11.9 million for the nine months ended September 30, 2015. The increases in research and development expenses during the nine month period ended September 30, 2016 compared to the same period in 2015 are attributed to the following: an increase of \$2.6 million in salaries/stock based compensation expense due to an increase in headcount related to hiring personnel to support our AST-OPC1 program, an increase of \$668,000 in Catapult fees, an increase of \$640,000 in outside services, an increase of \$568,000 in clinical laboratory testing, an increase of \$525,000 in scientific consulting services, along with \$450,000 in laboratory supplies for our laboratory and production facility in Fremont, as well as an increase of \$394,000 in depreciation expense, and an increase of \$138,000 in building maintenance and repair.

*General and administrative expenses* – General and administrative expenses increased by approximately \$2.7 million to \$4.2 million for the three months ended September 30, 2016 compared to \$1.6 million for the same period in 2015. The increase in general and administrative expense is primarily attributable to the following: \$2.2 million in shareholder warrant distribution expense related to the extension of the warrants distributed in April 2016 and an increase of \$1 million in salaries/stock based compensation related expenses. These increases were offset partially by a decrease of \$0.6 million in general and administrative expenses, related consulting services, and project fees.

General and administrative expenses increased by approximately \$8 million to \$13.1 million for the nine months ended September 30, 2016 compared to \$5.1 million for the nine months ended September 30, 2015. The increase in general and administrative expenses is due to the following: an increase of \$5.3 million in shareholder warrant distribution expense, an increase of \$2.5 million in salaries/stock based compensation related expenses, and an increase of \$109,000 in accounting, audit, and tax services. These increases are offset by a decrease in general and administrative expenses, related consulting services, and tax related benefits.

### *Other income/(expenses), net*

*Other income/(expense), net* – Other expenses, net, in 2016 and 2015 consists primarily of the change in fair value for the warrants classified as liabilities and interest expense related to the amortization of the landlord liability.

## Income Taxes

A deferred income tax benefit of approximately \$0.9 million and \$2.2 million was recorded for the three and nine months ended September 30, 2016, respectively. A deferred income tax benefit of approximately \$4.4 million was recorded for the nine months ended September 30, 2015, of which approximately \$4.5 million was related to federal offset by an adjustment of \$100,000 related to a provision for state taxes. Asterias established deferred tax liabilities primarily related to its acquisition of certain intellectual property and available for sale securities held in BioTime and OncoCyte common stock. As of December 31, 2015, these deferred tax liabilities exceeded Asterias' deferred tax assets. Accordingly, management believes that it is more likely than not that the federal deferred tax assets are realizable since the income tax benefits are expected to be available to offset such deferred tax liabilities, and a valuation allowance was not required for the federal deferred tax assets as of December 31, 2015. For the California deferred tax assets, Asterias had a full valuation allowance at December 31, 2015 and expects to have a full valuation allowance for the year ending December 31, 2016.

Management believes that the Asterias net operating losses generated during the nine months ended September 30, 2016, and expected to be generated for the year ending December 31, 2016, will result in no income tax benefits in the current year due to the full valuation allowance expected on those federal deferred tax assets for the year ending December 31, 2016. Accordingly, the income tax benefits recorded during the three and nine months ended September 30, 2016, are principally due to the reversal of the deferred tax liabilities from the beginning of the year.

## Liquidity and Capital Resources

At September 30, 2016, we had \$17.9 million of cash and cash equivalents on hand, held 3,852,880 BioTime common shares and 192,644 shares of OncoCyte common stock, with a market value of \$15.0 million and \$1.0 million, respectively. We may raise capital from time to time through the sale of our Series A Shares or other securities, and our BioTime or OncoCyte common shares. We may sell our Series A Shares or other securities in public offerings registered under the Securities Act of 1933, as amended (the "Securities Act"), including in at-the-market transactions, or in private placements to select investors. We may sell our BioTime common shares, from time to time, by any method that is deemed to be an "at-the-market" equity offering as defined in Rule 415 promulgated under the Securities Act, including sales made directly on or through the NYSE MKT or any other existing trading market for the common shares in the U.S. or to or through a market maker, at prices related to the prevailing market price, or through block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction, or through one more of the foregoing transactions. We may also sell some or all of our BioTime common shares and OncoCyte common shares by any other method permitted by law, including in privately negotiated transactions. We will bear all broker-dealer commissions payable in connection with the sale of our Series A Shares, our BioTime common shares, OncoCyte common shares or other securities. Broker-dealers may receive commissions or discounts from us (or, if any broker-dealer acts as agent for the purchaser of shares, from the purchaser) in amounts to be negotiated. The prices at which we may issue and sell our Series A Shares, our BioTime common shares, OncoCyte common shares or other securities in the future are not presently determinable and will depend upon many factors, including prevailing prices for those securities in the public market.

On May 13, 2016, we completed the initial closing of an underwritten public offering and issued 5,147,059 shares of common stock, and warrants to purchase an aggregate of 2,573,530 shares of common stock at an exercise price of \$4.37 per share. The common stock and the warrants were sold for \$3.40 per unit. The underwriters also exercised their over-allotment option to purchase additional warrants to purchase 386,029 shares of common stock, and we issued such warrants on the same day. The net proceeds to us were approximately \$16.0 million after deducting underwriting discounts, commissions and offering expenses.

On May 23, 2016, Asterias issued an additional 742,421 shares of its common stock upon the full exercise of the over-allotment option by the underwriters for net proceeds of \$2.2 million, after deducting underwriting discounts, for aggregate net proceeds of \$18.2 million from the Asterias Offering.

On April 10, 2015, Asterias entered into an at-the-market issuance sales agreement (the "ATM") with MLV & Co. LLC ("MLV"), such that Asterias may sell up to a maximum of \$20.0 million of its common stock from time to time through MLV under Asterias' previously filed and currently effective shelf registration statement on Form S-3 (File No. 333-200745). During the three months ended September 30, 2016, Asterias raised approximately \$2.1 million in net proceeds under the ATM from the sale of 468,686 shares of its common stock at a weighted average price of \$4.59 per share. As of September 30, 2016, up to approximately \$13.0 million of shares of Asterias common stock are available for issuance and sale pursuant to the terms of the ATM.

We plan to use the proceeds and other cash we have available for general corporate purposes, including to fund our ongoing clinical programs, to develop certain of our product candidates and technology, to acquire new stem cell products and technology through licenses or similar agreements from other companies, and to defray overhead expenses and to pay general and administrative expenses. We expect to continue to incur operating losses and negative cash flows.

We have been awarded a \$14.3 million Strategic Partnership III grant by CIRM to help fund our clinical development of AST-OPC1. The grant provides funding for us to reinitiate clinical development of AST-OPC1 in subjects with spinal cord injury, to expand clinical testing of escalating doses in the target population intended for future pivotal trials, and for product development efforts to refine and scale manufacturing methods to support eventual commercialization. Under our amended agreement, effective March 2, 2016, CIRM will disburse the remaining grant funds to us in accordance with our attainment of certain progress milestones.

We received our first payment from CIRM in the amount of \$917,000 during October 2014 and we had received \$6.6 million through December 31, 2015. For the nine months ended September 30, 2016, we received an additional \$3.7 million from the CIRM grant and expect to receive the remaining \$4.0 million upon further clinical milestone achievements. As the remaining distributions of the CIRM grant are subject to meeting certain milestones, there can be no assurance that we will receive the entire amount granted.

Pursuant to the Cancer Research United Kingdom (“CRUK”) Agreement, CRUK has agreed to fund Phase 1/2 clinical development of our AST-VAC2 product candidate. We have completed process development and manufacturing scale-up of the AST-VAC2 manufacturing process and transferred the resulting cGMP-compatible process to CRUK. CRUK will, at its own cost, manufacture clinical grade AST-VAC2 and will carry out the Phase 1/2 clinical trial of AST-VAC2 in cancer patients both resected early-stage and advanced forms of lung cancer.

Since inception, we have incurred net losses and have funded our operations primarily through the support from BioTime, issuance of equity securities, payments from research grants, and royalties from product sales. At September 30, 2016, we had an accumulated deficit of \$74.4 million, working capital of \$27 million and stockholders’ equity of \$42.7 million. We have evaluated our projected cash flows and believe that our cash and cash equivalents of \$17.9 million as of September 30, 2016 and our available for sale securities of \$16.0 million as of September 30, 2016 will be sufficient to fund our operations through the third quarter of 2017. Some of the clinical trials being conducted by Asterias will continue to be funded in part with funds from the \$14.3 million grant awarded in 2014 by CIRM, (\$4 million of which are still subject to meeting certain milestones as of September 30, 2016), and not from cash on hand and the value of our available for sale securities is subject to market risk. If Asterias were to lose its grant funding, the value of its available for sale securities decreases, or it is unable to obtain future adequate financing for its clinical trials, it may be required to delay, postpone, or cancel its clinical trials or limit the number of clinical trial sites, or otherwise reduce or curtail its operations. Future financings, if necessary, may not be available to Asterias at acceptable terms, or if at all. Sales of additional equity securities would result in the dilution of interests of current shareholders.

## **Cash Flows**

### *Cash used in operations*

Since our inception, we have incurred losses from operations and negative cash flows from our operations. During the nine months ended September 30, 2016, our total research and development expenditures were \$17.6 million and our general and administrative expenses were \$13.1 million. Net loss for the nine months ended September 30, 2016 amounted to \$26.1 million. Our sources of cash during 2016 primarily consisted of \$5.2 million from grant income and royalty and license fees. As of September 30, 2016 and December 2015, we had a working capital surplus of \$27 million and \$19.5 million, respectively.

Net cash used in operating activities during the nine months ended September 30, 2016 amounted to \$15.1 million. The difference between the net loss and net cash used in operating activities during the period was primarily attributable to the following noncash items: Asterias warrants noncash expense to its shareholders in the amount of \$5.3 million, stock-based compensation of \$3.6 million, \$2.4 million in unrealized loss on the Asterias Offering Warrants classified as a liability, \$2.0 million in amortization of intangible assets, \$643,000 of stock issued in lieu of cash to a contract vendor and \$909,000 in depreciation expense. The noncash increases were offset by \$2.3 million in federal deferred income tax benefit. Changes in working capital contributed by \$1.6 million as a use of cash.

### *Investing and financing activities*

During the nine months ended September 30, 2016, we paid \$643,000 for property, plant and equipment including tenant improvements and other fixed assets.

In May 2016, we completed an underwritten public offering and issued 5,147,059 shares of common stock, and warrants to purchase an aggregate of 2,573,530 shares of common stock at an exercise price of \$4.37 per share; we issued an additional 742,421 shares of common stock upon the full exercise of the over-allotment option by the underwriters for aggregate net proceeds of \$18.2 million from the Asterias Offering.

During the third quarter, Asterias raised approximately \$2.1 million in net proceeds under its ATM from the sale of 468,686 shares of its common stock at a weighted average price of \$4.59 per share.

During the nine months ended September 30, 2016, we received \$567,000 from our landlord on reimbursable construction in progress financed by the landlord. In addition, we received \$2.0 million from the exercise of stock options, offset by payments made for the landlord liability and capital lease obligations of \$0.3 million.

#### **Contractual Obligations**

As of September 30, 2016, there were no material changes to the contractual obligations information in Item 7 in our Annual Report on Form 10-K filed with the SEC on March 29, 2016.

#### **Off-Balance Sheet Arrangements**

As of September 30, 2016 and December 31, 2015, we did not have any off-balance sheet arrangements, as defined in Item 303(a)(4)(ii) of SEC Regulation S-K.

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

There have been no material changes in Asterias' qualitative and quantitative market risk since the disclosure in Asterias' Annual Report on Form 10-K for the year ended December 31, 2015, except as follows.

##### *Available for sale securities at fair value*

We hold 3,852,880 BioTime common shares and 192,644 shares of OncoCyte common stock at fair value, therefore our available for sale investment values are subject to changes in the stock price of BioTime and OncoCyte. BioTime common stock trades on the NYSE MKT under the ticker "BTX" and OncoCyte common stock trades on the NYSE MKT under the ticker "OCX". As of September 30, 2016, the 52 week high/low stock price per share range for BioTime and OncoCyte shares were \$2.02 - \$4.51 and \$2.45 - \$10.24, respectively.

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

##### *Evaluation of Disclosure Controls and Procedures*

Our management, including our principal executive officer and principal financial officer, have reviewed and evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this report. Following this review and evaluation, the principal executive officer and principal financial officer determined that our disclosure controls and procedures are effective to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act (i) is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms, and (ii) is accumulated and communicated to management, including our principal executive officer, and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

##### *Changes in Internal Controls*

There were no changes in our internal control over financial reporting that occurred during the period covered by this Quarterly Report on Form 10-Q that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## PART II - OTHER INFORMATION

### Item 1. Legal Proceedings.

From time to time, we may be involved in routine litigation incidental to the conduct of our business. We are not presently involved in any other material litigation or proceedings, and to our knowledge no such litigation or proceedings are contemplated.

### Item 1A. Risk Factors

*Our operations and financial results are subject to various risks and uncertainties, including those described in Part I, Item 1A, "Risk Factors" in our Form 10-K for the year ended December 31, 2015 and under the heading "Risk Factors" in Part II, Item 1A of our Form 10-Q for the quarter ended March 31, 2016, which could adversely affect our business, financial condition, results of operations, cash flows, and the trading price of our securities. There have been no material changes to our risk factors since our Annual Report on Form 10-K for the year ended December 31, 2015, as updated by the Form 10-Q for the quarter ended March 31, 2016.*

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

None.

### Item 3. Default Upon Senior Securities

None.

### Item 4. Mine Safety Disclosures

Not applicable.

### Item 5. Other Information

None.

### Item 6 Exhibits

Exhibit Numbers	Description
<a href="#">10.1</a>	*+ Development and Manufacturing Services Agreement, dated August 3, 2016, between Asterias and Cognate BioServices, Inc.
<a href="#">31.1</a>	* Certification of Chief Executive Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
<a href="#">31.2</a>	* Certification of Chief Financial Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
<a href="#">32.1</a>	** Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101	* XBRL Instance Document
101.INS	* XBRL Taxonomy Extension Schema
101.CAL	* XBRL Taxonomy Extension Calculation Linkbase
101.DEF	* XBRL Taxonomy Extension Definition Linkbase
101.LAB	* XBRL Taxonomy Extension Label Linkbase
101.PRE	* XBRL Taxonomy Extension Presentation Linkbase

\* Filed herewith.

\*\* Furnished herewith.

+ Portions of this exhibit have been omitted pursuant to a request for confidential treatment and have been separately filed with the Securities and Exchange Commission.

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ASTERIAS BIOTHERAPEUTICS, INC.

Date: November 14, 2016

/s/ Stephen L. Cartt

Stephen L. Cartt  
President and Chief Executive Officer

Date: November 14, 2016

/s/ Russell L. Skibsted

Russell L. Skibsted  
Chief Financial Officer

Confidential Materials Omitted and Filed Separately with the Securities and Exchange Commission Pursuant to a Request for Confidential Treatment under Rule 24b-2 under the Exchange Act of 1934, as amended. Confidential Portions are marked: [\*\*\*]

FINAL – EXECUTION COPY

**DEVELOPMENT AND MANUFACTURING SERVICES AGREEMENT**

THIS DEVELOPMENT AND MANUFACTURING SERVICES AGREEMENT is made as of August 3, 2016 (the “Effective Date”) by and between **ASTERIAS BIOTHERAPEUTICS, INC.**, a Delaware corporation with an office at 6300 Dumbarton Circle, Fremont, CA 94555 (“Asterias”) and **COGNATE BIOSERVICES, INC.**, a Delaware corporation, with an office at 7513 Connelly Drive, Suite I, Hanover, MD 21076 (“Cognate”).

**RECITALS:**

WHEREAS, Asterias desires to engage Cognate to perform certain Development and Manufacturing Services (as those terms are defined below), on the terms and conditions set forth below, and Cognate desires to perform such Services for Asterias.

**AGREEMENT:**

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants of the parties set forth in this Agreement, the parties hereto agree to the recitals, terms and conditions set forth herein.

1. **Definitions.** Unless this Agreement expressly provides to the contrary, the following terms, whether used in the singular or plural, have the respective meanings set forth below.

1.1 “Affiliate” means, with respect to either Asterias or Cognate, any corporation, company, partnership, joint venture and/or firm which controls, is controlled by or is under common control with Asterias or Cognate, as the case may be. As used in the definition of Affiliate, “control” means (a) in the case of corporate entities, direct or indirect ownership of more than fifty percent (50%) of the stock or shares having the right to vote for the election of directors (or such lesser percentage that is the maximum allowed to be owned by a foreign corporation in a particular jurisdiction), and (b) in the case of non-corporate entities, the direct or indirect power to manage, direct or cause the direction of the management and policies of the non-corporate entity or the power to elect more than fifty percent (50%) of the members of the governing body of such non-corporate entity; provided, however, that, as applied to Asterias, the terms of clause (b) will apply equally to corporate as well as non-corporate entities.

1.2 “Aggregate Development Cost” has the meaning set forth in Section 6.9.

1.3 “Agreement” means this Development and Manufacturing Services Agreement, together with all Appendices attached hereto, as amended from time to time by the parties in accordance with Section 15.6, and all fully signed SOWs and Change Orders entered into by the parties during the term of this Agreement, whether or not references to the “Agreement” are followed by the words Appendix, SOW or Change Order.

1.4 “Applicable Law” means all applicable ordinances, rules, regulations, laws, requirements and court orders of any kind whatsoever of any competent Authority or other competent governmental entity, as amended from time to time including cGMP (if applicable) and in effect during the term of this Agreement.

1.5 “Application” has the meaning set forth in Section 15.13.

1.6 “Asterias Approvals” has the meaning set forth in Section 5.4(a).

1.7 “Asterias Equipment” has the meaning set forth in Section 4.3.

1.8 “Asterias Indemnities” has the meaning set forth in Section 12.2.

1.9 “Asterias [\*\*\*]” has the meaning set forth in Section 9.5(b).

1.10 “Asterias Materials” means the AML leukapheresis packs and all other materials identified in the applicable SOW as being provided by Asterias, including labels (if any) for Product.

1.11 “Asterias Technology” means (a) Product and any intermediates, components, or derivatives of Product; (b) Specifications; (c) the Manufacturing Process and any methods, processes, protocols and procedures for Manufacturing of Product or obtaining and processing patient samples for use in Manufacturing Product that are in each case provided to or identified by Asterias to Cognate and owned or controlled by Asterias; and (d) Asterias’s Background Intellectual Property.

1.12 “Authority” means, with respect to Cognate, any competent government regulatory authority responsible for granting approvals for the performance of Services and with respect to Asterias, any competent regulatory authority responsible for granting approvals for the deliverables, results or products resulting from the Services) under this Agreement or, with respect to both parties, for issuing regulations pertaining to the Manufacture and/or use of Product in the intended country of manufacture, use or sale, including the United States Food and Drug Administration, and any successor agency having substantially the same functions (“FDA”).

1.13 “Background Intellectual Property” means any Intellectual Property either (i) owned or controlled by a party prior to the Effective Date or (ii) developed or acquired by a party independently from the performance of this Agreement, and which, in each case, does not rely upon, use or incorporate all or any part of the Confidential Information of the other party.

1.14 “Batch” means a specific quantity of Product that is produced during the same cycle of Manufacture as referenced by the applicable Batch Documentation.

1.15 “Batch Documentation” has the meaning set forth in Section 6.2.

1.16 [\*\*\*].

1.17 “Certificate of Analysis” means a document signed by an authorized representative of Cognate, describing Specifications for and testing methods applied to a Product, and the results of testing, and such other information (and meeting such other standards) as required for compliance with Applicable Law governing the content and quality of such documents.

1.18 “cGMP” means current good manufacturing practices and regulations applicable to the Manufacture of Product that are promulgated by FDA (or, as applicable, (i) other Authorities or (ii) the International Conference on Harmonization).

- 1.19 “Change Order” has the meaning set forth in Section 5.2(a).
- 1.20 “Claim” means any claim, action, suit, proceeding or investigation.
- 1.21 “Cognate Indemnitees” has the meaning set forth in Section 12.1.
- 1.22 “Cognate [\*\*\*].
- 1.23 “Cognate Manufacturing Improvements” has the meaning set forth in Section 9.5(a).
- 1.24 “Cognate [\*\*\*].
- 1.25 “Cognate [\*\*\*].
- 1.26 “Cognate Technology” means (i) Cognate’s Background Intellectual Property, (ii) Service Instruments, (iii) all Technology developed by Cognate hereunder[\*\*\*] (iv) all Technology owned or controlled by Cognate that is general-purpose in nature or applicable to performance of services for any of Cognate’s other customers [\*\*\*] (v) all Cognate Manufacturing Improvements, (vi) Specialized Product [\*\*\*] and (vii) all Improvements developed by Cognate [\*\*\*] to any of the Technology set forth in the foregoing clauses (i), (ii), (iii), (iv), and /or (vi).
- 1.27 “Confidential Information” has the meaning set forth in Section 10.1.
- 1.28 “Damages Waiver” has the meaning set forth in Section 12.5.
- 1.29 “Develop” or “Development” means the studies and other activities conducted by Cognate under this Agreement to develop and/or optimize all or any part of a Manufacturing Process including analytical tests and methods, formulations and dosage forms and stability, if applicable.
- 1.30 “Discloser” has the meaning set forth in Section 10.1.
- 1.31 “Effective Date” has the meaning set forth in the preamble.
- 1.32 “Equipment” means any equipment or machinery, including Asterias Equipment, used by Cognate in the Development and/or Manufacturing of Product, including without limitation the holding, processing, testing or release of Product.
- 1.33 “Facility” or “Cognate’s Facility” means the facilit(ies) of Cognate identified in the applicable SOW.
- 1.34 “FDCA” means the United States Federal Food, Drug and Cosmetic Act, 21 U.S.C. §321 et seq., as amended from time to time.
- 1.35 [\*\*\*].
- 1.36 “*force majeure*” has the meaning set forth in Section 15.2.

1.37 “Improvements” means all discoveries, inventions, developments, innovations, writings or rights (whether or not patented or protectable under patent, trademark, copyright or similar laws), in all such cases which constitute a modification, update, enhancement or improvement to a given Technology, that are conceived, discovered, invented, developed, created, made or reduced to practice, in whole or in part, in the performance of Services under this Agreement, and all associated Intellectual Property rights therein or thereto.

1.38 “Indemnitees” has the meaning set forth in Section 12.2.

1.39 “Initial SOW” means the first SOW for certain Development Services among other Services agreed to and executed by the parties on the Effective Date, and as attached hereto as Appendix A (as the same may be amended by the parties pursuant to a Change Order or other written agreement).

1.40 “Intellectual Property” means (i) inventions (whether or not patentable), patents, ideas, discoveries, trade secrets, copyrights, trademarks, trade names and domain names, rights in compositions of matter, rights in processes, rights in formulations, rights in articles of manufacture, rights in designs, rights in computer software, database rights, rights in confidential information (including know-how) and any other intellectual property rights, in each case whether registered or unregistered, (ii) all applications (or rights to apply) for, and renewals or extensions of, any of the rights described in the foregoing clause (i), and (iii) all rights and applications that are similar or equivalent to the rights and application described in the foregoing clauses (i) and (ii), which exist now, or which come to exist in the future, in any part of the world.

1.41 “Losses” has the meaning set forth in Section 12.1.

1.42 “Man-In-Plant” has the meaning set forth in Section 6.3.

1.43 “Manufacture” and “Manufacturing” means the conduct or performance of producing, manufacturing, processing, formulation, fill, finish, packaging, labeling, quality control testing, stability testing, release, storage, and/or supply of Product.

1.44 “Manufacturing Improvements” has the meaning set forth in Section 9.5(b).

1.45 “Manufacturing Process” means any steps, processes and activities actually performed by Cognate in producing Product including the manufacturing, processing, formulation, fill, finish, packaging, labeling, quality control testing, stability testing, release, or storage, of Product, as described in the applicable documents, protocols, SOPs, records and files.

1.46 “Permitted Agent” has the meaning as set forth in Section 10.3.

1.47 “Person” means any individual, partnership, corporation, trust, limited liability entity, unincorporated organization, association, governmental authority or any other entity.

1.48 “Product” means any drug product specified in the applicable SOW, including, if applicable, bulk packaging and/or labeling as provided in such SOW, in each case which is to be Developed or Manufactured by Cognate for Asterias pursuant to this Agreement.

1.49 “Product Invention” means any Technology specific [\*\*\*] the Product [\*\*\*] proprietary to Asterias, but excluding potential uses or applications that are general-purpose in nature or applicable to dendritic cell products generally[\*\*\*] except, in all cases, if general-purpose in nature or applicable to dendritic cell products generally[\*\*\*] in such combinations and amounts as are specific to the Product, [\*\*\*] specific to the Product [\*\*\*].

1.50 “Quality Agreement” has the meaning set forth in Section 2.2.

1.51 “QC” means quality control.

1.52 “Recipient” has the meaning set forth in Section 10.1.

1.53 “Records” has the meaning set forth in Section 5.3(a).

1.54 “Release” has the meaning set forth in Section 7.

1.55 “Representative” has the meaning set forth in Section 3.1.

1.56 “Service Instruments” has the meaning set forth in Section 9.7.

1.57 “Services” means the Development, Manufacturing and/or other services described in an SOW entered into by the parties.

1.58 “SOW” or “Statement of Work” means a written statement of work referencing this Agreement, substantially in the form attached hereto as Appendix B, for the performance of Services by Cognate under this Agreement (as the same may be amended by the parties pursuant to a Change Order or other written agreement).

1.59 “SOW 2” means the second SOW for Manufacturing Services agreed to and executed by the parties on the Effective Date, and as attached hereto as Appendix C, as the same may be amended by the written agreement of the parties, pursuant to a Change Order or otherwise.

1.60 “Specialized Product [\*\*\*]” means any Technology [\*\*\*] Manufacture of the Product [\*\*\*] the manufacture (and/or processing, formulation, fill, finish, packaging, labeling, quality control testing, stability testing, release, storage and/or supply) of a [\*\*\*] documents regarding the foregoing such as [\*\*\*] in all such cases to the extent [\*\*\*]. By way of example, Specialized Product [\*\*\*].

1.61 “Specifications” means the list of tests, references to any analytical procedures and appropriate acceptance criteria to which raw materials, process intermediates or final Product conforms, as such specifications are amended or supplemented from time to time by mutual agreement of the parties in writing.

1.62 “Submission” has the meaning set forth in Section 5.4(a).

1.63 “Technology” means all methods, techniques, trade secrets, inventions, processes, protocols, copyrights, know-how, data, documentation, regulatory submissions, specifications and other Intellectual Property of any kind (whether or not protectable under patent, trademark, copyright or similar laws).

1.64 “Termination Effective Date” means the date upon which termination by a party of either this Agreement, or in the event of termination of the applicable SOW, such SOW, is effective.

1.65 “Use of Confidential Information” has the meaning set forth in Section 10.4.

## 2. Engagement of Cognate.

2.1 Services and SOWs. Cognate will provide to Asterias those Services as are set forth in an SOW. Cognate will perform the Services set forth in each such fully signed SOW in a competent, diligent and professional manner in accordance with industry standards, cGMP (if applicable) and other Applicable Laws. Each SOW will be appended to this Agreement, will contain the material terms for the applicable project, and may include the scope of work, specified Services, Specifications, deliverables, timelines, milestones, quantity, budget, payment schedule and such other details and special arrangements as are agreed to by the parties with respect to the activities to be performed under such SOW. No SOW will be effective unless and until it has been agreed to and signed by authorized representatives of both parties. Each fully signed SOW will be subject to the terms of this Agreement and will be incorporated herein and form part of this Agreement. Cognate will perform the Services specified in each fully signed SOW (as the same may be amended by agreement of the parties), and in accordance with the terms and conditions of such SOW and this Agreement.

2.2 Quality Agreement. The parties will also agree upon a Quality Agreement containing, among other provisions, quality assurance provisions for the Manufacture of Product, the respective roles of Asterias and Cognate in these processes, the standards and procedures for the handling of any deviations from the usual quality standards or product release requirements, the allocation of responsibilities for reporting of these matters, and related subjects, all in accordance with, and including such other provisions required to comply with, cGMP and other Applicable Laws (“Quality Agreement”).

2.3 Conflict Between Documents. If there is any conflict, discrepancy, or inconsistency between the terms of this Agreement and any SOW, Quality Agreement, purchase order, or other document or form used by the parties, the terms of this Agreement will control and take precedence, except, in the case of the Quality Agreement, with respect to matters specifically directed to Product quality, cGMP and regulatory compliance with respect to the Manufacture of Products (for which the Quality Agreement shall control and take precedence) and in the case of the applicable SOW with respect to the fees, costs and expenses for individual Services (for which the applicable SOW shall control and take precedence).

2.4 **Non-Exclusive Agreement.** For clarity (and without limiting the confidentiality provisions herein), this Agreement does not limit Cognate's right to manufacture, sell, provide or agree to provide any services to any other Person, nor does this Agreement limit Asterias's right to obtain services (including without limitation the manufacture or supply of Product) from any other Person.

3. **Project Performance.**

3.1 **Representatives.** Each party will appoint a representative having primary responsibility for day-to-day interactions with the other party for the Services (each, a "**Representative**"), who will be identified in the applicable SOW. Each party may change its Representative by providing written notice to the other party in accordance with Section 15.3; provided that each party will use reasonable efforts to provide the other party with [\*\*\*] prior written notice of any change in its Representative for the Services. Except for notices or communications required or permitted under this Agreement, which will be subject to Section 15.3, or unless otherwise mutually agreed by the

parties in writing, all communications between Cognate and Asterias regarding the conduct of the Services pursuant to such SOW will be addressed to or routed directly through the parties' respective Representatives.

3.2 **Communications.** The parties will hold project team meetings via teleconference or in person, on a periodic basis as agreed upon by the Representatives.

3.3 **Third Party Providers.** Asterias will execute agreements with certain third party providers in connection with the performance of assays and other services in connection with the Services rendered by Cognate as may be set forth in an SOW as Asterias' responsibility (if any), including testing entities, suppliers, distributors, consultants or agents. Asterias will be responsible for the performance by such third party providers and all costs and expenses in respect of such performance. For clarity, Cognate will not be responsible for the performance of any such third party retained by Asterias.

3.4 **Subcontractors.** Other than a third party provider providing services to Asterias under a separate agreement between such third party and Asterias pursuant to Section 3.3, any use of subcontractors (or any change to existing subcontractors) by Cognate hereunder (or any other delegation of Cognate's obligations hereunder) shall be subject to (and may not be utilized without) Asterias's prior written consent, which consent will not be unreasonably withheld, conditioned or delayed. Upon receipt of any such consent (if given), before allowing any such subcontractor (or delegate) to begin performing under this Agreement, Cognate shall ensure that each such subcontractor (or delegate) is bound by a written agreement with Asterias that obligates such subcontractor or delegate (and its personnel involved in the performance of this Agreement) to be bound by the applicable terms and conditions of this Agreement in the same manner as such terms and conditions apply to Cognate (including for example and without limitation the obligations of confidentiality and the assignments and licenses to certain Intellectual Property expressly provided for herein). [\*\*\*]. Asterias acknowledges and agrees that Cognate may subcontract its obligations under this Agreement in whole or in part to an Affiliate of Cognate with prior written notice to Asterias (which Affiliate shall be subject to the terms and conditions of this Agreement), and any such subcontracting does not require Asterias's prior written consent. Prior to any Affiliate of Cognate performing under this Agreement, Cognate shall ensure such Affiliate is bound by the terms and conditions of this Agreement in the same manner as Cognate (and all references herein to Cognate shall include such Affiliate). Cognate shall be fully responsible and liable for such Affiliate's compliance with and performance under this Agreement.

3.5 **Timing of Performance by Parties; Timing of Cognate Manufacture of Product.** Both parties will use commercially reasonable efforts in the performance of their respective obligations hereunder to meet any timelines, schedules or other target dates or deadlines in this Agreement or in any SOW. As it pertains to Manufacture of Product, Cognate understands the importance of its timely performance of the Manufacturing Services and will use reasonable efforts to timely Manufacture Product for use in clinical trials or other clinical use by patients, and to otherwise timely satisfy any timelines, deadlines, schedules or target dates in any SOW with respect to such Product Manufacturing.

4. **Materials and Equipment.**

4.1 **Supply of Materials.** Cognate will supply, in accordance with the payment and/or delivery schedule(s) included in the applicable SOW, all materials to be used by Cognate in the performance of Services under an SOW, other than any Asterias Materials specified in such SOW. Asterias or its designees will provide Cognate with all Asterias Materials. [\*\*\*] Cognate shall not be responsible for any loss, wastage or need to replace [\*\*\*] Products [\*\*\*] caused by a force majeure event.

4.2 **Storage of Materials.** Cognate will provide within the Facility an area or areas where the Asterias Materials, Product, any intermediates and components of Asterias Materials or Product, and any work in process are stored in accordance with the Specifications and cGMP (if applicable) and the applicable SOW (if relevant). Asterias will provide the Asterias Materials (and, if expressly required to be provided by Asterias under a SOW, any intermediates and components of any Asterias Materials) to Cognate free and clear of all liens and encumbrances as and when delivered and both Asterias and Cognate will not permit or cause to be suffered by any liens or encumbrances on such Asterias Materials (and intermediates and components) while in the possession of Cognate.

4.3 **Supply and Use of Equipment.** Unless otherwise agreed in an SOW, Cognate will supply all Equipment necessary to perform the Services, other than that equipment unique to and necessary for the Manufacture of Asterias's Product, which equipment will be identified as such in the applicable SOW and supplied by Asterias or purchased or otherwise acquired by Cognate, in each case, at Asterias's cost and expense (the "Asterias Equipment"). The Asterias Equipment will be delivered to Cognate's Facility free and clear of all liens and encumbrances as and when delivered and both Asterias and Cognate will not permit or cause to be suffered by any liens or encumbrances on such Asterias Equipment while in the possession of Cognate. Subject to the terms of this Section 4.3, title to any such delivered Asterias Equipment will remain with Asterias and Asterias will ensure that the Asterias Equipment is properly labeled as Asterias's property. Cognate will be responsible, at Asterias's cost, for maintenance of the Asterias Equipment for so long as the same is useful in the performance of the Services. At such time as the Asterias Equipment is not useful in the Manufacture of the Product (including without limitation upon any termination or expiration of this Agreement), Cognate will notify Asterias in writing. [\*\*\*] following delivery by Cognate of such written notice, Asterias will instruct Cognate in writing to return to Asterias or its designee, the Asterias Equipment or retain or dispose of (i.e. destroy) the Asterias Equipment, in each case, at Asterias's cost and expense. If Asterias does not provide such written instructions [\*\*\*] the [\*\*\*] period, Cognate will deliver to Asterias a final notice thereof and give Asterias a final [\*\*\*] grace period to respond to Cognate with written instructions. If Asterias does not provide such written instructions [\*\*\*] the final [\*\*\*] grace period, Cognate will in Cognate's sole discretion, either retain or dispose of (i.e. destroy) the Asterias Equipment. If the equipment is disposed of or destroyed, such disposal or destruction will be at Asterias's cost and expense; Cognate will use commercially reasonable efforts to effect such disposal or destruction in an efficient manner. During the term of this Agreement or until returned, disposed of or retained in accordance with this Section 4.3, Cognate will use commercially reasonable efforts to keep all Asterias Equipment secure and not use such Asterias Equipment for any purpose other than performing the Services for Asterias hereunder. [\*\*\*].

5. **Development and Manufacture of Product.**

5.1 **Facility.**

(a) **Performance of Services.** Cognate will perform the Services at the Facility, provide all staff necessary to perform the Services in accordance with the terms of the applicable SOW and this Agreement and, except as set forth in an SOW, hold at such Facility, all Equipment, Asterias Equipment, Asterias Materials and other items used in the Services. Cognate will notify Asterias if Cognate changes the location of such Facility or uses any additional facility for the performance of Services under this Agreement (other than those provided by any third party provider which will be performed in such third party's facilities).

(b) **Facility Validation.** Cognate will be responsible for performing all necessary validation of all Equipment, unless otherwise agreed in an SOW. Cognate will be responsible for performing any required validation of the Facility and cleaning and maintenance processes employed in the Manufacturing Process in accordance with cGMP (if applicable), the applicable Quality Agreement, and any other validation procedures established by the parties and agreed to in writing by Cognate.

(c) **Licenses and Permits.** Cognate will be responsible for obtaining, at its expense, any licenses, permits or approvals from the applicable Authorities (or otherwise required under Applicable Laws) necessary for the performance of Services by Cognate under this Agreement. Following Asterias's written request, Cognate will provide Asterias with copies of licenses, permits or approvals and, subject to the obligations of confidentiality set forth herein, and Applicable Laws, during the term of this Agreement. Asterias will have the right to use any and all information contained in such licenses, permits or approvals if and solely to the extent required by the FDA and/or other applicable Authority with respect to the use and/or commercial development of the Product.

(d) **Consultation with Cognate; Access to Facility.** Asterias or its duly authorized representatives may consult with Cognate during the performance of Services under this Agreement, including with respect to the Manufacturing of any Batch. Subject to Cognate's obligations of confidentiality to any third parties and Cognate's monitoring and general access control policies then in effect, on mutually convenient dates, Asterias or its duly authorized representatives will be permitted to inspect (i) the Equipment and materials used in the performance of Services and those portions of the Facility used to Manufacture Products; (ii) the holding facilities used for storage of such materials and Equipment; and (iii) the Records relating to such Services and the Facility; provided that (A) Asterias gives Cognate [\*\*\*] prior written request of such inspection and (B) such inspection will not unduly interfere with or impede Cognate's normal business operations or timely performance of the Services. Cognate will not be responsible for any delays in or interruption of the Manufacture of the Product caused by such inspection or any other costs, expenses, damages, liabilities or losses of any nature related directly or indirectly to any such delay or interruption. Asterias will also have the right, at its expense, to conduct one (1) "mock" pre-approval audit upon reasonable prior written notice to Cognate. Asterias will (and will cause its duly authorized representatives (including any Man-In-Plant)) to comply with Cognate's reasonable instructions and/or monitoring and general access control policies (as the same may be amended from time to time) at all times any Asterias representatives are in the Facility. Notwithstanding any other provision contained herein, in no event will Asterias request or be entitled to more than one (1) inspection and one (1) "mock audit" in any twelve (12) month period.

(e) Neither the inspection rights granted to Asterias pursuant to Section 5.1(d), nor any inspection performed by or on behalf of Asterias, will, by themselves, impose any liability on Cognate or relieve Asterias of any liability that it may have under this Agreement or otherwise with respect to the Manufacture of the Product [\*\*\*]. Subject to permitted disclosure to Authorities under Section 5.4(a), information disclosed to Asterias or any of its representatives will be subject to the confidentiality provisions set forth in Article 10. All information obtained by Asterias or its designees during any inspection may be used by Asterias (or its representatives) solely for confirming Cognate's compliance with cGMP or this Agreement or for complying with Applicable Laws with respect to the Product.

5.2 **Changes to SOWs, Manufacturing Process and Specifications.**

(a) **Changes to SOWs.** If the scope of work within an SOW is required to be changed (or if the parties mutually agree to such change), then the applicable SOW may be amended as provided in this Section 5.2(a). If a required modification to an SOW is identified by Asterias or by Cognate, the identifying party will notify the other party in writing as soon as reasonably possible. Following identification by either party of any such required modification, Cognate will provide Asterias with a change order containing a description of the required modifications and their effect on the scope, fees, costs, expenses and timelines specified in the applicable SOW previously executed by the parties ("Change Order"). No Change Order will be effective unless and until it has been signed by authorized representatives of both parties. Asterias will be responsible for all additional fees, costs and expenses specified as payable by Asterias in any Change Order due to continued performance under any existing SOW as modified by such Change Order, whether the modifications are proposed by Asterias or Cognate.

(b) **Changes to Manufacturing Process or to Specifications.** Any amendment, change or other modification to the Manufacturing Process or Specifications or Equipment or Facility for a Product must be approved by both parties in writing and will be made in accordance with the change control provisions of the applicable Quality Agreement, if any.

(c) Cognate will not unreasonably withhold its consent and execution of any Change Orders or changes to the Manufacturing Process or Specifications or Equipment or Facility requested by Asterias which are, in each case either (i) required for compliance with cGMP or other Applicable Laws or (ii) required to comply with or obtain any Asterias Approval (assuming that Asterias satisfies all actions under Asterias's control or required by Asterias to obtain compliance with any of (i) or (ii)).

5.3 **Record and Sample Retention.**

(a) **Records.** Cognate will keep records of the Services performed by Cognate under this Agreement (including without limitation the results of such Services), in form and substance as specified in the applicable SOW, the applicable Quality Agreement, and this Agreement (collectively, the "**Records**"). Such Records shall in any event be generated, maintained and updated in accordance with and as required by cGMP and other Applicable Laws and, with respect to any non-GMP Services, standard industry practice. Asterias will be entitled to a copy (at Asterias's cost and expense) of relevant Records following written request therefor. Notwithstanding any other provision contained herein, Cognate reserves the right to use all data and results generated during the performance of the Services to support applications, assignments or other instruments necessary to protect any Intellectual Property rights (including apply for and obtain patents) in or to Cognate Technology. Except as required by or necessary to comply with Applicable Laws, any Authority, or in connection with the protection of Cognate's Intellectual Property rights, Cognate will not transfer, deliver or otherwise provide any such Records to any third party other than Asterias, without the prior written approval of Asterias. Asterias shall own the Records and have the full, unrestricted, perpetual right to use and disclose such Records for any purposes relating to Products in its sole discretion (which right shall survive any expiration or termination of this Agreement). All original Records of the Development and Manufacture of Product, or of the conduct of any other Services with respect to Product, under this Agreement will be retained and archived by Cognate in accordance with Applicable Law, but in no event for less than [\*\*\*] following completion of the applicable SOW. [\*\*\*] completion of an SOW, copies of Records will be sent to Asterias or Asterias's designee at Asterias's sole cost and expense; **provided, however,** that Asterias may elect to have the Records retained in Cognate's archives for an additional period of time at a reasonable charge to Asterias. For clarity, if this Agreement expires or is terminated in accordance with Section 14.2, Asterias' right to request copies of Records will survive until the [\*\*\*] anniversary of the completion of each corresponding SOW or such longer period of time as Asterias may elect to have Cognate retain such Records, in each case, in consideration for a reasonable charge to Asterias.

(b) **Product Samples.** Cognate will take and retain, for such period and in such quantities as may be required by cGMP (if applicable) and the applicable QC sampling plan and Quality Agreement, samples of final Product Manufactured under this Agreement. Upon Asterias's written request and to the extent not prohibited by Applicable Law, Cognate will submit requested samples to Asterias, at Asterias's sole cost and expense.

5.4 **Regulatory Matters.**

(a) **Regulatory Approvals.** Asterias will be solely responsible for obtaining, at its sole cost and expense, all approvals, licenses and permits of any governmental authority, including any Authority, necessary for Asterias's (or any Asterias sublicensee, collaborator or development partner's) commercialization, distribution, marketing, sale and, to the extent applicable, all other uses by Asterias of any Product Developed and/or Manufactured under this Agreement ("**Asterias Approvals**"). Cognate shall reasonably cooperate with and assist Asterias, in each case at Asterias's cost and expense, with respect to Manufacturing-related portions of such Asterias Approvals and any associated regulatory filings and requirements. Without limiting the foregoing or Section 5.3(a), Cognate will provide Asterias with copies of Records addressing the Development and/or Manufacture of Product that, in each case, (i) are in the possession or under the control of Cognate, (ii) are applicable to the Development and Manufacture of Product hereunder, and (iii) are required to enable Asterias to obtain the Asterias Approvals. In the event Cognate submits a regulatory filing with the FDA or other Authority (such as, for example, a drug master file), whether at Asterias's request, by Cognate's decision or otherwise (each, a "**Submission**") with respect to the Manufacturing Process or other aspects of Manufacturing Product for Asterias hereunder, Cognate hereby grants to Asterias a right of reference to such Submission with respect to Products and shall reasonably cooperate with Asterias, at Asterias's cost and expense, with respect to any such reference or use of such Submission by Asterias in connection with any such Product.

(b) **Regulatory Inspections.** Cognate agrees, in each case, to the extent not prohibited by Applicable Law or the applicable Authority, to advise Asterias by telephone and email as soon as reasonably possible of any proposed or announced visit or inspection, and as soon as possible but in any case [\*\*\*] any unannounced visit or inspection, by the FDA or other Authority of any Facility used to Manufacture Products under this Agreement. Subject to Cognate's obligations of confidentiality to any third parties, to the extent practicable and if not prohibited by Applicable Laws, Cognate will permit Asterias to be present and participate in any FDA or other Authority visit or inspection of the Facility to the extent such visit or inspection relates directly to the Product Manufactured for Asterias by Cognate pursuant to this Agreement. Cognate will (unless prohibited by Applicable Law from doing so) provide Asterias with a copy of any report, notice or other written communication received from the FDA or other Authority in connection with such visit or inspection relating to the Product or the Facility (if it relates directly to or directly affects the Development and/or Manufacture of Product), which report, notice or other communication will be redacted to remove information directly pertaining to or directly affecting any other third party. Cognate will provide, to the extent not prohibited by Applicable Law or the applicable Authority, Asterias with a copy of that portion of any written response or filing Cognate submits to the FDA or other Authority addressing the Manufacture of Product or the Manufacturing Process reasonably prior to submission of such response or filing so that Asterias may comment thereon (which comments Cognate shall reasonably consider but shall not be obligated to include). Notwithstanding the preceding sentence, in no event will Asterias require Cognate to delay or otherwise impair Cognate's ability to timely respond to or submit any filing to FDA or any other Authority.

5.5 **Waste Disposal; Safety Procedures; Environmental Compliance.** Cognate will be responsible for maintaining health, environmental and safety procedures for the performance of Services (in compliance with Applicable Law) and for the collection, storage, handling, transportation, movement and release of waste generated in connection with the Services at Cognate's sole cost and expense. Cognate, in consultation with Asterias, will develop safety and handling procedures for the Product. Without limiting the foregoing, Cognate shall comply with Applicable Law governing the Services and Facilities. Cognate shall inform Asterias without delay of any material and adverse safety, health, or environment issues directly related to or caused by the Manufacture of the Product.

6. **Testing and Acceptance Process.**

6.1 **Testing by Cognate.** Unless otherwise expressly stated in the applicable SOW, the Product Manufactured under this Agreement will be Manufactured in accordance with the Manufacturing Process approved by Asterias. Each Batch will be sampled and tested against the Specifications, and the quality assurance departments of Cognate and Asterias will review the documentation relating to the Manufacture of the Batch and assess if the Manufacture has taken place in compliance with cGMP (if applicable) and the Manufacturing Process. Cognate will follow the Product Release procedures (including the timelines therefor) set forth in the applicable SOW and/or the Quality Agreement with respect to Products it Manufactures hereunder, such Release procedures to be performed in collaboration with Asterias's quality assurance department and according to the procedures, timelines and responsibilities as set forth in the applicable SOW.

6.2 **Batch Documentation**. A Certificate of Analysis, the Specifications, and a copy of the Batch records (collectively, the “**Batch Documentation**”) for each Batch (in all cases generated by Cognate in accordance with cGMP and the Quality Agreement) will be delivered by Cognate to Asterias in accordance with the schedule and procedures stated in the applicable SOW and/or the Quality Agreement. If Asterias requires additional copies of such Batch Documentation, these will be provided by Cognate to Asterias at Asterias’s sole cost and expense following Asterias’ written request.

6.3 **Man-In-Plant**. At Asterias’s discretion, and in consideration of the fee payable pursuant to the applicable SOW (in all cases not to exceed [\*\*\*]), Asterias may designate an individual (the “**Man-In-Plant**”) who will be present in the Facility during the testing and production phases of the Manufacturing Process.

6.4 **Product Non-Conformance and Remedies**. If the parties agree or if determined in accordance with Section 6.7, that a Batch is [\*\*\*], then Cognate will (with respect to such Batch of [\*\*\*] or a subsequent Batch Manufactured to replace a Batch of [\*\*\*] that is [\*\*\*]), at Cognate’s option and as Asterias’s sole remedy, either:

(a) if possible and compliant with cGMP, the Specifications and other Applicable Law, rework or reprocess the [\*\*\*] so that such Batch conforms to the Specifications (and qualifies as having been Manufactured in compliance with cGMP (if applicable) and the Manufacturing Process) as soon as reasonably possible [\*\*\*]; or

(b) as soon as reasonably practicable, Manufacture a new Batch without charging Asterias [\*\*\*] such new Batch. If a Batch is patient-specific and requires leukapheresis of the applicable patient to Manufacture such new Batch, Asterias shall [\*\*\*]. In addition, [\*\*\*] as described above [\*\*\*] with respect to the [\*\*\*] for such patient-specific Batch; provided, however, that [\*\*\*]. For clarity, Asterias’ right to receive the foregoing remedies applies with respect to any Batch Manufactured and any subsequent Batch Manufactured or reprocessed or reworked to replace a previously Manufactured Batch that was [\*\*\*].

Nothing in this Section 6.4 will eliminate or reduce Asterias’s liability under this Agreement (except as expressly provided for in other provisions of this Agreement or any SOW) for fees, costs or expenses associated with the Manufacture of any Batch in accordance with the provisions of this Agreement and any SOW, and Asterias will be responsible for payment in full of all amounts payable under this Agreement, together with all amounts payable under the relevant provisions of any applicable SOW in respect of such Batch.

6.5 **No Cognate Liability**. If the parties agree or if determined in accordance with Section 6.7, that either (i) there is no non-conformity of a Batch or (ii) there is a non-conformity but the non-conformity did not result in [\*\*\*], then, in all cases of (i) and (ii), Cognate will have no obligation or liability to Asterias with respect to such non-conforming Batch and will only rework, reprocess or Manufacture a new Batch in consideration for payment in full (as and if agreed to by Asterias), and Asterias will remain responsible for payment to Cognate of all amounts payable under the express provisions of this Agreement, including under Articles 6 through 9, 12 and 14 of this Agreement, together with all amounts payable under the relevant provisions of any applicable SOW or as otherwise agreed to by the parties in writing with respect to such Batch of non-conforming Product that did not result in [\*\*\*]. In furtherance and not in limitation of the foregoing, in no event will Cognate have any liability with respect to claims of non-conformance of a Batch Manufactured by Cognate for Asterias under this Agreement, any SOW or otherwise unless Asterias first notifies Cognate thereof in writing (or unless the parties agree) at any time on or prior to the end of the 60 day period following Release of such Batch of Product pursuant to Article 7.

6.6 **Disposition of All Non-Conforming Product.** The ultimate disposition of [\*\*\*] and of non-conforming Product will be the responsibility of Asterias's quality assurance department.

6.7 **Disputes.** In case of any disagreement between the parties as to whether Product conforms to the applicable Specifications or cGMP (if applicable), or as to whether the failure of such Product to conform is attributable to Cognate's failure to comply with cGMP, the performance of the Manufacturing Process by Cognate, the Quality Agreement, or the mutually agreed SOPs, the quality assurance representatives of the parties will attempt in good faith to resolve any such disagreement and Asterias and Cognate will follow their respective SOPs to determine the conformity of the Product to the Specifications and cGMP (if applicable). If the foregoing discussions do not resolve the disagreement in a reasonable time (not to exceed [\*\*\*]), a representative sample of such Product and/or relevant documentation will be submitted to an independent testing laboratory (in the case of an alleged failure to meet Specifications) and/or independent cGMP consultant (in the case of an alleged failure to comply with cGMP), as appropriate, that is, in each case, mutually agreed upon by the parties, for testing and final determination of whether such Product conforms with Specifications and/or cGMP (if applicable). The laboratory and consultant, as applicable, must be of recognized standing in the industry, and consent to the appointment of such laboratory and consultant will not be unreasonably withheld or delayed by either party. Such laboratory will use the test methods contained in the applicable Specifications. The determination of conformance by such laboratory and/or cGMP consultant, as applicable, with respect to all or part of such Product will be final and binding on the parties absent manifest error. The fees, costs and expenses of the laboratory and/or consultant, as applicable, incurred in making such determination will be paid by the party against whom the determination is made.

6.8 **Cognate [\*\*\*]** If the Release of any Products and associated Batch Documentation, [\*\*\*] and as the direct result [\*\*\*] to receive the Product (whether or not [\*\*\*] such Product may [\*\*\*] in the following sentence shall apply [\*\*\*] associated with such patient [\*\*\*] for such patient [\*\*\*] except to the extent Asterias is [\*\*\*]. In addition, the applicable SOW may contain provisions for [\*\*\*]. For clarity, this Section 6.8 expressly excludes the Initial SOW and all other SOWs or portions of SOWs for Development Services or other Services that are not Manufacture of Product.

6.9 **Development Services.** Cognate warrants that it will (i) use commercially reasonable efforts to deliver the Development Services and such other Services that are not Manufacture of Product (and the deliverables from such Services) pursuant to any SOW in all material respects in accordance with the specifications and requirements set forth herein and by the ultimate deadline set forth in such SOW (which ultimate deadline may be extended by agreement of the parties) and, in all cases, without regard to any interim deadlines and (ii) engage personnel with the qualification and training customary in the industry to perform such Development and other Services that are not Manufacture of Product. In the event of a [\*\*\*] the individual, specific Development Services and other Services that are not Manufacture of Product that [\*\*\*] fully [\*\*\*] reasonable detail [\*\*\*] those specific, individual [\*\*\*] the applicable Development Services [\*\*\*]. Notwithstanding anything in this Agreement or any SOW to the contrary, [\*\*\*] Development Services and other Services that are not Manufacture of Product [\*\*\*].

7. **Shipping and Delivery.** Cognate will deliver Batches of Product EXW (Incoterms 2010), Cognate's Facility following Release of such Product (which Product will be released in accordance with the applicable SOW and the Quality Agreement, including the issuance of a Certificate of Analysis and any other documentation as specified therein, "Release"). A bill of lading will be furnished to Asterias with respect to each shipment. Without limiting the terms of Article 6 above and subject to the following sentence, Cognate is responsible for Batches of Product until, but not following, Release of such Batch of Product in accordance with the Release requirements defined by the applicable SOW and the Quality Agreement. Products shall be made available by Cognate for collection by the carrier designated by Asterias (or if not so designated, as reasonably selected by Cognate) at Cognate's Facility and shall be shipped to the destination designated by or on behalf of Asterias, and Cognate shall use reasonable care to store and safeguard such Products until so tendered by Cognate to such carrier. Title and risk of loss of the Products shall pass to Asterias upon delivery of the Products pursuant to the first sentence of this Article 7. For purposes of this Agreement, delivery of Product is a delivery by Cognate in accordance with this Article 7.

8. **Payment of Fees; Cost of Shutdown.**

8.1 **Price; Payments.** The price of Product and/or the fees and expenses related to the performance of Services will be set forth in the applicable SOW or invoiced pursuant to other applicable express provisions of this Agreement. If Asterias [\*\*\*] fails to cure such failure(s) [\*\*\*] of Cognate's notice to Asterias specifying such [\*\*\*] breach(es) then, notwithstanding anything in this Agreement or any other agreement of the parties to the contrary, [\*\*\*] Cognate will have the option to restrict or reduce Manufacturing capacity previously allocated to Asterias.

All dollar (\$) amounts specified in this Agreement are United States dollar amounts and all payments to be made under this Agreement will be made in United States dollars and will be due from Asterias and must be received by Cognate on or before the relevant time frames set forth in the applicable SOW.

8.2 **Invoice.** Cognate will invoice Asterias according to the invoice schedule in the applicable SOW, referencing in each such invoice the SOW(s) to which such invoice relates. Cognate will provide Asterias with reasonable supporting documentation evidencing disbursements and other pass-through expenses upon Asterias's written request. Payment of invoices will be due and the payment from Asterias must be received by Cognate [\*\*\*] the date of electronic transmission by Cognate to Asterias of the invoice. A [\*\*\*] monthly service charge will be applied to all overdue balances from the date payment was first due until the date of payment in full of such monies. If any collection action is undertaken to collect unpaid (when due) amounts owed under this Agreement or any SOW(s), and it is determined by judgment, settlement or other competent authority with proper jurisdiction over such action, that Cognate is entitled to payment of such invoices, Asterias will pay all reasonable out-of-pocket fees, costs and expenses associated with such collection actions including, without limitation, reasonable attorneys' fees incurred.

8.3 **Taxes.** All duty, sales, use or excise taxes imposed by any governmental entity that apply to the provision of Services to Asterias will be borne solely by Asterias (other than taxes based upon the income of Cognate). Cognate will include all such taxes in its invoice to Asterias if required to collect them from Asterias under Applicable Law, and in such case Cognate will properly remit, in accordance with Applicable Law, any such taxes to the appropriate governmental entity.

8.4 **SOW Payment Terms.** If any payments, charges, fees or other amounts to be paid by or due from Asterias and set forth in a SOW are estimates, subject to change, open ended, undefined or not specific as to the quantity or magnitude, then the specific amount must be confirmed with and approved by Asterias in writing before Asterias shall have any obligation or liability to pay such amount or otherwise be liable with respect thereto. Notwithstanding the foregoing, estimated amounts need not be confirmed with or approved by Asterias solely to the extent the actual charge or fee is not more than [\*\*\*] than highest estimated amount.

8.5 **Asterias [\*\*\*]. [\*\*\*].**

8.6 **Accrued Costs or Expenses.** With respect to any costs or expenses of Cognate which are payable or reimbursable by Asterias to Cognate in accordance with this Agreement or any SOW, if such costs or expenses are accrued, such accrual shall be done by Cognate in accordance with standard accounting practices. In the event such accrued costs and expenses are subsequently not actually incurred by Cognate or adjusted downward in Cognate's books, Cognate shall refund to Asterias the amount of such costs and expenses not incurred or adjusted as soon as Cognate receives the benefit of such costs or expenses no longer being charged or such costs or expenses are adjusted downward (e.g. upon Cognate's receipt of a refund).

9. **Intellectual Property Rights.**

9.1 **Background Intellectual Property; Cognate Technology; Asterias Technology.** As between the parties, except as expressly provided in this Agreement each party will

retain exclusive right, title and interest in and to such party's Background Intellectual Property and all Improvements to such party's Background Intellectual Property. Notwithstanding any other provision in this Agreement except for, and subject to, any rights or licenses expressly granted in this Agreement, Cognate will retain all rights in and to the Cognate Technology and Asterias will retain all rights in and to the Asterias Technology.

9.2 **Grant to Cognate.** Asterias hereby grants to Cognate an irrevocable (during the term of this Agreement) non-exclusive, worldwide, royalty-free, fully paid-up license to use Asterias's Background Technology, Product Inventions and all other Technology of Asterias as provided by Asterias to Cognate under this Agreement, in all such cases solely to enable Cognate to perform the Services and all other obligations under this Agreement during the term of this Agreement.

9.3 **Grant to Asterias.** Cognate hereby grants to Asterias a nonexclusive, royalty-free, perpetual, irrevocable, transferable (solely in connection with a permitted assignment of this Agreement), sublicensable, worldwide license under and to only that Cognate Technology actually used to Manufacture (or practiced in the course of Manufacturing or using) Products hereunder [\*\*\*]. This license shall survive any expiration or termination of this Agreement.

9.4 **Product Inventions.** Cognate will provide Asterias notice of any Product Invention. All Product Inventions shall be the exclusive property of Asterias. Cognate hereby assigns and transfers, and agrees to assign and transfer, fully to Asterias all rights, title and interests in, to and under all Product Inventions (including without limitation any Intellectual Property therein). Cognate shall provide Asterias reasonable cooperation and assistance, at Asterias's cost and expense as provided below, with respect to effectuating the foregoing assignment and filing for, protecting and defending any Intellectual Property in the Product Inventions, including without limitation, if Asterias so requests in writing, Cognate will execute any applications, assignments or other instruments and give testimony necessary to permit Asterias to apply for and obtain patents on any such Product Inventions and Asterias will advance or reimburse Cognate (at Cognate's option and sole discretion) for all out-of-pocket expenses incurred and all accrued out-of-pocket expenses (including legal fees, costs and expenses) accrued by Cognate according to Cognate's standard accounting practices and will compensate Cognate [\*\*\*] for the time devoted to such activities. Cognate will fully disclose all Product Inventions to Asterias and provide Asterias with copies of any embodiments and documentation thereof.

9.5 **Improvements.**

(a) Subject to Sections 9.1, 9.2, 9.3, 9.4 and 9.8, Cognate will own all right, title and interest in all Intellectual Property that [\*\*\*] (“Cognate Manufacturing Improvements”). For clarity, the term “Cognate Manufacturing Improvements” includes [\*\*\*].

(b) Subject to Sections 9.1 and 9.2, Asterias will own all right, title and interest in all Intellectual Property that [\*\*\*] ([\*\*\*] the Cognate Manufacturing Improvements, the “Manufacturing Improvements”). For clarity, the term “[\*\*\*] Manufacturing Improvements” includes [\*\*\*].

9.6 **No Implied Licenses.** Except to the extent expressly provided in this Agreement, neither party shall acquire any right, title or interest (express or implied) in any of the trademarks, service marks, copyrights or other intellectual property rights belonging to the other party. No right or license, whether express or implied (by implication, estoppel or otherwise), is granted to one party by the other party, except to the extent expressly authorized by this Agreement.

9.7 **Protocols.** Protocols, methods, controls, SOPS, specifications, pre-existing products, materials, tools, methodologies, technologies, Cognate Intellectual Property or documents generally used by Cognate in the normal course of its business that are used by Cognate for the Services (collectively, “Service Instruments”) are furnished solely with respect to Services, and, subject to the license granted to Asterias in Section 9.3, Cognate will retain all common law, statutory, ownership, and other rights in such Service Instruments. For clarity, the term “Service Instruments” excludes Batch Documentation and Product Inventions produced, created, conceived, invented, developed or reduced to practice by Cognate as a result of Services and excludes any Asterias Technology and any [\*\*\*].

9.8 [\*\*\*]. [\*\*\*] information [\*\*\*] in each case [\*\*\*] according to the applicable SOW if so specified therein [\*\*\*] or pursuant to any other written agreement of the parties [\*\*\*] information [\*\*\*] in each case, specific to [\*\*\*] making relevant [\*\*\*] in each case, at [\*\*\*] according to the applicable SOW if so specified therein [\*\*\*] pursuant to any other written agreement of the parties [\*\*\*] to the extent necessary [\*\*\*]. For the avoidance of doubt, [\*\*\*]. Asterias will pay [\*\*\*] the foregoing [\*\*\*] set forth in the applicable SOW (if any) [\*\*\*] the parties will [\*\*\*]. Cognate will not [\*\*\*].

9.9 **License to Specialized Product [\*\*\*].** Cognate hereby grants to Asterias (a) [\*\*\*] to the Specialized Product [\*\*\*] solely to [\*\*\*]; and (b) [\*\*\*] to perform the Services and all other obligations under this Agreement during the term of this Agreement), [\*\*\*] to the Specialized Product [\*\*\*] solely to [\*\*\*].

9.10 **Prosecution, Maintenance and Enforcement of arising Intellectual Property.** As between the Parties, each Party shall be responsible, at its own expense, for preparing, filing, prosecuting and maintaining patent applications and patents relating to Intellectual Property owned or controlled by such Party, and conducting any interferences, re-examinations, reissues or oppositions relating to such Intellectual Property. [\*\*\*] reasonably apprised of the status of prosecution and maintenance of, [\*\*\*] strategies for, and [\*\*\*] strategy for [\*\*\*]. If [\*\*\*] patent application or issued patent [\*\*\*].

Each Party shall promptly notify the other Party of its knowledge of any potential infringement of Intellectual Property [\*\*\*] Cognate will have the initial right, at its sole expense, but not the obligation, to take reasonable legal action necessary to protect the [\*\*\*] against infringement by a third parties, or to defend any declaratory judgement or other action concerning [\*\*\*]. In the event that Cognate has not initiated an infringement action [\*\*\*] Asterias first notifies Cognate of a suspected infringement of Intellectual Property covering [\*\*\*], Asterias shall have the right, but not the obligation, to prosecute such infringement under its sole control and at its sole expense. Cognate agrees to cooperate and render such assistance, at Asterias’ expense, as Asterias may reasonably request in pursuing such legal action at Asterias’ expense, including permitting to be joined as a party-plaintiff.

The Party controlling an action involving any infringement of Intellectual Property covering [\*\*\*] shall consider in good faith the interests of the other Party in so doing, shall notify the other Party in advance of any proposed settlement or consent, and shall not settle or consent to an adverse judgement in any such action without the prior express written consent of such other Party (which shall not be unreasonably withheld).

10. **Confidentiality.**

10.1 **Definition.** “**Confidential Information**” means any and all non-public scientific, technical, financial regulatory or business information, or data or trade secrets in whatever form (written, oral or visual) that is furnished or made available by one party (the “**Discloser**”) to the other (the “**Recipient**”) or developed by the Discloser under this Agreement (except that Product Inventions shall be deemed the Confidential Information of Asterias and Asterias shall be deemed the Discloser and Cognate the Recipient with respect to any such Product Inventions for purposes of this Agreement). Confidential Information of Asterias includes Asterias Materials, Product Inventions, [\*\*\*] and Asterias Technology, development and marketing plans, regulatory and business strategies, financial information, and forecasts of Asterias, as well as other non-public, scientific information disclosed to Cognate or any of its Permitted Agents by Asterias and all information of third parties that Asterias has an obligation to keep confidential. Confidential Information of Cognate includes Cognate Technology, Cognate Manufacturing Improvements, development and marketing plans, regulatory and business strategies, financial information, and forecasts of Cognate, as well as other non-public, scientific information disclosed to Asterias or any of its Permitted Agents by Cognate and all information of third parties that Cognate has an obligation to keep confidential. The terms of this Agreement and for clarity, all appendices and all other agreements entered pursuant to this Agreement constitute Confidential Information of both parties subject to the provisions of Section 10.3 and Section 15.12.

10.2 **Confidentiality Obligations.** Recipient agrees to (a) hold in confidence all Discloser’s Confidential Information, and not disclose Discloser’s Confidential Information except as expressly provided in Sections 5.4(a) and 10.3, without the prior written consent of Discloser; (b) use Discloser’s Confidential Information solely to carry out Recipient’s obligations or exercise Recipient’s rights under this Agreement; (c) treat Discloser’s Confidential Information with the same degree of care Recipient uses to protect Recipient’s own confidential information but in no event with less than a reasonable degree of care; and (d) reproduce Discloser’s Confidential Information solely to the extent necessary to carry out Recipient’s obligations or exercise Recipient’s rights under this Agreement (and any agreements executed pursuant to this Agreement), with all such reproductions being considered Discloser’s Confidential Information.

10.3 **Permitted Disclosure.** Recipient may provide Discloser’s relevant Confidential Information to its Affiliates, and to its and their directors, employees, consultants (including, with respect to Asterias, the Man-In-Plant), contractors, permitted licensees, lenders and agents (each of which has reviewed or had access to the Discloser’s Confidential Information, a “**Permitted Agent**”) but only to the extent required to accomplish the purposes of, or exercise rights expressly granted under, this Agreement; provided, however, that in each case (a) each of such Affiliates, directors, employees, consultants, contractors, permitted licensees, lenders and agents have a bona fide need to know Discloser’s Confidential Information to perform its obligations or exercise its rights under this Agreement, (b) are bound by written obligations of confidentiality with respect to the Discloser’s Confidential Information that are at least as restrictive as those set forth in this Agreement; and (c) Recipient remains liable for the actual or threatened breach of its Permitted Agents of such obligations. Recipient may also disclose Discloser’s Confidential Information to third parties only to the extent such disclosure is required to comply with Applicable Law or to defend or prosecute litigation; provided, that to the extent not prohibited by Applicable Law, Recipient provides prior written notice of such disclosure to Discloser, takes reasonable and lawful actions to avoid or minimize the degree of such disclosure, and cooperates reasonably with Discloser in any efforts of Discloser to seek a protective order, in each case at Discloser’s sole cost and expense. If disclosure of Discloser’s Confidential Information is nevertheless required, Recipient will disclose only that portion of Discloser’s Confidential Information that is legally required and then only to those parties legally required.

10.4 **Use of Confidential Information.** Recipient will not, and will cause its Permitted Agents not to, directly or indirectly (a) make any use of Discloser's Confidential Information, including use of any data or information derived from or wholly or partly based upon, such Confidential Information (collectively, "Use of Confidential Information") other than for the performance of its obligations or exercise of its rights under this Agreement, (b) facilitate, authorize or allow any third party to make any Use of Confidential Information other than for the performance of its obligations or exercise of its rights under this Agreement, or (c) accept any benefit from Use of Confidential Information other than for the performance of its obligations or exercise of its rights under this Agreement. For clarity, Cognate is entitled to use Asterias's Confidential Information as necessary to perform its obligations under this Agreement and all agreements ancillary thereto.

10.5 **Exceptions.** Recipient's obligations of non-disclosure and limitations on Use of Confidential Information will not apply to any portion of Discloser's Confidential Information that Recipient can demonstrate, by competent proof:

(a) is generally known to the public at the time of disclosure or becomes generally known through no wrongful act or omission on the part of Recipient;

(b) is in Recipient's possession at the time of disclosure other than as a result of Recipient's or its Affiliate's breach of any legal obligation, as demonstrated by competent and contemporaneous written documentation;

(c) becomes known to Recipient or its Affiliates on a non-confidential basis through disclosure by sources other than the Discloser having the legal right to disclose such Confidential Information; or

(d) is independently developed by Recipient or its Affiliates without reference to or reliance upon Discloser's Confidential Information, as demonstrated by competent and contemporaneous written documentation.

If Recipient is required by any competent governmental authority or by order of a court of competent jurisdiction to disclose any Confidential Information of Discloser, Recipient will give Discloser prompt written notice of such requirement or order (to the extent not prohibited by Applicable Law and practicable) and Recipient will reasonably cooperate with Discloser's efforts to take reasonable and lawful actions to avoid or minimize the degree of such disclosure, at Discloser's cost and expense. Recipient will also cooperate reasonably with Discloser, at Discloser's cost and expense, in any efforts by Discloser to seek a protective order. If disclosure of Discloser's Confidential Information is nevertheless required, Recipient will disclose only that portion of Discloser's Confidential Information that is legally required and then only to those parties legally required.

10.6 **Injunctive Relief.** Recipient agrees that monetary damages would not be a sufficient remedy for any threatened or actual breach by Recipient or Permitted Agents, of the obligations of confidentiality and limitations on Use of Confidential Information in this Article 10 and that Discloser, without posting any bond, is entitled to equitable relief including an injunction to stop any actual or threatened breach. Discloser is entitled to pursue all available remedies, at law or in equity, alternatively or cumulatively, in the event of a threatened or actual breach by Recipient of this Article 10.

11. **Representations and Warranties.**

11.1 **Cognate Representations and Warranties.** Cognate represents and warrants to Asterias that:

(a) it has the full power and right to enter into this Agreement and that there are no outstanding agreements, assignments, licenses, encumbrances or rights of any kind held by other parties, private or public, that are inconsistent with the provisions of this Agreement;

(b) the execution and delivery of this Agreement by Cognate has been authorized by all requisite corporate action and this Agreement is and will remain a valid and binding obligation of Cognate, enforceable in accordance with its terms, subject to laws of general application relating to bankruptcy, insolvency and the relief of debtors;

(c) the Services will be performed, in all material respects, with requisite care, skill and diligence, by individuals who are appropriately trained and qualified; and in accordance with Applicable Law and industry standards;

(d) the Cognate personnel (including without limitation any consultants or contractors of Cognate) performing any of the Services are bound in writing by obligations of confidentiality at least as protective of Asterias' Confidential Information as the terms and conditions of this Agreement, and are bound in writing by obligations to assign all of their right, title and interest in and to all Technology and Intellectual Property developed, created, conceived, invented, authored or otherwise generated by them in the conduct of the Services to Cognate;

(e) neither Cognate itself nor, to the best of Cognate's knowledge, any of the Persons used by Cognate to perform Services under this Agreement have been debarred pursuant to section 306 of the United States Food, Drug and Cosmetic Act, 21 U.S.C. § 335a; nor have any of them been convicted of a criminal offense related to the provision of healthcare items or services. In the event that Cognate becomes aware that Cognate, or any of its officers, directors, employees, or subcontractors has become debarred, pursuant to any action by an Authority or becomes aware of any threat of action by an Authority with respect to its debarment or is informed in writing of any debarment or action or becomes aware of threat of action with respect to the debarment of any individual, corporation, partnership or other entity whose services are utilized in the performance of this Agreement, Cognate shall promptly notify Asterias in writing;

(f) at the time delivered to Asterias pursuant to Article 7, Product Manufactured under this Agreement will have been Manufactured in accordance with cGMP (if applicable) and will have satisfied the Release requirements defined in the applicable Quality Agreement;

(g) all Products delivered to Asterias pursuant to Article 7 will comply in all material respects with the Specifications at the time of Release;

(h) upon delivery of Products to Asterias pursuant to Article 7, Cognate shall convey and Asterias shall have good title to such Products, free and clear of any encumbrances;

(i) Cognate has the right to grant the licenses and make the assignments granted to Asterias under this Agreement;

(j) to the best of Cognate's knowledge, the use of the Cognate Technology does not infringe the intellectual property rights of any third party; and Cognate will notify Asterias in writing should it become aware of any claims asserting such violation. For clarity, Cognate makes no representations or warranties regarding whether any of (i) the Asterias Materials, (ii) any intermediates, components, or derivatives of Asterias Materials, (iii) Product and/or any intermediates, components and/or derivatives of Product, (iv) Specifications, (v) the Asterias Technology and/or (vi) any intellectual property rights in any of (i) through (v) infringes or will infringe any proprietary or intellectual property rights of any third party.

11.2 **Asterias Representations and Warranties.** Asterias represents and warrants to Cognate that:

(a) it has the full power and right to enter into this Agreement and that there are no outstanding agreements, assignments, licenses, encumbrances or rights held by other parties, private or public, that are inconsistent with the provisions of this Agreement;

(b) the execution and delivery of this Agreement by Asterias has been authorized by all requisite corporate action and this Agreement is and will remain a valid and binding obligation of Asterias, enforceable in accordance with its terms, subject to laws of general application relating to bankruptcy, insolvency and the relief of debtors; and

(c) Asterias has the right to grant the licenses granted to Cognate under this Agreement;

(d) to the best of Asterias's knowledge, the use of (i) the Asterias Materials, (ii) any intermediates, components, or derivatives of Asterias Materials provided by or on behalf of Asterias to Cognate (or required to be derived according to any SOW), (iii) Product or any intermediates, components or derivatives of Product provided by or on behalf of Asterias to Cognate (or required to be derived according to any SOW), (iv) Specifications, (v) the Asterias Technology or (vi) any intellectual property rights in any of (i) through (v), for performance of the Services in accordance with this Agreement or pursuant to any SOW or other agreement executed by the parties under and in connection with this Agreement does not infringe the intellectual property rights of any third party; and Asterias will notify Cognate in writing should it become aware of any claims asserting such violation.

11.3 **Disclaimer of Other Representations and Warranties.** EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATIONS OR EXTENDS ANY WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OR NON-INFRINGEMENT WITH RESPECT TO ANY SUBJECT MATTER OF THIS AGREEMENT, INCLUDING ANY PRODUCTS OR ANY SERVICES RENDERED HEREUNDER, OR ANY TECHNOLOGY, MATERIALS OR INFORMATION THAT MAY BE PROVIDED HEREUNDER OR USED IN SUCH SERVICES OR INCORPORATED INTO SUCH PRODUCTS.

12. **Indemnification Obligations and Procedures.**

12.1 **Indemnification of Cognate by Asterias.** Asterias will indemnify, defend and hold harmless Cognate, its Affiliates and its and their respective present and former officers, directors, employees, consultants, advisors, agents, successors and assigns (collectively, the "Cognate Indemnitees") against any and all costs, expenses, losses, damages, liabilities and penalties of any kind ("Losses") in connection with and directly resulting from any and all Claims that may be brought or instituted by a third party against any Cognate Indemnitee arising out of [\*\*\*]. Notwithstanding any provision herein to the contrary, Asterias will have no obligation to indemnify the Cognate Indemnitees for any Losses or Claims that are within the scope of Cognate's indemnification obligations under Section 12.2.

12.2 **Indemnification of Asterias by Cognate.** Cognate will indemnify, defend and hold harmless Asterias, its Affiliates and its and their respective present and former officers, directors, employees, consultants, advisors, agents, successors, assigns and each Man-In-Plant (collectively, the "Asterias Indemnitees") and, together with the Cognate Indemnitees, each an "Indemnitee") against any and all Losses in connection with and directly resulting from any and all Claims that may be brought or instituted by a third party against any Asterias Indemnitee arising out of [\*\*\*]. Notwithstanding any provision herein to the contrary, Cognate will have no obligation to indemnify any Asterias Indemnitee for any Losses or Claims that are within the scope of Asterias's indemnification obligations under Section 12.1 or for any Losses or Claims with respect to cold-chain logistics, storage, washing, preparation or administration of the Product by the hospital, clinic, pharmacy or other recipient responsible for storage or administration of Product to patients or the progression or onset of any patient's disease.

12.3 **Indemnification Procedures: Calculation of Losses.** Either party will notify the other of any Claim which may be the subject of the other party's indemnification obligations hereunder. Subject to Section 12.4, the indemnifying party will have the sole right to defend, negotiate, and settle such Claims and is solely responsible for fully indemnifying the Indemnitee to the extent required by and in accordance with the express provisions above; provided that the indemnifying party will keep Indemnitee informed of the progress and status of any Claim. The Indemnitee will be entitled to participate in the defense of such matter and to employ counsel at its expense to assist in such defense (unless the indemnifying party is not actively and vigorously defending such Claim in which case the indemnifying party will be responsible for the fees, costs and expenses of Indemnitee's counsel); provided, however, that the indemnifying party will have final decision-making authority regarding all aspects of the defense of any Claim so long as such indemnifying party is actively and vigorously defending such Claim and the Indemnitee is fully and finally released from (or fully indemnified for) all liability in respect of such Claim. The Indemnitee will provide the indemnifying party with such information and assistance as the indemnifying party may reasonably request, at the expense of the indemnifying party. Losses incurred by an Indemnitee will be net of all amounts recovered under the Indemnitee's insurance (net of any increase in insurance premiums as a result thereof) and any tax benefits received by reason of such Losses.

12.4 **Settlement.** The indemnifying party will not settle any Claim made without the Indemnitee's prior written consent, not to be unreasonably withheld. If requested by the indemnifying party, the Indemnitee will, at the indemnifying party's sole cost and expense, cooperate with the indemnifying party and its counsel in contesting, defending and settling any Claim or, if appropriate and related to the Claim in question, in making any counterclaim against the third party claimant, or any cross complaint against any other party (other than an Indemnitee or its Affiliates). The indemnifying party will advance any fees, costs and expenses necessary to permit such Indemnitee to cooperate with the indemnifying party in connection with any such Claim or counterclaim.

12.5 **Waiver of Certain Damages.** NEITHER PARTY WILL BE LIABLE UNDER ANY LEGAL THEORY (WHETHER TORT, CONTRACT OR OTHERWISE) FOR SPECIAL, INDIRECT, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES ARISING OUT OF OR RELATED TO THIS AGREEMENT OR THE EXERCISE OF ITS RIGHTS HEREUNDER, INCLUDING LOST PROFITS ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, HOWEVER CAUSED, EVEN IF THE PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES (“**DAMAGES WAIVER**”), EXCEPT AS A RESULT OF A BREACH OF THE CONFIDENTIALITY AND NON-USE OBLIGATIONS IN ARTICLE 10. NOTHING IN THIS DAMAGES WAIVER IS INTENDED TO (A) LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OF ANY OF THE INDEMNITEES OR THE OBLIGATIONS OF EITHER PARTY TO INDEMNIFY THE APPLICABLE INDEMNITEES UNDER SECTION 12.1 OR SECTION 12.2, AS APPLICABLE, WITH RESPECT TO LOSSES FOR INFRINGEMENT OF INTELLECTUAL PROPERTY RIGHTS OF A THIRD PARTY, OR (B) APPLY TO ANY AMOUNTS (INCLUDING AMOUNTS UNDER ARTICLES 6, 7, 8, 9, THIS ARTICLE 12 OR ARTICLE 14) PAYABLE TO COGNATE BY ASTERIAS (PURSUANT TO STATED PAYMENT OBLIGATIONS, INCLUDING INTEREST PAYABLE FOR BREACH OF PAYMENT OBLIGATIONS AND COLLECTION COSTS PAYABLE UNDER THIS AGREEMENT) UNDER THIS AGREEMENT, INCLUDING UNDER ANY STATEMENT OF WORK.

12.6 **Limitation of Liability.** NOTWITHSTANDING ANY PROVISION HEREIN (BUT EXCLUDING A BREACH OF THE CONFIDENTIALITY AND NON-USE OBLIGATIONS IN ARTICLE 10), (A) COGNATE’S MAXIMUM AGGREGATE LIABILITY UNDER THIS AGREEMENT WILL NOT [\*\*\*]AND (B) ASTERIAS’S MAXIMUM AGGREGATE LIABILITY UNDER THIS AGREEMENT WILL NOT EXCEED [\*\*\*].

13. **Insurance.**

13.1 **Insurance.** Cognate will secure and maintain in full force and effect throughout the term of this Agreement commercial general liability insurance coverage which is customary and appropriate for a manufacturer of products like the Products and Asterias will secure and maintain in full force and effect throughout the term of this Agreement commercial general liability insurance coverage which is customary and appropriate for a drug developer of products like the Products.

13.2 **Evidence of Insurance.** Following the other party’s written request, the insured party will provide to the requesting party, a Certificate of Insurance evidencing coverage required under this Article 13.

14. **Term and Termination.**

14.1 **Term.** This Agreement will take effect as of the Effective Date and, unless earlier terminated pursuant to this Article 14, will expire on the later of (a) three (3) years from the Effective Date; or (b) the completion of Services under all SOWs executed by the parties prior to the third (3rd) anniversary of the Effective Date. The term of this Agreement as well as, if and only if Asterias so elects, the term of any then pending (i.e., executed but not yet expired or terminated) SOW, may be extended by Asterias continuously for additional two (2) year periods upon written notice to Cognate at least thirty (30) days prior to the expiration of the then-current term.

14.2 **Termination Rights.**

- (a) **Termination of the Initial SOW and Agreement Pre-SOW 2.**

(i) Termination by Asterias. Asterias will have the right to terminate the Initial SOW or[\*\*\*], to terminate this Agreement along with both the Initial SOW and SOW 2, for any reason [\*\*\*] prior written notice to Cognate[\*\*\*], in which case, the Termination Effective Date will be the end of such [\*\*\*] period unless otherwise agreed by the parties in writing.

(i i) Termination by Cognate. Cognate will have the right to terminate the Initial SOW upon written notice to Asterias if Asterias fails to cure a breach of any payment obligation [\*\*\*] receiving written notice of such breach from Cognate, in which case the Termination Effective Date will be the date Asterias receives such notice of termination (which, for clarity, does not mean the initial notice of breach) unless otherwise agreed by the parties in writing.

(iii) Effect of Termination of Initial SOW. In the event of termination of the Initial SOW under this Section 14.2(a), Asterias will (A) purchase from Cognate all inventories of materials purchased by Cognate specifically for the Initial SOW which are not, in Cognate's good faith discretion, readily returnable and (B) pay Cognate (I) all fees for Services rendered from the Effective Date up through the Termination Effective Date, together with all past due amounts and all amounts in respect of in-process Services, and (II) all out-of-pocket fees, costs and expenses actually incurred (or accrued in accordance with Cognate's standard accounting practices) by Cognate in performance of the Initial SOW up through the Termination Effective Date and, in all cases of (B)(I) and (B)(II) plus interest due on past due amounts in accordance with this Agreement or the Initial SOW. [\*\*\*]

(i v) Asterias will pay Cognate [\*\*\*] set forth in Section 14.2(a)(iii) [\*\*\*] of Cognate's transmission of the notice of termination and invoice therefor, which invoice will set out the calculation of the amounts owed pursuant to Section 14.2(a)(iii) in reasonable detail, and Asterias will pay Cognate [\*\*\*] of transmission by Cognate of Cognate's invoice therefor each month thereafter through the Termination Effective Date (or such later date when all amounts payable under Section 14.2(a)(iii) are satisfied). If Cognate receives invoices for any third party disbursements (which are payable by Asterias under 14.2(a)(iii) but not included in Cognate's invoice) after issuance of any of the foregoing invoices, the aggregate amount of such disbursements, if any, will be added to a subsequent invoice. If as of the Termination Effective Date Asterias has already paid in excess of the amount due to Cognate under this Section 14.2(a)(iii) (including, for clarity, satisfaction of all past due amounts and interest thereon), Cognate shall promptly refund to Asterias the amount of such overpayment.

(b) **Termination of Agreement and SOWs (Other than Initial SOW)**

(i) Termination by Asterias. Asterias will have the right to terminate this Agreement or any SOWs that are pending (i.e., executed but not yet expired or terminated) for any reason [\*\*\*] prior written notice to Cognate (in which case the Termination Effective Date will be the end of such [\*\*\*] period unless otherwise agreed by the parties in writing) and the right to terminate SOW 2 pursuant to the last sentence of the last paragraph of Section 8 of SOW 2 [\*\*\*] prior written notice (in which case the Termination Effective Date will be the end of such [\*\*\*] period unless otherwise agreed by the parties in writing); provided however, that if Cognate [\*\*\*] (other than with respect to the Initial SOW which the parties agree is expressly excluded from this Section 14.2(b)(i)(A)) or [\*\*\*] then Asterias will have the right to terminate this Agreement or any SOW on [\*\*\*] prior written notice (in which case the Termination Effective Date will be the end of such [\*\*\*] period unless otherwise agreed by the parties in writing) and, in all such cases, [\*\*\*].

(ii) **Termination by Cognate.** Cognate will have the right to terminate this Agreement or any SOWs that are pending by written notice to Asterias if Asterias fails to cure breach of any payment obligation [\*\*\*] receiving written notice of such breach from Cognate, in which case the Termination Effective Date will be the date Asterias receives such notice of termination (which, for clarity, does not mean the initial notice of breach) unless otherwise agreed by the parties in writing.

(iii) **Effect of Termination Under Section 14.2(b).** In the event of termination under this Section 14.2(b), Asterias will (A) purchase from Cognate all in-process Product and inventories of Product Manufactured under the applicable SOW(s) up through the Termination Effective Date and (B) pay Cognate (I) all fees for all Services and all fees for all in-process Services, in all cases rendered under the applicable SOWs from the Effective Date up through the Termination Effective Date and (II) all out-of-pocket fees, costs and expenses actually incurred (or accrued in accordance with Cognate's standard accounting practices) by Cognate in performance of the applicable SOW(s) up through the Termination Effective Date and, in all cases of (B)(I) and (B)(II) plus interest due on past due amounts in accordance with this Agreement or the applicable SOW. The foregoing shall be subject to [\*\*\*]. Notwithstanding any of the foregoing to the contrary, in no event shall Asterias be obligated to pay or be liable for any amount or item more than once (e.g., a material purchased under (A) may also be an expense under (B)(II) and may also be included in fees charged under (B)(I) but Asterias should only have to pay such amount once) nor for any amount or item to the extent already included in other fees or payments previously satisfied by Asterias.

(iv) Asterias will pay Cognate [\*\*\*] set forth in Section 14.2(b)(iii) [\*\*\*] of Cognate's transmission of the notice of termination and invoice therefor, which invoice will set out the calculation of the amounts owed pursuant to Section 14.2(b)(iii) in reasonable detail, and Asterias will pay Cognate [\*\*\*] of transmission by Cognate of Cognate's invoice therefor each month thereafter through the Termination Effective Date or such later date when all amounts payable under Section 14.2(b)(iii) are satisfied. If Cognate receives invoices for any third party disbursements (which are payable by Asterias under 14.2(b)(iii) but not included in Cognate's invoice) after issuance of any of the foregoing invoices, the aggregate amount of such disbursements, if any, will be added to a subsequent invoice. [\*\*\*].

(c) **Termination of Agreement or any SOW (including the Initial SOW) by Either Party.** Either party will have the right to terminate this Agreement or any signed SOWs that are pending by written notice to the other party upon the occurrence of any of the following:

(i) the other party files a petition in bankruptcy, or applies for or consents to the appointment of a receiver or trustee, or enters into an agreement making an assignment for the benefit of creditors, or becomes subject to involuntary proceedings under any bankruptcy or insolvency law (which proceedings remain undismissed for [\*\*\*]);

(ii) the other party fails to cure a material breach of this Agreement [\*\*\*] receiving written notice from the other party of such breach (other than, for clarity, Asterias's breach of a payment obligation which Asterias must cure [\*\*\*]); or

(iii) a *force majeure* event that will, or continues to, prevent performance (in whole or substantial part) of this Agreement or any pending SOW for a period of [\*\*\*]. In the case of a *force majeure* event relating solely to a pending SOW, the right to terminate will be limited to such SOW.

The Termination Effective Date of a termination under any clause of this Section 14.2(c) will be effective upon receipt by the non-terminating party of the written notice of termination (which, for clarity, does not mean the initial notice of breach under Section 14.2(c)(ii)), unless otherwise agreed by the parties in writing. The written notice of termination delivered under this Section 14.2(c) will set forth the grounds for termination. The effect of termination under this Section 14.2(c) will be governed by the terms and conditions set forth in (x) Section 14.2(a)(iii) if either party terminates this Agreement (or any SOW) under this Section 14.2(c) prior to completion of the Initial SOW and (y) by Section 14.2(b)(iii) if either party terminates this Agreement (or any SOW) following completion of the Initial SOW.

14.3 **Actions of Cognate on Termination.**

- (a) From the first notice of termination until the Termination Effective Date, [\*\*\*].
- (b) From and after the Termination Effective Date, Cognate [\*\*\*] will use its commercially reasonable efforts to:
  - (i) [\*\*\*];
  - (ii) inform Asterias of any irrevocable commitments made in connection with any pending SOW(s) prior to termination;
  - (iii) at Asterias's option, return to Asterias or another third party or to the vendor, in each case at Asterias's cost and, as applicable, for storage or use or for a refund, to the extent a refund is available, all unused, unopened materials in Cognate's possession that are for any pending SOW and that do not, in each case, constitute irrevocable commitments;
  - (iv) inform Asterias of the cost of any remaining unused, unreturnable materials ordered pursuant to any pending SOW(s), and all residual inventories of work in progress; and
  - (v) [\*\*\*].

14.4 **Return of Materials/Confidential Information.** Upon the expiration or termination of this Agreement for any reason, Recipient agrees, except as otherwise provided in this Agreement (including without limitation in order to exercise any surviving licenses expressly granted hereunder (such that Confidential Information that is the subject of a surviving license may be retained and used by the licensee according to such license)), or as otherwise agreed in writing by the parties, and to the extent not prohibited by Applicable Law, to return to Discloser all documentation or other tangible evidence or embodiment of Discloser's Confidential Information that is not required by law to be retained by Recipient and not to Use such Confidential Information, unless otherwise agreed. Cognate will also promptly return to Asterias all Asterias Materials, Asterias Equipment, retained samples, data, reports and other property, information and know-how in recorded form that was provided by Asterias that are owned by or licensed to Asterias; provided that Asterias will be responsible for all costs and expenses associated with the return to Asterias of Asterias Materials, Asterias Equipment and/or Asterias Confidential Information by Cognate pursuant to this Agreement to the extent the return of any such items was not already accomplished prior to termination or expiration or already provided for in a SOW. Asterias will also promptly return to Cognate all samples, data, reports and other property, information and know-how that was provided by or on behalf of Cognate or is proprietary to or owned or licensed by Cognate, or developed in the performance of the Services, excluding, however in all such cases any Product Inventions and excluding any of the foregoing items that are the subject of surviving licenses expressly granted to Asterias hereunder, and Asterias shall not thereafter use or exploit any of the foregoing items required to be returned; provided that Cognate will be responsible for all costs and expenses associated with the return to Cognate of Cognate Materials, and/or Cognate Confidential Information by Asterias pursuant to this Agreement. Cognate and Asterias will take such actions and sign and execute those certifications or other instruments and documents as the other may reasonably require to evidence compliance with this Section 14.4.

14.5 **Preservation of Rights.** Notwithstanding any other provision of this Agreement including for clarity, any SOW, termination or expiration of this Agreement (or any SOW) in whole or in part will be without prejudice to Cognate's and Asterias's right to receive all payments accrued and unpaid through the Termination Effective Date (or expiration, as applicable); Cognate's and Asterias's remedy in respect of any breach by the other party of any provision of this Agreement or for clarity, any SOW (or any other agreement executed by the parties ancillary hereto); each provision that expressly or necessarily calls for performance (including Cognate's right to reimbursement for fees, costs and expenses associated with such performance) after the Termination Effective Date (or expiration as applicable); and each provision that survives pursuant to Section 14.6.

14.6 **Survival.** Expiration or termination of this Agreement or, for clarity, any SOW for any reason will not relieve either party of any right or obligation accruing prior to such expiration or, if earlier, prior to the Termination Effective Date. [\*\*\*] and any obligation, or liability of either party under this Agreement including, for clarity, any SOW or under any ancillary agreement executed in connection herewith, or any subsequent addenda hereto or thereto, that in all such cases by its nature and intent remains valid after termination or expiration will survive the Termination Effective Date or expiration of this Agreement or, for clarity, any pending SOW. Covenants will expire in accordance with their respective terms (or, if silent as to expiration or termination and not otherwise addressed in this Section 14.6, such covenants shall expire upon the expiration or termination of this Agreement), Sections 12.1 through 12.4 will survive until the [\*\*\*] anniversary of

such termination or expiration and Sections 11.1, 11.2 and 11.3 will survive until the [\*\*\*] of such termination or expiration.

15. **Miscellaneous.**

15.1 **Independent Contractor.** All Services will be rendered by Cognate as an independent contractor for federal, state and local income tax purposes and for all other purposes. This Agreement does not create an employer-employee, partnership, agency or joint venture relationship between Asterias on the one hand and Cognate or any employee, subcontractors, Affiliate of Cognate, or any Cognate personnel on the other. Neither party hereto will have any express or implied right or authority to assume or create any obligations on behalf of, or in the name of, the other party or to bind the other party to any contract, agreement or undertaking unless expressly so authorized in writing by the other party.

15.2 **Force Majeure.** Except as otherwise expressly set forth in this Agreement, neither party will have breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement when such failure or delay is caused by or results from causes beyond the reasonable control of the affected party, including fire, floods, embargoes, shortages, epidemics, quarantines, war, acts of war (whether war be declared or not), insurrections, riots, civil commotion, strikes, acts of God or acts, omissions, or delays in acting, by any governmental authority ("*force majeure*"). The party affected by any event of *force majeure* will promptly notify the other party, explaining the nature, details and expected duration of the *force majeure* event. Such party will also notify the other party from time to time as to when the affected party reasonably expects to resume performance in whole or in part of its obligations under this Agreement, and to notify the other party of the cessation of any such event. A party affected by an event of *force majeure* will use its commercially reasonable efforts to remedy, remove, or mitigate such event and the effects of it with all reasonable dispatch. If a party anticipates that an event of *force majeure* may occur, such party will notify the other party of the nature, details and expected duration of the *force majeure* event. Upon termination of the event of *force majeure*, the performance of any suspended obligation or duty will promptly recommence.

15.3 **Notices.** All notices must be in writing and sent to the address for the recipient set forth in this Agreement below or at such other address as the recipient may specify in writing under this procedure. All notices must be given by (a) personal delivery, with receipt acknowledged; or (b) prepaid certified or registered mail, return receipt requested; or (c) prepaid recognized next business day or express delivery service. Notices will be effective upon receipt or at a later date stated in the notice.

If to Cognate, to:

7513 Connelley Drive, Suite I  
Hanover MD 21076  
Attention: CEO

If to Asterias, to:

**For General Notices:**  
Asterias Biotherapeutics  
Attn: Legal/Contracts  
6300 Dumbarton Circle  
Fremont, CA 94555  
[legal@asteriasbio.com](mailto:legal@asteriasbio.com)  
(510) 456-3800

**For Invoices:**  
Asterias Biotherapeutics  
Attn: Accounts Payable  
6300 Dumbarton Circle  
Fremont, CA 94555  
[accountspayable@asteriasbio.com](mailto:accountspayable@asteriasbio.com)  
(510) 456-3800

15.4 **Assignment.** This Agreement may not be assigned or otherwise transferred by either party without the prior written consent of the other party, except that either party may assign this Agreement without consent to any Affiliate of the transferring party or in connection with a merger, acquisition, reorganization or sale of the transferring party or substantially all the assets of the transferring party to which this Agreement relates; provided, however, [\*\*\*]. Any purported assignment in violation of the preceding sentence will be void.

15.5 **Entire Agreement.** This Agreement, together with the attached Appendices and any executed SOWs and Change Orders, each of which are incorporated into this Agreement, constitute the entire agreement between the parties with respect to the specific subject matter of this Agreement and all prior agreements with respect such subject matter, including that certain Mutual Confidentiality and Nondisclosure Agreement dated as of August 10, 2015, by and between the parties (which Mutual Confidentiality and Nondisclosure Agreement shall remain in effect solely with respect to the period prior to the Effective Date of this Agreement and all Confidential Information disclosed thereunder shall be subject to the confidentiality provisions of this Agreement after the Effective Date), are superseded.

15.6 **No Modification.** This Agreement and and/or any SOW or Quality Agreement may be changed only by a writing signed by authorized representatives of each party.

15.7 **Severability; Reformation.** Each provision in this Agreement is independent and severable from the others, and no provision will be rendered unenforceable because any other provision is found by a proper authority to be invalid or unenforceable in whole or in part. If any provision of this Agreement is found by such an authority to be invalid or unenforceable in whole or in part, such provision will be changed and interpreted so as to best accomplish the objectives of such unenforceable or invalid provision and the intent of the parties, within the limits of Applicable Law.

15.8 **Governing Law.** This Agreement and any disputes arising out of or relating to this Agreement will be governed by, construed and interpreted in accordance with the laws of the State of Delaware, without regard to any choice of law principle that would require the application of the law of another jurisdiction.

15.9 **Waiver of Rights.** Any delay in enforcing a party's rights under this Agreement, or any waiver as to a particular default or other matter, will not constitute a waiver of such party's rights to the future enforcement of its rights under this Agreement, except with respect to an express written waiver relating to a particular matter for a particular period of time signed by an authorized representative of the waiving party, as applicable.

15.10 **No Benefit to Third Parties.** The representations, warranties, covenants and agreements set forth in this Agreement are for the sole benefit of the parties hereto and their successors and permitted assigns, and they will not be construed as conferring any rights on any other Persons.

15.11 **Construction; Headings.** This Agreement has been prepared jointly and will not be strictly construed against either party. The article and section headings of this Agreement are included solely for convenience of reference and will not control or affect the meaning or interpretation of any of the provisions of this Agreement. When used in this Agreement, (a) the singular includes the plural, the plural includes the singular, the use of any gender is applicable to all genders, (b) the word "or" has the inclusive meaning represented by the phrase "and/or", unless the context expressly requires otherwise (e.g., if the word "either" is used in the applicable phrase), (c) the words "include," "includes" and "including" are deemed to be followed by the phrase "but not limited to" even when not followed by such words and (d) references to "cost" or "cost and expense" with respect to Asterias are deemed to mean at Asterias's sole cost and expense.

15.12 **SEC Filings.** If Asterias determines that it is legally required to file this Agreement (or a description of the terms and conditions of this Agreement) with the Securities and Exchange Commission (SEC), Asterias will use its best efforts to seek confidential treatment of the terms of this Agreement (or such description) pursuant to Applicable Law, it being understood that Asterias cannot guaranty that its request will be successful. Prior to filing such confidential treatment request, Asterias will provide Cognate with the proposed filing [\*\*\*] days in advance of submission. Cognate will provide Asterias with instructions regarding any provisions for which it would like to seek confidential treatment [\*\*\*] days. Asterias will seek such confidential treatment in accordance with Cognate's reasonable instructions provided within such timeframe. [\*\*\*].

15.13 **Certain Regulatory Filings.** If the Services relate to a clinical phase III project or if Cognate is selected as one of the commercial sites of manufacture of the Product which is the subject of the Services under this Agreement, then reasonably promptly, but not later than the later to occur of (a) the execution of a SOW for Services relating to a phase III project or commercial manufacture of Products, or (b) or [\*\*\*] prior to filing with any relevant regulatory authority, any clinical trial application including (i) any amendment to any US Investigational New Drug Application or EU Investigational Medicinal Product Dossier seeking permission to initiate a Phase III trial, (ii) any Biologics License Application, or (iii) any documentation that is or is equivalent to such an application, Asterias will give Cognate a copy of the quality module (Drug Product section) of the common technical document or any equivalent document that relates to any such application (all such documentation herein referred to as the "Application"). This disclosure will permit Cognate to verify that the Application accurately describes the Services that Cognate has performed and the manufacturing and testing processes that Cognate will perform under this Agreement.

15.14 **Further Assurances.** Each party will promptly do and perform all further acts, and execute and deliver all further documents required by law or reasonably requested by the other party to establish, maintain and protect the respective rights and remedies of the parties and to carry out and effect the intent and purpose of this Agreement.

15.15 **Counterparts.** This Agreement may be executed in any number of counterparts, each of which will be deemed an original and all of which together will constitute one and the same instrument.

**[Remainder of page left blank intentionally]**

**IN WITNESS WHEREOF**, the parties hereto have caused this Agreement to be executed by their duly authorized representatives as of the date first above written.

**ASTERIAS BIOTHERAPEUTICS, INC.**

By /s/ Stephen L. Cartt

Print Name Stephen L. Cartt

Title CEO

**COGNATE BIOSERVICES, INC.**

By /s/ J. Kelly Ganjei

Print Name J. Kelly Ganjei

Title Chief Executive Officer

**APPENDIX A**

**INITIAL  
STATEMENT OF WORK**

**(Separately Attached)**

**APPENDIX A**  
**INITIAL**  
**STATEMENT OF WORK**

THIS INITIAL STATEMENT OF WORK (this “SOW 1”) is by and between ASTERIAS BIOTHERAPEUTICS, INC. (“Asterias”) and COGNATE BIOSERVICES, INC. (“Cognate”), and effective as of the last date of signature below, and upon execution will be incorporated into the Development and Manufacturing Services Agreement between Asterias and Cognate dated August 3, 2016 (the “Agreement”). Capitalized terms used in this SOW 1 that are not otherwise defined herein (including service items defined in the tables set forth in this SOW 1) will have the same meanings as set forth in the Agreement.

Asterias hereby engages Cognate to provide Services, as follows:

**1. Product.**

“AST-VAC1” and “Product” each mean a mature dendritic cell (“DC”) preparation that is loaded with telomerase and a sequence called LAMP in such amounts and in such configurations as are, in each case, specific to AST-VAC1 for use as an immunotherapy product which is prepared on a patient-specific basis from autologous leukapheresis product.

**2. Services.** Cognate will provide the following Services to Asterias:

Cognate will, in consideration for payment in full, including the milestone payment set forth in Section 4 of this SOW 1 [\*\*\*] provide, under accelerated circumstances the process development studies outlined in this SOW 1 (including preparation of the reports associated with each of such studies) in support of Asterias’s clinical and commercial development activities.

**2.1. Technology Transfer Services and Payments:**

**2.1.1 Technology Transfer Part 1 – Transfer from Asterias to Cognate Process Development**

Initial aspects of the technology transfer process will commence in this SOW 1. Technology Transfer Part 1 is focused on developing documentation required for the studies outlined in this SOW 1, and for the AST-VAC1 manufacturing assessment aimed to improve process robustness for Phase III trial(s) and commercial manufacturing – this is critical for the testing and development of the studies outlined in this SOW 1. The remainder of technology transfer will occur under that certain Statement of Work 2, effective as of August 3, 2016, by and between Asterias and Cognate (“SOW 2”) as Technology Transfer Part 2. Asterias will pay [\*\*\*] for Technology Transfer Part 1, which will include the following items:

- In depth review of AST-VAC1 process and analytical details
- Performance of gap assessment, including sourcing of critical reagents and critical review of each step of the process
- Performance of manufacturing assessment to evaluate options for [\*\*\*] (most of these development activities are outlined in this SOW 1, however, the manufacturing assessment may reveal additional process improvements for Asterias to consider, the fees, costs, expenses and payment terms for which will be detailed in a subsequent SOW.)

2.1.2 [\*\*\*]

A. Asterias Desires [\*\*\*]

- (i) If, during the term of this SOW 1, Asterias provides Cognate a written request [\*\*\*] described in this SOW 1 [\*\*\*] Cognate has performed the Services in all material respects [\*\*\*] of the Agreement or this SOW 1), then Asterias will pay Cognate [\*\*\*]. If Asterias requests [\*\*\*] after the [\*\*\*], the applicable [\*\*\*] provisions of SOW 2 shall apply with respect to [\*\*\*] Development Services [\*\*\*] Manufacturing Services [\*\*\*], in each case up to the date [\*\*\*].
- (ii) The [\*\*\*] will cover [\*\*\*] of [\*\*\*] Services, commencing [\*\*\*] choosing as set forth in [\*\*\*] the Agreement (other than travel and other reasonable and documented out-of-pocket disbursements which are addressed below in this clause (ii)) [\*\*\*] Development Services [\*\*\*]. Asterias will also be responsible for all reasonable and documented out-of-pocket travel and other reasonable and documented out-of-pocket disbursements as required for Cognate's performance of such Services and actually incurred by Cognate, whenever billed to Cognate, which disbursements will be invoiced to Asterias once Cognate has been billed for such disbursements (provided that any such disbursements in excess of [\*\*\*] in the aggregate require Asterias' prior written consent, not to be unreasonably withheld, before Asterias is obligated to pay for them). [\*\*\*] within the [\*\*\*] period covered by [\*\*\*] (despite Cognate's commercially reasonable efforts to do so and compliance with the Agreement and this SOW 1), Cognate may charge Asterias [\*\*\*] to complete [\*\*\*] (plus travel and all other reasonable disbursements in accordance with the foregoing). Upon request, [\*\*\*] prior written approval [\*\*\*]. If Cognate's failure to complete [\*\*\*] is due to a failure of Cognate to use commercially reasonable efforts or a breach of this Agreement or SOW 1 by Cognate, [\*\*\*], after which time the foregoing provisions regarding [\*\*\*] shall apply in accordance with their respective terms.

Any expenses or disbursements under any section of this SOW 1 that are accrued by Cognate will be accrued in accordance with standard accounting principles and any expenses billed to Asterias under this SOW 1 by Cognate at the time of accrual that are subsequently not actually incurred will be refunded to Asterias promptly after Cognate receives the benefit of such expense no longer being charged (e.g. upon Cognate's receipt of a refund).

- (iii) Cognate will provide Asterias with invoices (consistent with the foregoing) and reasonable supporting documentation and Asterias will satisfy in full the invoiced fees, costs and expenses of [\*\*\*] such that payment is received by Cognate [\*\*\*] delivery by Cognate to Asterias of each such invoice. Asterias agrees that its failure to timely satisfy in full any such invoice may result in delay of the progress or completion [\*\*\*], in which case, Cognate will not be responsible.

B. Asterias Desires [\*\*\*]

- (i) If, during the term of this SOW 1, Asterias provides Cognate a written request [\*\*\*] described in this SOW 1 [\*\*\*] to Asterias or its designee, and Cognate has not performed the Services in all material respects [\*\*\*] then Asterias will pay Cognate [\*\*\*]. If Asterias [\*\*\*] Asterias or its designee after the [\*\*\*], the applicable [\*\*\*] provisions of SOW 2 shall apply with respect to both [\*\*\*] Development Services [\*\*\*] Manufacturing Services [\*\*\*] in each case up to the date of [\*\*\*].
- (ii) The [\*\*\*] will cover [\*\*\*] of [\*\*\*] Services, commencing [\*\*\*] choosing as set forth in [\*\*\*] the Agreement (other than travel and other reasonable and documented out-of-pocket disbursements which are addressed below in this clause (ii)) to [\*\*\*] Development Services [\*\*\*]. Asterias will also be responsible for all reasonable and documented out-of-pocket travel and other disbursements as required for Cognate's performance of such Services and actually incurred by Cognate, whenever billed to Cognate, which disbursements will be invoiced to Asterias once Cognate has been billed for such disbursements (provided that any such disbursements in excess of [\*\*\*] in the cumulative aggregate require Asterias' prior written consent, not to be unreasonably withheld, before Asterias is obligated to pay for them). [\*\*\*] period covered by [\*\*\*] (despite Cognate's commercially reasonable efforts to do so and compliance with the Agreement and this SOW 1), Cognate may charge Asterias [\*\*\*], to complete [\*\*\*] (plus travel and all other reasonable disbursements in accordance with the foregoing). Upon request, [\*\*\*] prior written approval [\*\*\*]. If Cognate's failure to complete [\*\*\*] is due to a failure of Cognate to use commercially reasonable efforts or a breach of this Agreement or SOW 1 by Cognate, then [\*\*\*] in full [\*\*\*], after which time the foregoing provisions regarding [\*\*\*] shall apply in accordance with their terms. For clarity, any costs or expenses billed to Asterias by Cognate at the time of accrual that are subsequently not actually incurred by Cognate or adjusted downward in Cognate's books, Cognate will refund to Asterias the amount of such costs and expenses not incurred or adjusted as soon as Cognate receives the benefit of such costs or expenses no longer being charged or such costs or expenses are adjusted downward (e.g. upon Cognate's receipt of a refund).

- (iii) Cognate will provide Asterias with invoices (consistent with the foregoing) and reasonable supporting documentation and Asterias will satisfy in full the invoiced fees, costs and expenses of [\*\*\*] such that payment is received by Cognate [\*\*\*] delivery by Cognate to Asterias of each such invoice. Asterias agrees that its failure to timely satisfy in full any such invoice may result in delay of the progress or completion [\*\*\*], in which case, Cognate will not be responsible.

Service Item	Payment Amount	Payment Terms
[***]		
[***]	[***]	[***]
[***]	[***]	[***]
Travel and Miscellaneous costs in addition to the [***] or [ * * * ], as applicable	[***]	[***]

**2.2. Process Development and Optimization Studies:**

Upon execution of this SOW 1, Cognate will commence the studies described in this Section 2.2 of this SOW 1.

Cognate has assessed the information provided in the Asterias request for proposals (“RFP”) and other confidential materials provided by Asterias for the generation of the prices listed in this Section 2.2. of this SOW 1 (Process Development and Optimization Studies); provided, that Asterias understands and hereby agrees that all of the fees and timelines set forth in this Section 2.2 are based on Cognate’s reasonable estimate and are subject to amendment following further evaluation. Asterias will be responsible for all fees, costs and expenses of all assays performed in connection with this SOW 1 (including, for clarity, all assays referenced in other sections of this SOW 1 or otherwise performed pursuant to the mutual agreement of Asterias and Cognate); provided that any such fees, costs and expenses to be paid to Cognate for Cognate’s performance of assays or paid by Asterias to a third party provider pursuant to an agreement between Asterias and such third party provider, shall be either in such amount as specified in this SOW 1 or else as in such amounts as are agreed to by the parties. Asterias understands and hereby agrees that any amendments, if necessary, will be captured in a subsequent Change Order that is agreed to and executed by both parties and that Asterias will be responsible for any increases to the fees, costs and expenses set forth in such Change Order.

**2.2.1. Placebo Formulation Development:**

Asterias has requested (and Cognate has agreed) that Cognate develop a matching placebo for AST-VAC1 that appears as identical as possible to the final product with respect to its physical characteristics, including color, turbidity, viscosity and volume. The placebo will not contain any cellular material and will be formulated using pharmacologically inert materials that are Generally Recognized as Safe (GRAS). Possible fine tuning of the placebo may be required at the completion of the process development studies, if the output of said studies requires a change to the physical characteristics of the final product.

Development work will include formulation of the placebo within the above stated parameters. Assays for turbidity and viscosity will be determined and defined as Cognate’s PD team fully understands the sample matrix for the placebo for use in later comparability studies. Appearance, pH, and osmolality parameters will be determined as part of the Placebo Formulation Study. Development and testing can be expected to take [\*\*\*] with deliverables of a placebo formulation in a study report. [\*\*\*] of this study [\*\*\*] related to [\*\*\*] all of which will be invoiced to Asterias pursuant to Section 2.4 of this SOW 1. Additionally, if third-party providers are required to support any aspect of this study, Asterias will execute agreements with such third party providers in connection therewith. Asterias will be responsible for the performance by such third party providers and all costs and expenses in respect of such performance.

**Placebo Comparability Testing**

To ensure the placebo appears as identical as possible to the product, the final formulation will undergo comparability testing for color, turbidity, and viscosity. Comparability testing will be done using [\*\*\*] lots of placebo as compared to [\*\*\*] lots of AML patient-derived VAC1 final product with the number of vials to be tested to be jointly defined – this number shall be determined based on the batch size/number of vials produced. Testing, with results delivered as a final report, can be expected to take [\*\*\*].

Placebo Formulation Development			
Phase	Time	Description	Payment/Term
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
Documents Reports	[***]	[***]	[***]

**2.2.2. Placebo Stability Study:**

The final formulation of placebo will undergo a study to support the stability of the placebo over the duration of its intended use. The placebo used for this study will be packaged and stored similar to final product. At least [\*\*\*] lots of placebo will be used in the stability study. [\*\*\*] vials of placebo will be tested at each time point (see table 1) by the following assays: [\*\*\*] Deliverables for this study include a study plan and report.

The timeline for this study is determined by the protocol, with a total cost for [\*\*\*] thereafter, plus [\*\*\*] priced at [\*\*\*]. Asterias will execute an agreement with [\*\*\*] in connection with the sterility assay and will be responsible for the performance by [\*\*\*] and will pay all costs and expenses in respect of the sterility assay to [\*\*\*] directly.

Time Point	[***]	[***]							
		[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]

Description	Payment	Payment Terms
Placebo Stability Study [***]	[***]	[***]
Placebo Stability Study [***]	[***]	[***]
Interim Report	[***]	[***]
Stability Report (upon request from Asterias)	[***]	[***]

2.2.3. [\*\*\*] **Optimization and Improvement Studies:**

Cognate will perform certain [\*\*\*] optimization studies to obtain more consistent and improved [\*\*\*] via the study of [\*\*\*]. These efforts will be closely coordinated with Asterias' efforts to [\*\*\*]. Cognate estimates the [\*\*\*] improvement study to take approximately [\*\*\*], including technology transfer, with a total cost of [\*\*\*]. The time table in section 3 provides [\*\*\*] for this study to account for potential delays caused by external vendors and/or to provide the client with more time to make data-driven decisions throughout the course of development. The [\*\*\*] Optimization and Improvement Studies will initiate once Asterias has approved the study design/protocol – the final study timelines will be documented in the mutually agreed to study design/protocol. [\*\*\*] the aggregate fees, costs and expenses of this study (in the amounts specified in the table below) will be invoiced to Asterias [\*\*\*].

The study will include 4 phases of work and documentation creation. Phase 1 of the [\*\*\*] study will assess suitability and risk considerations in the effort to identify potential process changes along with risk associated with each change - study design will also be initiated in Phase 1. Phase 2 will focus on fine tuning of the study design and development. Upon completion of the development studies, Cognate will initiate comparability testing including comparability runs and other appropriate testing (Phase 3) to verify that change(s) to process do not change AST-VAC1. The final timeline for the study and the criteria for assessment of comparability will be agreed in writing between Cognate and Asterias in the approved study design/protocol for the [\*\*\*] Optimization and Improvement Studies. Upon completion of Phase 3, Cognate will, at the direction of Asterias, develop new Specifications, adjust BPR and draft the final comparability reports.

[***] Optimization and Improvement Studies			
[***]	[***]	[***]	Payment
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
<b>Total Cost</b>			[***]

2.2.4. [\*\*\*] Studies:

Cognate will perform certain [\*\*\*] studies that are intended to [\*\*\*]. Cognate estimates the [\*\*\*] Studies will take approximately [\*\*\*], including technology transfer, with a total cost of [\*\*\*]. The time table in Section 3 provides [\*\*\*] for this study to account for potential delays caused by external vendors and/or provides extra time to provide the client with more time to make data-driven decisions throughout the course of development. The [\*\*\*] Studies will initiate once Asterias has approved the study design/protocol – the final study timelines will be documented in the mutually agreed to study design/protocol. [\*\*\*] the aggregate fees, costs and expenses of this study (in the amounts specified in the table below) will be invoiced to Asterias [\*\*\*].

The study will include 4 phases of work and documentation creation. Phase 1 of the [\*\*\*] studies will assess suitability and risk considerations in the effort to identify potential process changes along with risk associated with each change - study design will also be initiated in Phase 1. Phase 2 will focus on fine tuning of the study design and development - depending on the number of systems in development, the timeline may vary from [\*\*\*]. Upon completion of the development studies, Cognate will initiate comparability testing including comparability runs and other appropriate testing (Phase 3) to verify that change(s) to process do not change AST-VAC1. The final timeline for the study and the criteria for assessment of comparability will be agreed in writing between Cognate and Asterias in the approved study design/protocol for these studies. Upon completion of Phase 3, Cognate will, at the direction of Asterias, develop new Specifications, adjust BPR and draft the final comparability reports.

[***] Studies			
[***]	[***]	[***]	Payment
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
<b>Total Cost</b>			[***]

2.2.5. [\*\*\*] Evaluation:

Cognate will perform certain [\*\*\*] studies to [\*\*\*]. The estimated timeline for these studies, including technology transfer, is [\*\*\*], with a total cost of [\*\*\*]. The time table in Section 3 provides [\*\*\*] for this study to account for potential delays and/or lead times for the sourcing of certain cGMP materials. The [\*\*\*] Studies will initiate once Asterias has approved the study design/protocol – the final study timelines will be documented in the mutually agreed to study design/protocol. [\*\*\*] the aggregate fees, costs and expenses of this study (in the amounts specified in the table below) will be invoiced to Asterias [\*\*\*].

The study will include 4 phases of work and documentation creation. Phase I of the [\*\*\*] studies and [\*\*\*] will assess suitable US and EU compliant media and reagent alternatives and risk considerations in the effort to identify potential process changes along with risk associated with each change - study design will also be initiated in Phase 1. Phase 2 will focus on fine tuning the study design and development. The Phase 2 timeline may extend beyond [\*\*\*] depending on the number of media and reagent alternatives under development and the time required for supplier to send samples for testing. Upon completion of the development studies, Cognate will initiate comparability testing including comparability runs and other appropriate testing (Phase 3) to verify that change(s) to process do not change AST-VAC1. The final timeline for the study and the criteria for assessment of comparability will be agreed in writing between Cognate and Asterias in the approved study design/protocol for these studies. Upon completion of Phase 3, Cognate will, at the direction of Asterias, develop new Specifications, adjust BPR and draft the final comparability reports.

[***] Evaluation			
[***]	[***]	[***]	Payment
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
Total Cost			[***]

2.2.6. [\*\*\*] Studies:

Cognate will perform certain [\*\*\*] studies to compare the effect parameters of various process points such as [\*\*\*]. Cognate will work to support Asterias in optimizing [\*\*\*]. To the extent possible, the [\*\*\*] Studies will be performed [\*\*\*]. The estimated timeline for [\*\*\*] studies, including technology transfer, is [\*\*\*], with a total cost of [\*\*\*]. The [\*\*\*] Studies will initiate once Asterias has approved the study design/protocol – the final study timelines will be documented in the mutually agreed to study design/protocol. [\*\*\*] the aggregate fees, costs and expenses of this study (in the amounts specified in the table below) will be invoiced to Asterias [\*\*\*].

The study will include 4 phases of work and documentation creation. Phase 1 of the [\*\*\*] studies will assess suitability and risk considerations in an effort to identify potential process changes along with risk associated with each change - study design will also be initiated in Phase 1. Phase 2 will focus on fine tuning of the study design and development. Upon completion of the development studies, Cognate will initiate comparability testing including comparability runs and other appropriate testing (Phase 3) to verify that change(s) to process do not change AST-VAC1. The final timeline for the study and the criteria for assessment of comparability will be agreed in writing between Cognate and Asterias in the approved study design/protocol for these studies. Upon completion of Phase 3, Cognate will, at the direction of Asterias, develop new Specifications, adjust BPR and draft the final comparability reports.

[***] Studies			
[***]	[***]	[***]	Payment
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
<b>Total Cost</b>			[***]

2.2.7. [\*\*\*] Studies

Cognate will perform [\*\*\*] studies to investigate the use of [\*\*\*]. With the incorporation of a best-in-class system, Cognate aims to support Asterias in [\*\*\*]. The estimated timeline for the accelerated [\*\*\*] studies is [\*\*\*] (assuming no equipment or material [\*\*\*]), including technology transfer, with a total cost of [\*\*\*]. The time table in Section 3 of this SOW 1 provides [\*\*\*] for this study to account for delays caused by [\*\*\*] vendors and lead-times and/or to provide the client with more time to make data-driven decisions. The [\*\*\*] will initiate once Asterias has approved the study design/protocol – the final study timelines will be documented in the mutually agreed to study design/protocol. [\*\*\*] the aggregate fees, costs and expenses of this study (in the amounts specified in the table below) will be invoiced to Asterias [\*\*\*].

The study will include 4 phases of work and documentation creation. Phase 1 of the [\*\*\*] studies will assess suitable technologies and risk considerations in the effort to identify potential process changes along with risk associated with each change - study design and necessary 3<sup>rd</sup> party partnerships will also be initiated in Phase 1. Phase 2 will focus on fine tuning of the study design and development in partnership with the selected technology provider. Upon completion of the development studies, Cognate will initiate comparability testing including comparability runs and other appropriate testing (Phase 3) to verify that change(s) to process do not change AST-VAC1. The final timeline for this study and the criteria for assessment of comparability will be agreed in writing between Cognate and Asterias in the approved study design/protocol for these studies. Upon completion of Phase 3, Cognate will, at the direction of Asterias, develop new Specifications, adjust BPR and draft the final comparability reports.

[***] Studies			
[***]	[***]	[***]	Payment
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
Total Cost			[***]

2.2.8. [\*\*\*] Studies:

Cognate will perform certain [\*\*\*] studies to investigate the [\*\*\*]. The estimated timeline for the functional closure studies is [\*\*\*], including technology transfer, with a total cost of [\*\*\*]. The time table in Section 3 of this SOW 1 provides [\*\*\*] for this study. [\*\*\*] are for preliminary work that will be done early in the development timeline and then the final [\*\*\*] work will take place at a later date [\*\*\*]. The [\*\*\*] will initiate once Asterias has approved the study design/protocol – the final study timelines will be documented in the mutually agreed to study design/protocol. [\*\*\*] the aggregate fees, costs and expenses of this study (in the amounts specified in the table below) will be invoiced to Asterias [\*\*\*], [\*\*\*] final comparability report described in Section 2.2.10 below. [\*\*\*].

The study will include 4 phases of work and documentation creation. Phase 1 of the [\*\*\*] studies will assess suitable technologies/closure methods and risk considerations in the effort to identify potential process changes along with risk associated with each change – study will also be initiated in Phase 1. Phase 2 will focus on fine tuning of the study design. Upon completion of the development studies, Cognate will initiate comparability testing including comparability runs and other appropriate testing (Phase 3) to verify that change(s) to process do not change AST-VAC1. The final timeline for this study and the criteria for assessment of comparability will be agreed in writing between Cognate and Asterias in the approved study design/protocol for these studies. Upon completion of Phase 3, Cognate will, at the direction of Asterias, develop new Specifications, adjust BPR and draft the final comparability reports.

[***] Studies			
[***]	[***]	[***]	Payment
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
Total Cost			[***]

2.2.9. Improving [\*\*\*]

Cognate will perform a series of studies to improve [\*\*\*]. Through these studies Cognate proposes to investigate [\*\*\*]. The estimated timeline for these studies is [\*\*\*], including technology transfer, with a total cost of [\*\*\*]. The [\*\*\*] studies will initiate once Asterias has approved the study design/protocol – the final study timelines will be documented in the mutually agreed to study design/protocol. [\*\*\*] the aggregate fees, costs and expenses of this study (in the amounts specified in the table below) will be invoiced to Asterias [\*\*\*] final comparability report described in Section 2.2.10 below. [\*\*\*].

The study will include 4 phases of work and documentation creation. Phase I of the [\*\*\*] studies will assess suitable technologies and methods and risk considerations in the effort to identify potential process changes along with risk associated with each change – study will also be initiated in Phase I. Phase II will focus on fine tuning of the study design. Upon completion of the development studies, Cognate will initiate comparability testing including comparability runs and other appropriate testing (Phase III) to verify that change(s) to process do not change AST-VAC1. The final timeline for this study and the criteria for assessment of comparability will be agreed in writing between Cognate and Asterias in the approved study design/protocol for these studies. Upon completion of Phase III, Cognate will, at the direction of Asterias, develop new Specifications, adjust BPR and draft the final comparability reports.

Improving [***]			
[***]	[***]	[***]	Payment
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
Total Cost			[***]

**2.2.10 Final Comparability Report**

Upon completion of the process development activities described in Sections 2.2.3 through 2.2.9, subject to Cognate’s receipt of payment in full of all amounts then payable to Cognate by Asterias pursuant to the Agreement and all additional amounts payable to Cognate under this SOW 1 and the fee for the final comparability report referred to in the following sentence, Cognate will provide to Asterias a final comparability report describing integrated comparability assessments for Product resulting from the combined process changes as established in the work packages described in Sections 2.2.3 through 2.2.7 in exchange for [\*\*\*].

**2.3. Analytical Method Development, Qualification and Verification**

Cognate has assessed the information provided in the Asterias RFP and other confidential materials provided by Asterias for the generation of the prices listed in this Section 2.3 of this SOW 1; provided, that Asterias understands and hereby agrees, that all of the fees set forth in this Section 2.3 are based on Cognate’s reasonable estimate and are subject to amendment following further evaluation. Asterias understands and hereby agrees that any amendments, if necessary, will be captured in a subsequent Change Order that is agreed to and executed by both parties and that Asterias will be responsible for any increases to the fees and expenses set forth in such Change Order.

2.3.1. [\*\*\*]

Cognate will develop [\*\*\*].

The estimated timeline for the [\*\*\*] is approximately [\*\*\*], including technology transfer and verification, with a total cost of [\*\*\*]. The time table in Section 3 of this SOW 1 provides for [\*\*\*] for this activity.

The [\*\*\*] studies will initiate once Asterias has approved the study design/protocol – the final study timelines will be documented in the mutually agreed to study design/protocol. [\*\*\*] the aggregate fees, costs and expenses of this study (in the amounts specified in the table below) will be invoiced to Asterias [\*\*\*].

[***]			
[***]	[***]	[***]	<b>Payment/Payment Terms</b>
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	
[***]	[***]	[***]	
[***]	[***]	[***]	
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	
[***]	[***]	[***]	
<b>Total Cost</b>			[***]

2.3.2. [\*\*\*]:

Cognate will develop [\*\*\*]. Cognate proposes 2 options to Asterias, both of which will require a similar develop and qualification time of approximately [\*\*\*].

The primary focus will be the development of a [\*\*\*].

If the [\*\*\*].

After an initial evaluation, Cognate will present options. Asterias will select the option it prefers and will be responsible for all fees, costs, and expenses associated therewith that have been quoted to Asterias in advance and agreed to by Asterias in writing in advance as per the below payment schedule and any dually executed written Change Order.

[\*\*\*] is estimated to take approximately [\*\*\*], including technology transfer, with a total cost of [\*\*\*].

The [\*\*\*] studies will initiate once Asterias has approved the study design/protocol – the final study timelines will be documented in the mutually agreed to study design/protocol. [\*\*\*] the aggregate fees, costs and expenses of this study (in the amounts specified in the table below) will be invoiced to Asterias [\*\*\*].

[***]			Payment/Payment Terms
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
Total Cost			[***]

2.3.3. [\*\*\*]:

The parties' respective technical teams will discuss the [\*\*\*]. Either Cognate will develop and qualify a [\*\*\*] with [\*\*\*]. If [\*\*\*]. Qualification and validation for this in-house [\*\*\*] is estimated to take approximately [\*\*\*], including technology transfer, with a total cost of [\*\*\*].

The second option (Cognate’s current testing procedure) is to outsource [\*\*\*] to [\*\*\*]. For this option, the assay is qualified with 3 Batches of product in [\*\*\*] validated [\*\*\*] assay before routine testing begins. Such qualification is estimated at [\*\*\*]. Outsourcing of this assay to [\*\*\*] will lower the release time from [\*\*\*]. For assay qualification and routine testing, Asterias will execute an agreement with [\*\*\*] in connection with the [\*\*\*] assay and will be responsible for the performance by [\*\*\*] and will pay all costs and expenses in respect of the assay to [\*\*\*] directly plus a [\*\*\*] (per shipment) to Cognate for administration of sample submission and data processing, and any applicable rush and/or STAT premium charges assessed by [\*\*\*].

The in-house [\*\*\*] studies will initiate once Asterias has approved the study design/protocol – the final study timelines will be documented in the mutually agreed to study design/protocol. [\*\*\*] the aggregate fees, costs and expenses of this study (in the amounts specified in the table below) will be invoiced to Asterias [\*\*\*].

<b>[***] Test</b>			
[***]	[***]	[***]	<b>Payment/Payment Terms</b>
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
<b>Total Cost</b>			[***]
<b>[***]Test ([***])</b>			
[***]	[***]	[***]	<b>Payment/Payment Terms</b>
[***]	[***]	[***]	[***]

2.3.4. [\*\*\*]

Cognate will develop and qualify/validate a [\*\*\*]. Cognate will have in-house validated equipment to provide BacT services to Asterias– [\*\*\*]. Qualification and validation of the assay typically requires 3 Batches of material and [\*\*\*]. Total price for qualification/validation and technology transfer is [\*\*\*].

[\*\*\*] will be invoiced upon completion of study and validation of the assay by Cognate.

<b>In-House [***]</b>			
[***]	[***]	[***]	<b>Payment/Payment Terms</b>
[***]	[***]	[***]	[***]

2.4. **Supplies:**

Asterias will pay a fixed amount of the pass-through expenses [\*\*\*]. The amount of such [\*\*\*] will [\*\*\*] be [\*\*\*]. [\*\*\*] will be adjusted accordingly depending on the amount of materials used in each subsequent [\*\*\*] of performance under this SOW 1, and as can be substantiated with the actual costs associated with such materials, consumables, and testing services; provided that any increase by more than [\*\*\*] requires Asterias’ prior written approval. [\*\*\*].

Asterias will pay the cost of all manufacturing and QC-related supplies including shipping plus a markup of [\*\*\*], unless Asterias sets up an account with a vendor and is billed directly, in which, in this case, no markup will be applied.

[\*\*\*]. The costs of supplies set forth in this Section 2.4 of this SOW 1 are in addition to those costs set forth in the timeline and cost table below.

3. Overall Project Timeline and Costs

Asterias will be responsible for all fees, costs and expenses specified as payable by Asterias in this SOW 1 (including, for clarity, all assays referenced in this SOW 1 or otherwise performed pursuant to the mutual agreement of Asterias and Cognate and the costs of supplies set forth in Section 2.4 of this SOW 1).

	[***] post-Effective Date	Total Cost (\$,000)
2.1. Technology Transfer Part 1 – Transfer from Asterias to Cognate	[***]	[***]
2.1.2 [***]	[***]	[***]
2.2.1 Placebo Formulation Development	[***]	[***]
2.2.2 Placebo Stability Study	[***]	[***]
2.2.3 [***] Studies	[***]	[***]
2.2.4 [***] Studies *	[***]	[***]
2.2.5 [***] Evaluation*	[***]	[***]
2.2.6 [***] Studies	[***]	[***]
2.2.7 [***] Studies*	[***]	[***]
2.2.8 [***] Studies *	[***]	[***]
2.2.9 Improving [***]	[***]	[***]
2.2.10 Final Comparability Report	[***]	[***]
2.3.1 [***]	[***]	[***]
2.3.2 [***]	[***]	[***]
2.3.3 Rapid Mycoplasma Qualification and Validation	[***]	[***]
2.3.4 Rapid Sterility Test Qualification and Validation	[***]	[***]

Cognate's timely performance of the Services hereunder is contingent upon receipt by Cognate from Asterias of all information and materials, including instructions, protocols, methods, controls, SOPS, specifications, tools, methodologies, technologies, approvals and signoffs to be delivered to Cognate by Asterias under the Agreement and under this SOW 1.

[\*\*\*]

[\*\*\*]

4. **Cognate Performance of Development Services;** [\*\*\*]. If Cognate delivers [\*\*\*] delivery date set forth in Section 3 of this SOW 1 (or such later date as agreed by the parties), then the fees, costs and expenses owed by Asterias to Cognate in respect of such Services or corresponding deliverables will be [\*\*\*]. If Cognate delivers the final deliverables or renders the final Development Services in conformance with the applicable requirements in this SOW 1 in advance of the ultimate deadlines set forth in Section 3 of this SOW 1 (or such later date as agreed by the parties), then Asterias will pay Cognate, in addition to all fees, costs and expenses invoiced pursuant to this SOW 1 [\*\*\*].

If the during the term of this SOW 1 the parties materially change the scope of Services to be performed hereunder, the parties will agree to any necessary or appropriate corresponding extension of the timelines or deadlines set forth in Section 3 of this SOW 1 for the performance of such Development Services or Services that are not Manufacture of Product and provision of deliverables of such Services.

5. **Facilit(ies).** The Services described in this SOW 1 will be rendered at the following facilities of Cognate:

a. **Memphis Tennessee (USA) cGMP Facility**

Cognate's cGMP manufacturing facility is located at 4600 East Shelby Drive, Suite 108, Memphis, TN 38118.

b. **Baltimore, Maryland (USA) Process Development and Corporate Headquarters:**

Cognate's Baltimore facility is home to its process development and corporate headquarters and is located at 7513 Connelley Drive Suite I, Hanover, MD 21076. Certain Development Services may be performed in Baltimore.

6. **Asterias Materials.** Asterias will provide to Cognate a bill of materials identifying the materials provided by Asterias to be used by Cognate to perform the Services:

[\*\*\*]

[\*\*\*]

*Describe specific materials being provided by Asterias to Cognate.*

7. **Asterias Equipment.**

None

*Describe any equipment that will be provided by Asterias to Cognate to be used by Cognate in performance of the Services.*

8. **Cognate Representative.** [\*\*\*]

9. **Asterias Representative.** [\*\*\*]

- 10. Compensation; Satisfaction of Invoices.** All fees, charges, costs, expenses and other amounts due or payable by Asterias to Cognate under this SOW 1 [\*\*\*] and in accordance with Section 4 of this SOW 1. Cognate will invoice Asterias for all amounts due under this SOW 1 in accordance with its terms and the Agreement. Such amounts will be invoiced in United States Dollars to the attention of **Asterias Accounts Payable** at the following email address: [accountspayable@asteriasbio.com](mailto:accountspayable@asteriasbio.com). [\*\*\*]. Payment of all amounts invoiced will be made by Asterias [\*\*\*] Asterias's receipt of electronic transmission of each invoice. In addition to all amounts due under invoices provided by Cognate to Asterias pursuant to this Section 8 of this SOW 1, Asterias will be responsible for the fees, if any, payable under the Agreement. [\*\*\*]. If any collection action is undertaken to collect unpaid amounts and it is determined by judgment, settlement or other competent authority with proper jurisdiction over such action, that Cognate is entitled to payment of such invoices, Asterias will pay all fees, costs and expenses associated with such collection actions including, without limitation, reasonable attorneys' fees, as incurred.

All dollar (\$) amounts specified in this SOW 1 are United States dollar amounts and all payments to be made under this SOW 1 will be made in United States dollars and the payment by check or otherwise must be received in accordance with the time frames set forth in this SOW 1.

Asterias understands and hereby agrees that the Services contemplated hereunder may need to be amended or changed subject to mutual written agreement of the parties, which amendments or changes, if necessary and mutually agreed, will be captured in a subsequent Change Order that is agreed to and executed by both parties, and may result in increases to the fees, costs and expenses initially contemplated as set forth in such mutually agreed Change Order; in which case, Asterias will be responsible for any increased fees, costs and expenses set forth in such Change Order. Fees, costs and expenses are reviewed annually and are subject to change for future SOWs (but will not affect existing SOWs unless such SOW expressly states otherwise).

- 11. Conflict.** All terms and conditions of the Agreement will apply to this SOW 1. If there is any conflict, discrepancy or inconsistency between the terms of this SOW 1 and the terms of the Agreement, the terms of the Agreement will control, except with respect to payment terms for Services provided by Cognate under this SOW 1, which, to the extent inconsistent or conflicting with the Agreement, will be governed by this SOW 1.

**[Remainder of page left blank intentionally]**

**STATEMENT OF WORK AGREED TO AND ACCEPTED BY:**

**ASTERIAS BIOTHERAPEUTICS, INC.**

By /s/ Stephen L. Cartt

Print Name Stephen L. Cartt

Title CEO

Date 8/3/16

**COGNATE BIOSERVICES, INC.**

By /s/ J. Kelly Ganjei

Print Name J. Kelly Ganjei

Title Chief Executive Officer

Date 8/3/16

**APPENDIX B**  
**FORM OF**  
**STATEMENT OF WORK**

THIS STATEMENT OF WORK (this “SOW”) is by and between ASTERIAS BIOTHERAPEUTICS, INC. (“Asterias”) and COGNATE BIOSERVICES, INC. (“Cognate”), will be effective as of the last date of signature below, and upon execution will be incorporated into the Development and Manufacturing Services Agreement between Asterias and Cognate dated August 3, 2016 (the “Agreement”). Capitalized terms used in this SOW that are not otherwise defined herein (including service items defined in the tables set forth in this SOW) will have the same meanings as set forth in the Agreement.

Asterias hereby engages Cognate to provide Services, as follows:

**1. Product.**

*Describe the specific Product(s).*

**2. Services.** Cognate will provide the following Services to Asterias:

*Describe the specific Services to be conducted by Cognate or attach Cognate’s proposal.*

**3. Timelines**

*Describe the specific timelines applicable to the performance of the Services.*

**4. Facilit(ies).** The Services described in this SOW will be rendered at the following facilities of Cognate:

*Insert Facility address(es).*

**5. Asterias Materials.** Asterias will provide to Cognate a bill of materials identifying the materials provided by Asterias to be used by Cognate to perform the Services:

*Cross reference the applicable bill of materials.*

**6. Asterias Equipment.**

*Describe any equipment that will be provided by Asterias to Cognate to be used by Cognate in performance of the Services.*

**7. Cognate Representative.** *Name and Title*

**8. Asterias Representative.** *Name and Title*

**9. Compensation; Satisfaction of Invoices.** Cognate will invoice Asterias for all amounts due under this SOW. Such amounts will be invoiced in United States Dollars to the attention of *[INSERT NAME]* at the following email address: *[INSERT]* Cognate will typically invoice Asterias for Batches of Product [\*\*\*]. Payment of all amounts detailed within invoices will be made by Asterias [\*\*\*] of Asterias’s receipt of electronic transmission of each invoice. In addition to all amounts due under invoices provided by Cognate to Asterias pursuant to Section 8 of this SOW, Asterias will be responsible for the fees, costs, and expenses payable under the Agreement. [\*\*\*]. If any collection action is undertaken to collect unpaid amounts and Cognate prevails in such action, Asterias will pay all out-of-pocket fees, costs and expenses associated with such collection actions including, without limitation, reasonable attorneys’ fees, as incurred.

All dollar (\$) amounts specified in this SOW are United States dollar amounts and all payments to be made under this SOW will be made in United States dollars and the payment by check or otherwise must be received in accordance with the time frames set forth in this SOW.

Asterias understands and hereby agrees that the Services contemplated hereunder may need to be amended or changed subject to mutual written agreement of the parties, which amendments or changes, if necessary and mutually agreed, will be captured in a subsequent Change Order that is agreed to and executed by both parties, and may result in increases to the fees, costs and expenses initially contemplated as set forth in such mutually agreed Change Order; in which case, Asterias will be responsible for any increased fees, costs and expenses. Fees, costs and expenses are reviewed annually and are subject to change for future SOWs (but will not affect existing SOWs unless such SOW expressly states otherwise).

- 10. Conflict.** All terms and conditions of the Agreement will apply to this SOW. If there is any conflict, discrepancy or inconsistency between the terms of this SOW and the terms of the Agreement, the terms of the Agreement will control, except with respect to fees, costs and expenses for individual Services provided by Cognate under the Agreement (including under this SOW), for which this SOW shall control and take precedence.

**[Remainder of page left blank intentionally]**

**STATEMENT OF WORK AGREED TO AND ACCEPTED BY:**

**ASTERIAS BIOTHERAPEUTICS, INC.**

**COGNATE BIOSERVICES, INC.**

By \_\_\_\_\_

By \_\_\_\_\_

Print Name \_\_\_\_\_

Print Name \_\_\_\_\_

Title \_\_\_\_\_

Title \_\_\_\_\_

Date \_\_\_\_\_

Date \_\_\_\_\_

**APPENDIX C**

**STATEMENT OF WORK 2**

**(Separately Attached)**

FINAL EXECUTION COPY

**STATEMENT OF WORK 2**

THIS STATEMENT OF WORK (this “SOW 2”) is by and between ASTERIAS BIOTHERAPEUTICS, INC. (“Asterias”) and COGNATE BIOSERVICES, INC. (“Cognate”), will be effective as of the last date of signature below, and upon execution will be incorporated into the Development and Manufacturing Services Agreement between Asterias and Cognate dated August 3, 2016 (the “Agreement”). Capitalized terms used in this SOW 2 that are not otherwise defined herein (including service items defined in the tables set forth in this SOW 2) will have the same meanings as set forth in the Agreement.

Asterias hereby engages Cognate to provide Services, as follows:

**1. Product.**

“AST-VAC1” and “Product” each mean a mature dendritic cell (“DC”) preparation that is loaded with telomerase and a sequence called LAMP in such amounts and in such configurations as are, in each case, specific to AST-VAC1 for use as an immunotherapy product which is prepared on a patient-specific basis from autologous leukapheresis product.

**2. Services.** Cognate will provide the following Services to Asterias:

Cognate will provide, under accelerated circumstances, the production under cGMP of AST-VAC1, in support of Asterias’ clinical and commercial development and manufacturing activities. Services under this SOW 2 will commence upon the later of [\*\*\*] For the avoidance of doubt, [\*\*\*] under this SOW 2 [\*\*\*] SOW 2 [\*\*\*], if the Agreement or SOW 1 is terminated or expires in accordance with the Agreement [\*\*\*] SOW 2 [\*\*\*], this SOW 2 shall also automatically terminate on the Termination Effective Date or date of expiration as applicable (without limiting any other termination rights or surviving obligations (under the Agreement) of either Asterias or Cognate or any other provisions in the Agreement).

Written communications required under this SOW 2 may be effected via email.

**2.1. Technology Transfer Services and Payments**

**2.1.1. Technology Transfer Part 2:**

Asterias will pay [\*\*\*] of technology transfer Services in connection with Technology Transfer Part 2. [\*\*\*] shall be due [\*\*\*] Cognate’s invoice provided to Asterias upon [\*\*\*]. Technology transfer will include the following:

- Draft, review and/or approve SOP’s, BPRs, material Specifications and QC assay procedures, as Cognate deems appropriate or necessary, and as agreed to by Asterias.
- Transfer documentation into Cognate’s controlled document system
- Development of new SOP’s, material Specifications and forms as Cognate deems appropriate or necessary, and as agreed to by Asterias.

- Execution of [\*\*\*] engineering runs to ensure the staff is properly trained and process documentation (BPR(s), test methods and other process documentation) is well defined, clear and executable. Only [\*\*\*] engineering runs will be performed unless Asterias provides prior written consent or requests for additional engineering runs.
- Performance and completion of [\*\*\*] consecutive, successful aseptic media fills per trained operator and per established production line
- Performance of additional engineering runs (if Cognate or Asterias determines in its reasonable discretion that the same are required and both parties agree to the performance of such runs in writing in advance) will be billed by Cognate to Asterias at [\*\*\*]. Notwithstanding the foregoing, and without limiting the terms of the Agreement, if Cognate fails to complete sterile media fills [\*\*\*] pursuant to [\*\*\*] the Agreement, Cognate shall repeat such media fill or engineering run [\*\*\*] to Asterias.
- Develop and document a mutually agreed Product release process, including protocols, timelines and time limits for various testing, documentation and other process steps, required batch records and other documentation (as well as the sequence and timing of when such records and documentation are produced and when they are provided to Asterias and/or designated third parties).
- Negotiation and execution of a Quality Agreement between Cognate and Asterias in accordance with Section 2.2 of the Agreement; the parties will use their respective commercially reasonable efforts to commence negotiating the Quality Agreement concurrently with the drafting, review and/or approval of the SOP's, BPRs, material Specifications and QC assay procedures.

If the technology transfer Services have not been completed upon the expiration of the above-referenced [\*\*\*] period because [\*\*\*] requisite technology transfer Services (and for clarity, that in all cases under this SOW 2, Asterias did not contribute, in whole or in part, to the failure to meet the [\*\*\*] timeline), payment [\*\*\*] this SOW 2) [\*\*\*] until the technology transfer is completed and Cognate shall continue to perform the technology transfer Services [\*\*\*] to Asterias for an additional [\*\*\*], after which time, if further such Services are needed for completion, Cognate will charge Asterias and Asterias will pay for such Services, in each case as provided below. If Cognate has performed its obligations in connection with the technology transfer Services and additional [\*\*\*] of technology transfer Services are nevertheless required, the additional cost will be quoted [\*\*\*] provided that any such additional payments and Services shall be subject to Asterias' prior written approval. [\*\*\*].

Service Item	Payment Amount	Payment Terms
Technology Transfer Part 2	[***]	[***]

2.1.2 [\*\*\*]

A. Asterias Desires [\*\*\*]

(i) If Asterias provides Cognate a written request [\*\*\*] the Manufacturing Process with respect to AST-VAC1 because [\*\*\*] in the reasonable, good faith judgment [\*\*\*] in the reasonable, good faith judgment [\*\*\*] for Products [\*\*\*] Manufacture of Products to be used by Asterias [\*\*\*] initiate Manufacture using incoming leukapheresis products at the Facility [\*\*\*] of such leukapheresis materials [\*\*\*], and Asterias continues to have Cognate provide [\*\*\*] this SOW 2, then Asterias will pay Cognate an [\*\*\*] of which [\*\*\*] of which [\*\*\*] set forth under clause (ii) of Section 2.1.2(A) of this SOW 2. Cognate will provide [\*\*\*] and will use commercially reasonable efforts to complete [\*\*\*] within the estimated time frame, provided that Asterias acknowledges and agrees that [\*\*\*] may affect the time frame for completion.

(ii) The [\*\*\*] will cover [\*\*\*] of Services (other than travel and other reasonable and documented out-of-pocket disbursements which are addressed below in this clause (ii)) [\*\*\*]. Asterias will also be responsible for all reasonable and documented out-of-pocket travel and other disbursements as required for Cognate's performance of such Services and actually incurred by Cognate, whenever billed to Cognate, which disbursements will be invoiced to Asterias once Cognate has been billed for such disbursements (provided that any such disbursements in excess of [\*\*\*] in the aggregate require Asterias' prior written consent, not to be unreasonably withheld, before Asterias is obligated to pay for them [\*\*\*] period covered by the [\*\*\*], for the fees, costs and expenses incurred to the extent reimbursable by Asterias as described in the previous sentence to complete [\*\*\*] (despite Cognate's commercially reasonable efforts to do so and compliance with the Agreement and this SOW 2), Cognate may charge Asterias [\*\*\*] (plus travel and all other reasonable disbursements in accordance with the foregoing), unless otherwise agreed in writing by the Parties. Upon request, [\*\*\*] use commercially reasonable efforts [\*\*\*] this Agreement or SOW 2 [\*\*\*], after which time the foregoing provisions regarding [\*\*\*] shall apply in accordance with their terms.

For clarity, any expenses or disbursements under any section of this SOW 2 that are accrued by Cognate will be accrued in accordance with standard accounting principles and any expenses billed to Asterias under this SOW 2 by Cognate at the time of accrual that are subsequently not actually incurred will be refunded to Asterias promptly at such time that Cognate receives the benefit of such expense no longer being charged (e.g. upon Cognate's receipt of a refund).

(iii) Cognate will provide Asterias with invoices (consistent with the foregoing) and reasonable supporting documentation and Asterias will satisfy in full the invoiced fees, costs and expenses of [\*\*\*] with payment received by Cognate [\*\*\*] delivery by Cognate to Asterias of each such invoice. Asterias agrees that its failure to timely satisfy in full any such invoice may result in delay of the progress or completion [\*\*\*], in which case, Cognate will not be responsible.

B. Asterias Desires [\*\*\*]

(i) If Asterias provides Cognate a written request [\*\*\*] of the Agreement with respect to AST-VAC1 under circumstances that do not fall within Section 2.1.2.A. above, then Asterias will pay Cognate an [\*\*\*] set forth under clause (ii) of Section 2.1.2(B) of this SOW 2. Cognate will provide Asterias with a reasonable estimated time frame [\*\*\*] will use commercially reasonable efforts to complete [\*\*\*] within the estimated time frame, provided that Asterias acknowledges and agrees that [\*\*\*] may affect the time frame for completion.

(ii) The [\*\*\*] will cover [\*\*\*] of Services (other than travel and other reasonable and documented out-of-pocket disbursements which are addressed below in this clause (ii)) [\*\*\*]. Asterias will also be responsible for all reasonable and documented out-of-pocket travel and other disbursements as required for Cognate's performance of such Services and actually incurred by Cognate, whenever billed to Cognate, which disbursements will be invoiced to Asterias once Cognate has been billed for such disbursements (provided that any such disbursements in excess of [\*\*\*] in the cumulative aggregate require Asterias' prior written consent, not to be unreasonably withheld, before Asterias is obligated to pay for them). [\*\*\*] period [\*\*\*] for the fees, costs and expenses incurred to the extent reimbursable by Asterias as described in the previous sentence to complete [\*\*\*], (despite Cognate's commercially reasonable efforts to do so and compliance with the Agreement and this SOW 2), Cognate may charge Asterias [\*\*\*] (plus travel and all other reasonable disbursements in accordance with the foregoing), unless otherwise agreed in writing by the parties. Upon request, [\*\*\*] prior written approval [\*\*\*]. [\*\*\*] use commercially reasonable efforts [\*\*\*] of this Agreement or SOW 2 by Cognate, [\*\*\*], after which time the foregoing provisions regarding [\*\*\*] shall apply in accordance with their terms.

(iii) Cognate will provide Asterias with invoices (consistent with the foregoing) and reasonable supporting documentation and Asterias will satisfy in full the invoiced fees, costs and expenses of [\*\*\*] with payment received by Cognate [\*\*\*] of delivery by Cognate to Asterias of each such invoice. Asterias agrees that its failure to timely satisfy any such invoice may result in delay of the progress or completion [\*\*\*], in which case, Cognate will not be responsible.

[\*\*\*] whether provided under A or B above [\*\*\*] the Agreement [\*\*\*] Product-specific [\*\*\*] in each case in accordance with [\*\*\*] the Agreement.

Service Item	Payment Amount	Payment Terms
[***]		
[***]	[***]	[***]
[***]	[***]	[***]
Travel and Miscellaneous costs in addition to the [***] or [***], as applicable	[***]	[***]

**2.2. Manufacturing Services Capacity and Commitment Payments:**

Cognate will provide [\*\*\*] dedicated manufacturing suites for the manufacturing of AST-VAC1. Cognate will provide Asterias [\*\*\*] dedicated US and EU compliant manufacturing suite that is available for occupancy/production following [\*\*\*] SOW 2 [\*\*\*], and, if and when requested by Asterias in the future (at its sole option in its sole discretion) and subject to availability from Cognate at the time of such request, [\*\*\*] dedicated US and EU compliant manufacturing suite (“Suite AST-B” [\*\*\*] “Asterias Suites” [\*\*\*] Suite AST-A [\*\*\*] Suite AST-A).

**2.2.1. Suite AST-A:**

Asterias will pay [\*\*\*] Suite AST-A [\*\*\*] US and EU compliant manufacturing of AST-VAC1. [\*\*\*] US and EU compliant [\*\*\*].

**2.2.2. Suite AST-B:**

If and when Asterias so requests in writing during the term of the Agreement, and subject to availability from Cognate at the time of such request (which Cognate shall confirm one way or the other upon receipt of Asterias’ request), Asterias will pay [\*\*\*] Suite AST-B [\*\*\*] US and EU compliant Manufacturing of AST-VAC1. [\*\*\*] US and EU compliant [\*\*\*].

**2.2.3. [\*\*\*]:**

[\*\*\*] Suite AST-A [\*\*\*], [\*\*\*] Suite AST-B is available [\*\*\*]. [\*\*\*] equipment that is necessary for either Asterias Suite [\*\*\*] the preceding sections of this SOW 2, [\*\*\*] Suite AST-A or Suite AST-B, as the case may be, [\*\*\*] applicable Suite [\*\*\*] Asterias Suite [\*\*\*].

[\*\*\*] does not include any Asterias specific capital expenditures specified in this SOW 2 or other non-recurring costs required to be incurred by Asterias under the Agreement or this SOW 2.

Service Item	Payment Amount	Payment Term
[***] fee [***]	[***]	[***]
[***] fee [***]	[***]	[***]

**2.3. Manufacturing Services, and Supplies [\*\*\*]:**

**2.3.1 [\*\*\*] Capacity:**

To permit Cognate to allocate personnel to each Asterias Suite, Asterias will pay Cognate [\*\*\*] and Cognate will Manufacture up to estimated [\*\*\*] of AST-VAC1 [\*\*\*] Asterias Suite [\*\*\*] Asterias Suite; [\*\*\*] Suite AST-A [\*\*\*] (i) an executed Quality Agreement between Asterias and Cognate, (ii) the development and documentation of a mutually agreed Product release process, (iii) [\*\*\*] successful engineering runs and (iv) [\*\*\*] consecutive, sterile media fills and will run through the expiration or Termination Effective Date of the Agreement (and/or this SOW 2) under Article 14 of the Agreement or as expressly provided for in this SOW 2. The [\*\*\*] Suite AST-B [\*\*\*] Asterias Suites are to be made and will run through the expiration or Termination Effective Date of the Agreement or this SOW 2. [\*\*\*] Suite AST-B [\*\*\*] Section 2.2 of this SOW 2 [\*\*\*].

[\*\*\*] will be invoiced by Cognate [\*\*\*]. For the avoidance of doubt, Asterias will pay [\*\*\*]. If Asterias requests the Manufacture in excess of [\*\*\*] will be billed [\*\*\*] to and Asterias will pay [\*\*\*] pursuant to the applicable invoice. For further avoidance of doubt, [\*\*\*].

If during any [\*\*\*], Cognate is prevented from Manufacturing because Cognate (A) does not have a sufficient number of personnel, (B) failed to maintain sufficient quantities of Materials, or (C) failed to maintain a cGMP compliant Asterias Suite, then payment by Asterias [\*\*\*] in (A), (B) or (C) [\*\*\*].

With [\*\*\*] Asterias Suites in full operation, the maximum production capacity of AST-VAC1 will be [\*\*\*]. Our current understanding of the AST-VAC1 process leads us to believe that [\*\*\*] is the maximum Batch capacity per each manufacturing suite without the incorporation of process improvements and/or additional understanding of the manufacturing process. This understanding may change [\*\*\*] during the normal course of manufacturing AST-VAC1, or at any point during the term of performance under this SOW 2. Additionally, Cognate understands that Asterias will be performing additional diligence to determine projected rates of enrollment in the AST-VAC1 clinical trial in parallel with the performance of the activities under SOW 1, and that these activities may result in increases to Asterias' projected maximum production capacity requirements; provided, however, that in no event will [\*\*\*] be reduced including if Asterias enrolls less patients than projected. Subject to the foregoing proviso, this Section 2.3 of this SOW 2 may change, or need to be changed, if Cognate or Asterias determines such modifications are appropriate, subject to mutual written approval of any such changes, not to be unreasonably withheld or delayed.

[\*\*\*] will be determined upon completion [\*\*\*], subject to mutual prior written approval, not to be unreasonably withheld or delayed.

Service Item	Payment Amount	Payment Term
[***]	[***]	[***]
[***]	[***]	[***]

**2.3.2 Supplies:**

[\*\*\*] SOW 2 [\*\*\*] Asterias will pay a fixed amount of the pass-through expenses [\*\*\*]. The amount [\*\*\*] will be adjusted accordingly depending on the amount of materials used in [\*\*\*] of performance under this SOW 2, and as can be substantiated with the actual costs associated with such materials, consumables, and testing services [\*\*\*]. For the avoidance of doubt, Cognate will not be responsible for the purchase of any materials and consumables for Manufacture of Product under this SOW 2 unless the [\*\*\*]. Moreover, Cognate will not be responsible for any delays (under this SOW 2 or the Agreement) caused by Asterias's failure to fully satisfy the [\*\*\*] or that result from Cognate's right to restrict or reduce Manufacturing capacity previously allocated to Asterias under Section 8.1 of the Agreement.

The [\*\*\*] will be based on Cognate's estimated, out-of-pocket cost for the applicable materials and consumables used in Manufacturing hereunder plus shipping [\*\*\*].

[\*\*\*].

**2.3.3. Staffing:**

Cognate will retain, hire, train and maintain sufficient technical staff for the manufacture of AST-VAC1 as specified herein, and for ongoing regulatory compliance.

- Cognate will be responsible for staffing and training sufficient manufacturing personnel to handle the [\*\*\*] Asterias Suite [\*\*\*] or [\*\*\*] Asterias Suites [\*\*\*] capacity including manufacturing staff for potential day and night working shifts and additional manufacturing staff as backup for such emergency situations.
- Cognate will be responsible for staffing and training sufficient personnel in materials management; for each shift.
- Cognate will be responsible for staffing and training sufficient QC personnel; for environmental monitoring and for standard and on demand QC testing.

Cognate will be responsible for staffing and training sufficient personnel in quality assurance; personnel for document management and control services, personnel for line clearance and production support, and personnel for Batch release.

**2.4. AST-VAC1 In-Process Testing and Release Testing Assays**

As stated in Section 2.3.1 of this SOW 2, [\*\*\*]. Any outsourced QC testing [\*\*\*] will be billed directly to Asterias by the laboratory conducting the analysis [\*\*\*] to Cognate for administration of sample submission and data processing and any applicable rush and/or STAT premium charges. Asterias will pay the cost of all QC related supplies including shipping [\*\*\*] in 2.3.2 of this SOW 2.

**Assay Overview:**

[\*\*\*]

AST-VAC1 QC/Release Assays – QC Support Services and Fees		
Item	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]

**2.5. AST-VAC1 Stability Study:**

The stability study will be conducted on approximately [\*\*\*] of AST-VAC1. Asterias will pay [\*\*\*] and [\*\*\*]. Asterias will additionally pay a [\*\*\*] for each stability and/or interim stability study report generated by Cognate. Required testing which includes [\*\*\*] are all included in the stability study fee(s). [\*\*\*] may be outsourced to [\*\*\*] and, if so, paid for directly by Asterias pursuant to agreement between Asterias and [\*\*\*] (otherwise, if done in-house, at the price mutually agreed in writing).

**AST-VAC1 Stability Study**

[\*\*\*]

**2.8. Cryopreservation, Storage and Holding Cost:**

[\*\*\*] Asterias will pay [\*\*\*] this SOW 2. Liquid nitrogen consumption will be billed separately as a material under Section 2.3.2 of this SOW 2. [\*\*\*] and equipment will be quoted and billed accordingly, subject to prior written approval from Asterias.

Service Item	Payment Amount	Payment Term
[***]	[***]	[***]

**2.9. Client Purchase of Capital Equipment:**

The list of equipment to be provided by Asterias will be agreed between the parties upon the completion of the work package under SOW 1. Asterias will deliver to Cognate all Asterias Equipment free and clear of all liens and encumbrances. Upon installation, Cognate will support Asterias in the qualification and validation of the Asterias Equipment. The costs associated with qualification and validation will be determined (subject to prior written approval by Asterias) once the final equipment list is agreed to with Asterias. Asterias will purchase [\*\*\*] of final Product and such other equipment as agreed by Cognate and Asterias.

**Equipment Provided by Cognate with Asterias Suites:**

Each Asterias Suite will be provided by Cognate furnished with the following equipment:

[\*\*\*]

**2.10. Shipping and Logistics:**

Shipping will be billed directly to Asterias, through Asterias’s courier account. Delivery terms will be EXW (Incoterms 2010).

Service Item	Payment Amount	Payment Term
Miscellaneous Shipping/Courier Fees	-	Billed directly to Asterias by 3 <sup>rd</sup> Party Shipper

2.11. **Man-In-Plant:** Asterias may designate a Man-In-Plant who will be present in the Facility during the testing and production phases of the Manufacturing Process in consideration of a fee based on the specific Services the Man-In-Plant will participate in, but not to exceed [\*\*\*] per Man-In-Plant.

**3. Facility(ies).** The Services described in this SOW 2 will be rendered at the following facilities of Cognate:

**a. Memphis Tennessee (USA) cGMP Facility**

Cognate’s cGMP manufacturing facility is located at 4600 East Shelby Drive, Suite 108, Memphis, TN 38118.

**b. Baltimore, Maryland (USA) Process Development and Corporate Headquarters:**

Cognate’s Baltimore facility is home to its Process Development and corporate headquarters and is located at 7513 Connelley Drive Suite I, Hanover, MD 21076. Services to be conducted in Baltimore include non-cGMP studies and may include the Stability Study outlined in this SOW 2.

**4. Asterias Materials.** Asterias will provide to Cognate a bill of materials identifying the materials provided by Asterias to be used by Cognate to perform the Services: [\*\*\*]

Any additional Asterias materials to be determined between the parties upon the completion of the work package under SOW 1.

**5. Asterias Equipment.**

[\*\*\*]

Additional Asterias Equipment to be determined between the parties upon completion of the work package under SOW 1.

**6. Cognate Representative.** [\*\*\*]

**7. Asterias Representative.** [\*\*\*]

**8. Compensation; Satisfaction of Invoices.** Cognate will invoice Asterias for all amounts due under this SOW 2 in accordance with its terms and the Agreement. Such amounts will be invoiced in United States Dollars to the attention of Asterias Accounts Payable at the following email address: [accountspayable@asteriasbio.com](mailto:accountspayable@asteriasbio.com). [\*\*\*] this SOW 2 and the Agreement [\*\*\*]. Payment of all amounts invoiced will be made by Asterias to Cognate and must be received by Cognate [\*\*\*] of Asterias's receipt of electronic transmission of each invoice. In addition to all amounts due under invoices provided by Cognate to Asterias pursuant to this Section 8 of this SOW 2, Asterias will be responsible for the fees, if any, payable under the Agreement. [\*\*\*]. For clarity, such [\*\*\*] service charge will only be applied once (either under this SOW 2 or under the Agreement). If any collection action is undertaken to collect unpaid amounts and it is determined by judgment, settlement or other competent authority with proper jurisdiction over such action, that Cognate is entitled to payment of such invoices, [\*\*\*] Asterias will pay all fees, costs and expenses associated with such collection actions including, without limitation, reasonable attorneys' fees incurred.

All dollar (\$) amounts specified in this SOW 2 are United States dollar amounts and all payments to be made under this SOW 2 will be made in United States dollars and will be due from Asterias and received by Cognate in accordance with the time frames set forth in this SOW 2.

Asterias understands and hereby agrees that the Services contemplated hereunder may need to be amended or changed, which amendments or changes, if necessary, will be captured in a subsequent Change Order that is agreed to and executed by both parties (prior to such changes or amendments being effective), and may result in increases to the fees, costs and expenses initially contemplated as set forth in such mutually agreed Change Order; in which case, Asterias will be responsible for any increased fees, costs and expenses set forth in such mutually agreed Change Order. Fees, costs and expenses are reviewed annually and are subject to change, which changes, if any, will be captured in a subsequent Change Order that is agreed to and executed by both parties prior to any such changes being effective, and may result in increases to the fees, costs and expenses initially contemplated as set forth in such mutually agreed Change Order; in which case, Asterias will be responsible for any increased fees, costs and expenses. If this SOW 2 is required to be changed [\*\*\*] production of Products [\*\*\*] SOW 2 [\*\*\*] and the proposed Change Order from Cognate [\*\*\*] existing SOW 2, [\*\*\*] proposed Change Order [\*\*\*] SOW 2 [\*\*\*] prior written notice [\*\*\*] of the Agreement [\*\*\*].

9. **Expiration and Termination.** This SOW 2 shall expire (and terminate) immediately upon the completion of enrollment and Manufacture for, or cessation of, all clinical trials for which Products under this SOW 2 are being manufactured, unless terminated earlier in accordance with Section 14.2 of the Agreement.
10. **Conflict.** All terms and conditions of the Agreement will apply to this SOW 2. If there is any conflict, discrepancy or inconsistency between the terms of this SOW 2 and the terms of the Agreement, the terms of the Agreement will control, except with respect to payment terms for Services provided by Cognate under this SOW 2, which, to the extent inconsistent or conflicting with the Agreement, will be governed by this SOW 2.

**[Remainder of page left blank intentionally]**

**STATEMENT OF WORK AGREED TO AND ACCEPTED BY:**

**ASTERIAS BIOTHERAPEUTICS, INC.**

By /s/ Stephen L. Cartt

Print Name Stephen L. Cartt

Title CEO

Date 8/3/16

**COGNATE BIOSERVICES, INC.**

By /s/ J. Kelly Ganjei

Print Name J. Kelly Ganjei

Title Chief Executive Officer

Date 8/3/16

**CERTIFICATIONS**

I, Stephen L. Cartt, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Asterias Biotherapeutics, 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 Rule 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 periodic report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of 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: November 14, 2016

/s/ Stephen L. Cartt

Stephen L. Cartt  
President and Chief Executive Officer  
(principal executive officer)

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**CERTIFICATIONS**

I, Russell L. Skibsted, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Asterias Biotherapeutics, 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 Rule 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 periodic report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of 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: November 14, 2016

/s/ Russell L. Skibsted

Russell L. Skibsted  
Chief Financial Officer  
(principal financial officer)

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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 on Form 10-Q of Asterias Biotherapeutics, Inc. (the "Company") for the quarter ended September 30, 2016 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned, Stephen L. Cartt and Russell L. Skibsted, certify pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

Date: November 14, 2016

*s/ Stephen L. Cartt*

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Stephen L. Cartt  
President and Chief Executive Officer

*s/ Russell L. Skibsted*

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Russell L. Skibsted  
Chief Financial Officer

The Foregoing certification is being furnished pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, or otherwise subject to the 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.

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