

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

**FORM 10-Q**

(Mark One)

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

For the quarterly period ended September 30, 2014

OR

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

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

Commission file number **1-12830**

**BioTime, Inc.**

(Exact name of registrant as specified in its charter)

**California**

(State or other jurisdiction of incorporation or organization)

**94-3127919**

(IRS Employer Identification No.)

**1301 Harbor Bay Parkway, Suite 100  
Alameda, California 94502**

(Address of principal executive offices)

**(510) 521-3390**

(Registrant's telephone number, including area code)

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate 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  Accelerated filer

Non-accelerated filer  (Do not check if a smaller reporting company) Smaller reporting company

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

**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: 83,121,710 common shares, no par value, as of November 5, 2014

## 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 “we” means BioTime, Inc. and its subsidiaries unless the context otherwise indicates.*

*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.*

**BIOTIME, INC. AND SUBSIDIARIES**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**

	September 30, 2014 (Unaudited)	December 31, 2013
<b>ASSETS</b>		
<b>CURRENT ASSETS</b>		
Cash and cash equivalents	\$ 7,416,235	\$ 5,495,478
Inventory	253,567	178,694
Trade accounts and grants receivable, net	1,014,183	998,393
Prepaid expenses and other current assets	1,255,479	1,277,405
<b>Total current assets</b>	<b>9,939,464</b>	<b>7,949,970</b>
Equipment, net	2,758,456	2,997,733
Deferred license and consulting fees	364,208	444,833
Deposits	435,317	129,129
Other long-term assets	53,127	-
Intangible assets, net	42,104,092	46,208,085
<b>TOTAL ASSETS</b>	<b>\$ 55,654,664</b>	<b>\$ 57,729,750</b>
<b>LIABILITIES AND EQUITY</b>		
<b>CURRENT LIABILITIES</b>		
Accounts payable and accrued liabilities	\$ 5,550,698	\$ 6,722,624
Capital lease liability, current portion	57,500	-
Related party convertible debt, net of discount	3,088	-
Deferred license and subscription revenue, current portion	177,574	235,276
<b>Total current liabilities</b>	<b>5,788,860</b>	<b>6,957,900</b>
<b>LONG-TERM LIABILITIES</b>		
Capital lease, net of current portion	44,963	-
Deferred tax liability, net	10,787,141	8,277,548
Other long-term liabilities	79,108	231,981
<b>Total long-term liabilities</b>	<b>10,911,212</b>	<b>8,509,529</b>
Commitments and contingencies		
<b>STOCKHOLDERS' EQUITY</b>		
Preferred shares, no par value, authorized 2,000,000 shares as of September 30, 2014 and December 31, 2013; 70,000 and nil issued and outstanding as of September 30, 2014 and December 31, 2013, respectively	3,500,000	-
Common shares, no par value, authorized 125,000,000 shares as of September 30, 2014 and December 31, 2013; 73,690,302 issued and 68,291,760 outstanding as of September 30, 2014 and 67,412,139 issued and 56,714,424 outstanding at December 31, 2013	201,298,235	203,456,401
Contributed capital	59,934	93,972
Accumulated other comprehensive (loss)/income	(150,691)	62,899
Accumulated deficit	(171,606,642)	(145,778,547)
Treasury stock at cost: 5,398,542 and 10,697,715 shares at September 30, 2014 and at December 31, 2013, respectively	(22,119,467)	(43,033,957)
BioTime stockholders' equity	10,981,369	14,800,768
Non-controlling interest	27,973,223	27,461,553
<b>Total stockholders' equity</b>	<b>38,954,592</b>	<b>42,262,321</b>
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<b>\$ 55,654,664</b>	<b>\$ 57,729,750</b>

See accompanying notes to the condensed consolidated interim financial statements.

**BIOTIME, INC. AND SUBSIDIARIES**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS**  
**(UNAUDITED)**

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
<b>REVENUES:</b>				
License fees	\$ 285,157	\$ 382,767	\$ 880,740	\$ 1,094,843
Royalties from product sales	147,811	80,592	321,806	291,505
Grant income	647,580	160,431	1,863,310	941,226
Sale of research products and services	110,555	90,272	299,615	214,277
<b>Total revenues</b>	<b>1,191,103</b>	<b>714,062</b>	<b>3,365,471</b>	<b>2,541,851</b>
Cost of sales	(230,901)	(206,678)	(614,080)	(570,237)
<b>Gross Profit</b>	<b>960,202</b>	<b>507,384</b>	<b>2,751,391</b>	<b>1,971,614</b>
<b>EXPENSES:</b>				
Research and development	(8,836,341)	(6,441,462)	(26,267,792)	(17,389,409)
General and administrative	(4,261,450)	(4,267,875)	(12,764,324)	(11,273,948)
<b>Total operating expenses</b>	<b>(13,097,791)</b>	<b>(10,709,337)</b>	<b>(39,032,116)</b>	<b>(28,663,357)</b>
Loss from operations	(12,137,589)	(10,201,953)	(36,280,725)	(26,691,743)
<b>OTHER INCOME/(EXPENSES):</b>				
Interest (expense)/income, net (see Note 6)	(7,632)	509	(29,786)	2,033
(Loss)/gain on sale or write off of fixed assets	(133)	5,830	(8,709)	5,120
Other (expense)/income, net	(118,796)	(60,704)	165,135	(169,512)
<b>Total other (expenses)/income, net</b>	<b>(126,561)</b>	<b>(54,365)</b>	<b>126,640</b>	<b>(162,359)</b>
<b>LOSS BEFORE INCOME TAX BENEFIT</b>	<b>(12,264,150)</b>	<b>(10,256,318)</b>	<b>(36,154,085)</b>	<b>(26,854,102)</b>
Deferred income tax benefit	2,312,693	-	5,174,977	-
<b>NET LOSS</b>	<b>(9,951,457)</b>	<b>(10,256,318)</b>	<b>(30,979,108)</b>	<b>(26,854,102)</b>
Net loss attributable to non-controlling interest	1,683,532	1,253,150	5,151,013	2,583,581
<b>NET LOSS ATTRIBUTABLE TO BIOTIME, INC.</b>	<b>(8,267,925)</b>	<b>(9,003,168)</b>	<b>(25,828,095)</b>	<b>(24,270,521)</b>
Dividends on preferred shares	(34,038)	-	(34,038)	-
<b>Net loss attributable to common shareholders</b>	<b>(8,301,963)</b>	<b>(9,003,168)</b>	<b>(25,862,133)</b>	<b>(24,270,521)</b>
Unrealized loss on available-for-sale assets	(1,210)	-	(2,740)	-
Foreign currency translation (loss)/gain	(66,768)	7,016	(216,330)	184,310
<b>TOTAL COMPREHENSIVE LOSS</b>	<b>\$ (8,335,903)</b>	<b>\$ (8,996,152)</b>	<b>\$ (26,047,165)</b>	<b>\$ (24,086,211)</b>
<b>BASIC AND DILUTED NET LOSS PER COMMON SHARE</b>	<b>\$ (0.12)</b>	<b>\$ (0.16)</b>	<b>\$ (0.41)</b>	<b>\$ (0.45)</b>
<b>WEIGHTED AVERAGE NUMBER OF COMMON STOCK OUTSTANDING:</b>				
<b>BASIC AND DILUTED</b>	<b>67,920,853</b>	<b>55,621,564</b>	<b>62,594,212</b>	<b>53,545,834</b>

See accompanying notes to the condensed consolidated interim financial statements

**BIOTIME, INC. AND SUBSIDIARIES**  
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**  
**(UNAUDITED)**

	Nine Months Ended September 30,	
	2014	2013
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss attributable to BioTime, Inc.	\$ (25,828,095)	\$ (24,270,521)
Adjustments to reconcile net loss attributable to BioTime, Inc. to net cash used in operating activities:		
Depreciation expense	794,414	419,630
Amortization of intangible assets	4,103,994	1,927,718
Amortization of deferred consulting fees	18,993	48,838
Amortization of deferred license fees	82,125	82,125
Amortization of deferred rent	(14,241)	(6,669)
Amortization of discount on related party convertible debt	3,667	-
Amortization of deferred license, royalty and subscription revenues	(280)	(124,882)
Amortization of prepaid rent in common stock	42,293	-
Net loss allocable to non-controlling interest	(5,151,013)	(2,583,581)
Stock-based compensation	3,320,773	2,375,354
Deferred income tax benefit	(5,174,977)	-
Gain/(loss) on sale or write-off of equipment	8,709	(5,120)
Write-off for uncollectible receivables	(16,356)	-
Changes in operating assets and liabilities:		
Accounts receivable, net	(86,124)	(66,310)
Grant receivable	65,859	932,925
Inventory	(74,873)	(5,816)
Prepaid expenses and other current assets	(113,635)	284,785
Other long-term assets	-	(15,000)
Accounts payable and accrued liabilities	(1,544,520)	177,631
Accrued interest on convertible debt	1,143	-
Deferred revenues	(57,422)	(4,464)
Other long-term liabilities	(124,442)	(48,322)
Net cash used in operating activities	<u>(29,744,008)</u>	<u>(20,881,679)</u>
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Purchase of equipment	(497,119)	(1,976,042)
Security deposit paid, net	(306,244)	(61,923)
Proceeds from the sale of equipment	4,000	30,900
Cash used in investing activities	<u>(799,363)</u>	<u>(2,007,065)</u>
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from exercise of employee stock options	12,500	-
Proceeds from exercise of director stock options	207,000	-
Proceeds from issuance of common stock	-	23,810,421
Fees paid on sale of common stock	(297,932)	(748,072)
Proceeds from sale of common stock	14,724,107	-
Proceeds from sale of treasury stock and subsidiary warrants	13,582,209	1,819,500
Proceeds from sale of preferred stock	3,500,000	-
Proceeds from sale of common shares of subsidiary	468,000	255,502
Proceeds from issuance of related party convertible debt	466,690	-
Repayment of capital lease obligation	(12,537)	-
Net cash provided by financing activities	<u>32,650,037</u>	<u>25,137,351</u>
Effect of exchange rate changes on cash and cash equivalents	<u>(185,909)</u>	<u>118,769</u>
<b>NET INCREASE IN CASH AND CASH EQUIVALENTS</b>	<b>1,920,757</b>	<b>2,367,376</b>
<b>CASH AND CASH EQUIVALENTS:</b>		
At beginning of the period	5,495,478	4,349,967
At end of the period	<u>\$ 7,416,235</u>	<u>\$ 6,717,343</u>
<b>SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:</b>		
Cash paid during the period for interest	\$ 24,387	\$ 61
<b>SUPPLEMENTAL SCHEDULE OF NON CASH FINANCING AND INVESTING ACTIVITIES:</b>		
Employee options exercised with common stock	\$ 972,700	\$ -
Capital expenditure funded by capital lease borrowing	\$ 115,000	\$ -
Common shares issued for consulting services	\$ -	\$ 173,100
Common shares issued for rent	\$ -	\$ 253,758

See accompanying notes to the condensed consolidated interim financial statements.

**1. Organization, Basis of Presentation, and Summary of Select Significant Accounting Policies**

*General* – BioTime is a biotechnology company focused on the field of regenerative medicine; specifically human embryonic stem (“hES”) cell and induced pluripotent stem (“iPS”) cell technology. Regenerative medicine refers to therapies based on stem cell technology that are designed to rebuild cell and tissue function lost due to degenerative disease or injury. hES and iPS cells provide a means of manufacturing every cell type in the human body and therefore show considerable promise for the development of a number of new therapeutic products. BioTime and its subsidiaries plan to develop stem cell products for research and therapeutic use. BioTime’s primary therapeutic products are based on its *HyStem*<sup>®</sup> hydrogel technology and include *Renevia*<sup>™</sup> a product currently in clinical trials in Europe to facilitate cell transplantation; *ReGlyde*<sup>™</sup> a product under development for tendon surgery applications, and *Premvia*<sup>™</sup> for which 510(k) certification has been received for use in wound-management. Asterias Biotherapeutics, Inc. (“Asterias”) is developing pluripotent stem-cell based therapies in neurology and oncology, including AST-OPC1 neural cells in spinal cord injury, multiple sclerosis and stroke, and AST-VAC2, a pluripotent stem cell-derived cancer vaccine. OncoCyte Corporation (“OncoCyte”) is developing products and technologies to diagnose cancer. ES Cell International Pte Ltd. (“ESI”), a Singapore private limited company, is marketing hES cell lines and stem cell related research products in domestic and overseas markets under the ESI BIO branding program. OrthoCyte Corporation (“OrthoCyte”) is developing therapies to treat orthopedic disorders, diseases and injuries. ReCyte Therapeutics, Inc. (“ReCyte Therapeutics”) is developing therapies to treat a variety of cardiovascular and related ischemic disorders, as well as products for research using cell reprogramming technology. Cell Cure Neurosciences Ltd. (“Cell Cure Neurosciences”) is an Israel-based biotechnology company focused on developing stem cell-based therapies for retinal and neurological disorders, including the development of retinal pigment epithelial cells for the treatment of macular degeneration, and treatments for multiple sclerosis. LifeMap Sciences, Inc. (“LifeMap Sciences”) markets, sells and distributes *GeneCards*<sup>®</sup>, the leading human gene database and an integrated database suite that includes *GeneCards*<sup>®</sup>, the *LifeMap Discovery*<sup>®</sup> database of embryonic development, stem cell research and regenerative medicine, and MalaCards, the human disease database. LifeMap Sciences’ subsidiary LifeMap Solutions, Inc. (“LifeMap Solutions”) is developing mobile health software products.

BioTime is focusing a portion of its efforts in the field of regenerative medicine on the development and sale of advanced human stem cell products and technologies that can be used by researchers at universities and other institutions, at companies in the bioscience and biopharmaceutical industries, and at other companies that provide research products to companies in those industries. Products for the research market generally can be sold without regulatory (United States Food and Drug Administration (“FDA”)) approval, and are therefore relatively near-term business opportunities when compared to therapeutic products.

BioTime previously developed blood plasma volume expanders and related technology for use in surgery, emergency trauma treatment and other applications. BioTime’s operating revenues are now derived primarily from research grants, from licensing fees and advertising from the marketing of the LifeMap Sciences database products, and from the sale of products for research.

At September 30, 2014, we had \$7,416,235 of cash and cash equivalents on hand, of which \$5,025,499 was held by Asterias. During October 2014, we raised \$29,425,962 of cash through the issue and sale of 9,431,398 BioTime common shares for \$3.12 per share in a transaction registered under the Securities Act of 1933, as amended. The \$3.12 price per share was the closing price of BioTime common shares on the NYSE MKT on the date on which we and the investors agreed upon the purchase price. In addition, during October 2014 certain of our subsidiaries received approximately \$1,574,352 of gross proceeds from the sale of 504,600 BioTime common shares that they held. The subsidiaries sold those shares through Cantor Fitzgerald & Co., as sales agent. The capital raised by our subsidiaries through those stock sales belongs to the subsidiaries and not to BioTime.

The unaudited condensed consolidated interim balance sheet as of September 30, 2014, the unaudited condensed consolidated interim statements of operations and comprehensive loss for the three and nine months ended September 30, 2014 and 2013, and the unaudited condensed consolidated interim statements of cash flows for the nine months ended September 30, 2014 and 2013 have been prepared by BioTime's management in accordance with the instructions from Form 10-Q and Regulation S-X. In the opinion of management, all adjustments (consisting only of normal recurring adjustments) necessary to present fairly the financial position, results of operations, and cash flows at September 30, 2014 have been made. The consolidated balance sheet as of December 31, 2013 is derived from the Company's annual audited financial statements as of that date. The results of operations for the nine months ended September 30, 2014 are not necessarily indicative of the operating results anticipated for the full year of 2014.

Certain information and footnote disclosures normally included in consolidated financial statements prepared in accordance with generally accepted accounting principles have been condensed or omitted as permitted by regulations of the Securities and Exchange Commission ("SEC") except for the consolidated balance sheet as of December 31, 2013, which was derived from audited financial statements. Certain previously furnished amounts have been reclassified to conform with presentations made during the current periods. It is suggested that these condensed consolidated interim financial statements be read in conjunction with the annual audited consolidated financial statements and notes thereto included in BioTime's Form 10-K for the year ended December 31, 2013.

*Principles of consolidation* – BioTime's consolidated financial statements include the accounts of its subsidiaries. The following table reflects BioTime's ownership, directly or through one or more subsidiaries, of the outstanding shares of its subsidiaries.

Subsidiary	Field of Business	BioTime Ownership	Country
Asterias Biotherapeutics, Inc.	Research, development and commercialization of human therapeutic products from stem cells, focused initially in the fields of neurology and oncology	70.6%	USA
BioTime Asia, Limited	Stem cell products for research	81%	Hong Kong
Cell Cure Neurosciences Ltd.	Age-related macular degeneration Multiple sclerosis Parkinson's disease	62.5%(1)	Israel
ES Cell International Pte Ltd	Stem cell products for research, including clinical grade cell lines produced under cGMP	100%	Singapore
LifeMap Sciences, Inc.	Genetic, disease, and stem cell databases	74.52%	USA
LifeMap Sciences, Ltd.	Stem cell database	(2)	Israel
LifeMap Solutions, Inc.	Mobile health software	(2)	USA
OncoCyte Corporation	Cancer diagnostics	75.3%	USA
OrthoCyte Corporation	Orthopedic diseases, including chronic back pain and osteoarthritis	100%(3)	USA
ReCyte Therapeutics, Inc.	Vascular disorders, including cardiovascular-related diseases, ischemic conditions, vascular injuries  Stem cell-derived endothelial and cardiovascular related progenitor cells that have applications in research, drug testing, and therapeutics	94.8%	USA

- (1) Includes shares owned by BioTime, Asterias, and ESI.  
(2) LifeMap Sciences, Ltd. and LifeMap Solutions, Inc. are wholly-owned subsidiaries of LifeMap Sciences, Inc.  
(3) Includes shares owned by BioTime and Asterias.

All material intercompany accounts and transactions have been eliminated in consolidation. The consolidated financial statements are presented in accordance with accounting principles generally accepted in the U.S. (“GAAP”) and with the accounting and reporting requirements of SEC Regulation S-X. As of September 30, 2014, BioTime consolidated Asterias, ReCyte Therapeutics, OncoCyte, OrthoCyte, ESI, Cell Cure Neurosciences, BioTime Asia, Limited (“BioTime Asia”), LifeMap Sciences, LifeMap Sciences, Ltd., and LifeMap Solutions as BioTime has the ability to control their operating and financial decisions and policies through its ownership, and the non-controlling interest is reflected as a separate element of equity on BioTime’s condensed consolidated balance sheets.

*Certain significant risks and uncertainties* – The operations of BioTime and its subsidiaries are subject to a number of factors that can affect their operating results and financial condition. Such factors include but are not limited to, the following: the results of clinical trials of their respective therapeutic product and medical device candidates; their ability to obtain FDA and foreign regulatory approval to market their respective therapeutic and medical device product candidates; their ability to develop new stem cell research products and technologies; competition from products manufactured and sold or being developed by other companies; the price and demand for their products; their ability to obtain additional financing and the terms of any such financing that may be obtained; their ability to negotiate favorable licensing or other manufacturing and marketing agreements for its products; the availability of ingredients used in their products; and the availability of reimbursement for the cost of their therapeutic products and medical devices (and related treatment) from government health administration authorities, private health coverage insurers, and other organizations.

*Use of estimates* – The preparation of condensed consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

*Revenue recognition* – BioTime complies with ASC 605-10 and recognizes revenue when persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered, the price is fixed or determinable, and collectability is reasonably assured. Grant income and the sale of research products are recognized as revenue when earned. Revenues from the sale of research products are primarily derived from the sale of hydrogels and stem cell products. Royalty revenues consist of product royalty payments. License fee revenues consist primarily of subscription and advertising revenue from our online databases which are recognized based upon respective subscription or advertising periods. Other license fees under certain license agreements were recognized during prior periods when earned and reasonably estimable. Royalties earned on product sales are recognized as revenue in the quarter in which the royalty reports are received from the licensee, rather than the quarter in which the sales took place. When BioTime is entitled to receive up-front nonrefundable licensing or similar fees pursuant to agreements under which BioTime has no continuing performance obligations, the fees are recognized as revenues when collection is reasonably assured. When BioTime receives up-front nonrefundable licensing or similar fees pursuant to agreements under which BioTime does have continuing performance obligations, the fees are deferred and amortized ratably over the performance period. If the performance period cannot be reasonably estimated, BioTime amortizes nonrefundable fees over the life of the contract until such time that the performance period can be more reasonably estimated. Milestone payments, if any, related to scientific or technical achievements are recognized in income when the milestone is accomplished if (a) substantive effort was required to achieve the milestone, (b) the amount of the milestone payment appears reasonably commensurate with the effort expended, and (c) collection of the payment is reasonably assured.

*Cash and cash equivalents* – BioTime considers all highly liquid investments purchased with an original maturity of three months or less to be cash equivalents.

*Accounts receivable and allowance for doubtful accounts* – Total trade receivables amounted to approximately \$662,000 and \$575,900 and grants receivable amounted to approximately \$452,600 and \$539,300 as of September 30, 2014 and December 31, 2013, respectively. Some of these amounts are deemed uncollectible; as such, BioTime recognized allowance for doubtful accounts of approximately \$100,500 and \$116,800 as of September 30, 2014 and December 31, 2013, respectively. BioTime evaluates the collectability of its receivables based on a variety of factors, including the length of time receivables are past due and significant one-time events and historical experience. An additional reserve for individual accounts will be recorded if BioTime becomes aware of a customer’s inability to meet its financial obligations, such as in the case of bankruptcy filings or deterioration in the customer’s operating results or financial position. If circumstances related to customers change, estimates of the recoverability of receivables would be further adjusted.



*Concentrations of credit risk* – Financial instruments that potentially subject BioTime to significant concentrations of credit risk consist primarily of cash and cash equivalents. BioTime limits the amount of credit exposure of cash balances by maintaining its accounts in high credit quality financial institutions. Cash equivalent deposits with financial institutions may occasionally exceed the limits of insurance on bank deposits; however, BioTime has not experienced any losses on such accounts.

*Inventory* – Inventories are stated at the lower of cost or market. Cost, which includes amounts related to materials, labor, and overhead, is determined in a manner which approximates the first-in, first-out (“FIFO”) method.

*Equipment* – Equipment is stated at cost. Equipment is being depreciated using the straight-line method over a period of 36 to 120 months. See Note 3.

*Intangible assets* – Intangible assets with finite useful lives are amortized over their estimated useful lives and intangible assets with indefinite lives are not amortized but rather are tested at least annually for impairment. Acquired in-process research and development intangible assets are accounted for depending on whether they were acquired as part of an acquisition of a business, or as assets that do not constitute a business. When acquired in conjunction with the acquisition of a business, these assets are considered to be indefinite-lived until the completion or abandonment of the associated research and development efforts and are capitalized as an asset. If and when development is complete, the associated assets would be deemed finite-lived and would then be amortized based on their respective estimated useful lives at that point in time. However, when acquired in conjunction with an acquisition of assets that do not constitute a business (such as the acquisition of assets from Geron), in accordance with the accounting rules in ASC 805-50, such intangible assets related to in-process research and development (“IPR&D”) are expensed upon acquisition. See Note 8.

*Treasury stock* – BioTime accounts for BioTime common shares issued to subsidiaries for future potential working capital needs as treasury stock on the consolidated balance sheet. BioTime has the intent and ability to register any unregistered shares to support the marketability of the shares.

*Warrants to purchase common stock* – BioTime generally accounts for warrants issued in connection with equity financings as a component of equity. None of the warrants issued by BioTime as of September 30, 2014 include a conditional obligation to issue a variable number of shares; nor was there a deemed possibility that BioTime may need to settle the warrants in cash. If BioTime were to issue warrants with a conditional obligation to issue a variable number of shares or with the deemed possibility of a cash settlement, BioTime would record the fair value of the warrants as a liability and record changes in fair value in other income and expense in the consolidated statements of operations and comprehensive loss at each balance sheet date.

*Cost of sales* – BioTime accounts for the cost of research products acquired for sale and any royalties paid as a result of any revenues in accordance with the terms of the respective licensing agreements as cost of sales on the condensed consolidated statement of operations and comprehensive loss.

*Patent costs* – Costs associated with obtaining patents on products or technology developed are expensed as general and administrative expenses when incurred. This accounting is in compliance with guidance promulgated by the Financial Accounting Standards Board (the “FASB”) regarding goodwill and other intangible assets.

*Reclassification* – Certain prior year amounts have been reclassified to conform to the current year presentation. Trade and grant receivables are now reported separately from prepaid expenses and other current assets.

*Research and development* – BioTime complies with FASB requirements governing accounting for research and development costs. Research and development costs are expensed when incurred, and consist principally of salaries, payroll taxes, consulting fees, research and laboratory fees, rent of research facilities, and license fees paid to third parties to acquire patents or licenses to use patents and other technology.

*Foreign currency translation gain and comprehensive loss* – In countries in which BioTime operates, where the functional currency is other than the U.S. dollar, assets and liabilities are translated using published exchange rates in effect at the condensed consolidated balance sheet date. Revenues and expenses and cash flows are translated using an approximate weighted average exchange rate for the period. Resulting translation adjustments are recorded as a component of accumulated other comprehensive loss on the condensed consolidated balance sheet. For the three and nine months ended September 30, 2014 comprehensive loss includes foreign currency translation loss of \$66,768 and \$216,330, respectively and unrealized loss of \$1,210 and \$2,740, respectively on Geron common shares held by Asterias as of September 30, 2014. The unrealized loss from the Geron shares is a component of comprehensive loss because these shares are considered marketable equity securities that are available-for-sale. For the three and nine months ended September 30, 2013, comprehensive loss includes foreign currency translation gain of \$7,016 and loss of \$184,310, respectively.

*Income taxes* – BioTime accounts for income taxes in accordance with GAAP requirements, which prescribe the use of the asset and liability method, whereby deferred tax asset or liability account balances are calculated at the balance sheet date using current tax laws and rates in effect. Valuation allowances are established when necessary to reduce deferred tax assets when it is more likely than not that a portion or all of the deferred tax assets will not be realized. The FASB guidance also prescribes a recognition threshold and a measurement attribute for the financial statement recognition and measurement of tax positions taken or expected to be taken in a tax return. For those benefits to be recognized, a tax position must be more-likely-than-not sustainable upon examination by taxing authorities. Beginning October 1, 2013, Asterias began filing separate U.S. federal income tax returns but effectively BioTime combined Asterias' tax provision with BioTime's. For California, Asterias' activity for the entire 2013 calendar year was included in BioTime's combined tax return. BioTime recognizes accrued interest and penalties related to unrecognized tax benefits as income tax expense, however, no amounts were accrued for the payment of interest and penalties as of September 30, 2014 and December 31, 2013. BioTime files a U.S. federal income tax return and also files income tax returns in various state, local and foreign jurisdictions. BioTime is no longer subject to income tax examinations by major taxing authorities for years before 2010. Any potential examinations may include questioning the timing and amount of deductions, the nexus of income among various tax jurisdictions and compliance with U.S. federal, state and local and foreign tax laws. Management does not expect that the total amount of unrecognized tax benefits will materially change over the next year.

A deferred income tax benefit of approximately \$5,175,000 was recorded for the nine months ended September 30, 2014, of which approximately \$3,580,000 was related to federal and \$1,595,000 was related to state taxes. A deferred income tax benefit of approximately \$3,280,000 was recorded for the year ended December 31, 2013, of which approximately \$2,800,000 was related to federal and \$480,000 was related to state taxes. No tax benefit had been recorded through September 30, 2013 because of the net operating losses incurred and a full valuation allowance had been provided.

In June 2014, Asterias sold a portion of the BioTime common shares it held, resulting in a taxable gain of approximately \$10.3 million. The taxable gain, however, is expected to be fully offset by available net operating losses. The transaction was treated as a deemed distribution by Asterias and recorded against equity. BioTime's net operating losses may not be used to offset Asterias' taxable gains for federal income tax purposes as the two companies file separate federal tax returns and may not use each other's tax attributes.

*Stock-based compensation* – BioTime follows accounting standards governing share-based payments, which require the measurement and recognition of compensation expense for all share-based payment awards made to directors and employees, including employee stock options, based on estimated fair values. Consistent with FASB guidelines, BioTime utilizes the Black-Scholes Merton option pricing model for valuing share-based payment awards. BioTime's determination of fair value of share-based payment awards on the date of grant using that option-pricing model is affected by BioTime's stock price as well as by assumptions regarding a number of highly complex and subjective variables. These variables include, but are not limited to, BioTime's expected stock price volatility over the term of the awards, and actual and projected employee stock option exercise behaviors. The expected term of options granted is derived from historical data on employee exercises and post-vesting employment termination behavior. The risk-free rate is based on the U.S. Treasury rates in effect during the corresponding period of grant. Although the fair value of employee stock options is determined in accordance with recent FASB guidance, changes in the subjective assumptions can materially affect the estimated value.

*Impairment of long-lived assets* – BioTime's long-lived assets, including intangible assets, are reviewed annually for impairment and whenever events or changes in circumstances indicate that the carrying amount of an asset may not be fully recoverable. If an impairment indicator is present, BioTime will evaluate recoverability by a comparison of the carrying amount of the assets to future undiscounted net cash flows expected to be generated by the assets. If the assets are impaired, the impairment recognized is measured by the amount by which the carrying amount exceeds the estimated fair value of the assets.

*Deferred license and consulting fees* – Deferred license and consulting fees consist of the value of warrants issued to third parties for services, and deferred license fees paid to acquire rights to use the proprietary technologies of third parties. The value of the warrants is being amortized over the period the services are being provided, and the license fees are being amortized over the estimated useful lives of the licensed technologies or licensed research products. BioTime is applying a 10 year estimated useful life to the technologies and products that it is currently licensing. The estimation of the useful life any technology or product involves a significant degree of inherent uncertainty, since the outcome of research and development or the commercial life of a new product cannot be known with certainty at the time that the right to use the technology or product is acquired. BioTime will review the continued appropriateness of the 10 year estimated useful life for impairments that might occur earlier than the original expected useful lives.

*Loss per share* – Basic net loss per share attributable to common shareholders is computed by dividing net loss attributable to the common shareholders of BioTime by the weighted-average number of common shares outstanding for the period. Diluted net loss per share reflects the weighted-average number of common shares outstanding plus the potential effect of dilutive securities or contracts which are convertible to common shares, such as options and warrants (using the treasury stock method) and shares issuable in future periods. Diluted net loss per share for the three and nine months ended September 30, 2014 excludes any effect from 5,398,542 treasury shares, 3,420,068 options and 9,195,002 warrants, and for the three and nine months ended September 30, 2013 excludes 2,315,286 treasury shares, 4,655,884 options, and 1,751,615 warrants because inclusion would be antidilutive.

*Fair value of financial instruments* – The fair value of BioTime's assets and liabilities, which qualify as financial instruments under FASB guidance regarding disclosures about fair value of financial instruments, approximate the carrying amounts presented in the accompanying condensed consolidated balance sheets.

*Effect of recently issued and recently adopted accounting pronouncements* – The following accounting standards, which are not yet effective, are presently being evaluated by BioTime to determine the impact that they might have on its consolidated financial statements.

In May 2014, Financial Accounting Standards Board (the “FASB”) issued Accounting Standards Update (“ASU”) No. 2014-09 “Revenue from Contracts with Customers” (Topic 606). The guidance of this update affects any entity that either issues contracts with customers or transfers goods or services or enters into contracts for the transfer of non-financial assets. The core principal of the guidance is that an entity should recognize revenue to depict the transfer of promised goods or services to customers in the amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods and services. To achieve those core principals, the ASU specifies steps that the entity should apply for revenue recognition. The guidance also specifies the accounting for some costs to obtain or fulfill the contract with customer and disclosure requirements to enable users of financial statements to understand the nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers. For a public entity, ASU No. 2014-09 is effective for annual reporting periods beginning after December 15, 2016, including interim periods within that reporting period. Early application is not permitted. BioTime is currently evaluating the impact of the adoption of the ASU on its consolidated financial statements.

In June 2014, the FASB issued ASU No. 2014-12 “Compensation – Stock Compensation” (Topic 718). The ASU provides guidance for accounting for share-based payments when the terms of an award provide that a performance target could be achieved after the requisite service period. That is the case when an employee is eligible to retire or otherwise terminate employment before the end of the period in which a performance target (for example, profitability target) could be achieved and still be eligible to vest in the award if and when the performance target is achieved. The ASU requires a performance target that effects vesting and that could be achieved after the requisite service period be treated as a performance condition. Compensation cost should be recognized in the period in which it becomes probable that such performance condition would be achieved and should represent the compensation cost attributable to the periods for which the requisite service has already been rendered. For public business entities, the ASU is effective for annual reporting periods beginning after December 15, 2015, and interim periods therein. Early application is permitted. BioTime is in the process of evaluating the impact of adoption of the ASU on its consolidated financial statements.

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” requiring management to evaluate on a regular basis whether any conditions or events have arisen that could raise substantial doubt about the entity’s ability to continue as a going concern. The guidance 1) provides a definition for the term “substantial doubt,” 2) requires an evaluation every reporting period, interim periods included, 3) provides principles for considering the mitigating effect of management’s plans to alleviate the substantial doubt, 4) requires certain disclosures if the substantial doubt is alleviated as a result of management’s plans, 5) requires an express statement, as well as other disclosures, if the substantial doubt is not alleviated, and 6) requires an assessment period of one year from the date the financial statements are issued. The standard is effective for our reporting year ending December 31, 2016, and interim periods thereafter. Early adoption is permitted. We do not expect the adoption of this guidance to have a material impact on our financial statements.

## 2. Inventory

BioTime held \$240,644 and \$165,771 of inventory of raw materials and finished goods products on-site at its corporate headquarters in Alameda, California at September 30, 2014 and December 31, 2013, respectively. Finished goods products of \$12,923 were held by a third party on consignment at September 30, 2014 and December 31, 2013.

## 3. Equipment

At September 30, 2014 and December 31, 2013, equipment, furniture and fixtures were comprised of the following:

	September 30, 2014 (Unaudited)	December 31, 2013
Equipment, furniture and fixtures	\$ 4,952,472	\$ 4,431,586
Accumulated depreciation	(2,194,016)	(1,433,853)
Equipment, net	<u>\$ 2,758,456</u>	<u>\$ 2,997,733</u>

Equipment, furniture and fixtures includes \$115,000 financed by capital lease borrowings in June 2014. Depreciation expense amounted to \$794,414 and \$419,630 for the nine months ended September 30, 2014 and 2013, respectively.

#### 4. Intangible assets

At September 30, 2014 and December 31, 2013, intangible assets and intangible assets net of amortization were comprised of the following:

	September 30, 2014 (Unaudited)	December 31, 2013
Intangible assets	\$ 54,719,918	\$ 54,719,918
Accumulated amortization	(12,615,826)	(8,511,833)
Intangible assets, net	<u>\$ 42,104,092</u>	<u>\$ 46,208,085</u>

BioTime amortizes its intangible assets generally over an estimated period of 10 years on a straight line basis. BioTime recognized \$4,103,994 and \$1,927,718 in amortization expense of intangible assets during the nine months ended September 30, 2014 and 2013, respectively.

#### 5. Accounts Payable and Accrued Liabilities

At September 30, 2014 and December 31, 2013, accounts payable and accrued liabilities consisted of the following:

	September 30, 2014 (Unaudited)	December 31, 2013
Accounts payable	\$ 2,423,400	\$ 3,887,950
Accrued bonuses	310,875	600,000
Other accrued liabilities	2,816,423	2,234,674
	<u>\$ 5,550,698</u>	<u>\$ 6,722,624</u>

#### 6. Related Party Convertible Debt

In July and September 2014, Cell Cure Neurosciences issued certain convertible notes (the "Convertible Notes") to two Cell Cure Neurosciences shareholders other than BioTime in the principal amount of \$469,247. The Cell Cure Neurosciences shareholders who acquired Convertible Notes are considered related parties under ASC 850, *Related Party Disclosures*. The functional currency of Cell Cure Neurosciences is the Israeli New Shekel, however the Convertible Notes are payable in United States dollars. The Convertible Notes bear a stated interest rate of 3% per annum. The total outstanding principal balance of the Convertible Notes, with accrued interest, is due and payable on various maturity dates in July and September 2017. The outstanding principal balance of the Convertible Notes with accrued interest is convertible into Cell Cure Neurosciences ordinary shares at a fixed conversion price of \$20.00 per share, at the election of the holder, at any time prior to maturity. Any conversion of the Convertible Notes must be settled with Cell Cure Neurosciences ordinary shares and not with cash.

The conversion feature of the Convertible Notes is not accounted for as an embedded derivative under the provisions of ASC 815, *Derivatives and Hedging* since it is not a freestanding financial instrument and the underlying Cell Cure Neurosciences ordinary shares are not readily convertible into cash. Accordingly, the Convertible Notes are accounted for under ASC 470-20, *Debt with Conversion and Other Options*. Under ASC 470-20, BioTime determined that a beneficial conversion feature ("BCF") was present on the issuance dates of the Convertible Notes.

A conversion feature is beneficial if, on the issuance dates, the effective conversion price is less than the fair value of the issuer's capital stock. Since the effective conversion price of \$20.00 per share is less than the estimated \$41.00 per share fair value of Cell Cure Neurosciences ordinary shares on the dates the Convertible Notes were issued, a beneficial conversion feature equal to the intrinsic value is present. In accordance with ASC 470-20-30-8, if the intrinsic value of the BCF is greater than the proceeds allocated to the convertible instrument, the amount of the discount assigned to the BCF is limited to the amount of the proceeds allocated to the convertible instrument. The BCF is recorded as an addition to equity with a corresponding reduction to the carrying value of the convertible debt instrument. In the case of the Convertible Notes, this reduction represents a debt discount equal to the principal amount of \$469,247 on the issuance dates. This debt discount will be amortized to interest expense using the effective interest method over the three-year term of the debt, representing an approximate effective annual interest rate of 23%.

As of September 30, 2014, the carrying value of the Convertible Notes was \$3,088, comprised of principal and accrued interest of \$469,508, net of unamortized debt discount of \$466,420.

## 7. Equity

### *Preferred Shares*

BioTime is authorized to issue 2,000,000 shares of preferred stock. The preferred shares may be issued in one or more series as the board of directors may by resolution determine. The board of directors is authorized to fix the number of shares of any series of preferred shares and to determine or alter the rights, preferences, privileges, and restrictions granted to or imposed on the preferred shares as a class, or upon any wholly unissued series of any preferred shares. The board of directors may, by resolution, increase or decrease (but not below the number of shares of such series then outstanding) the number of shares of any series of preferred shares subsequent to the issue of shares of that series.

As of September 30, 2014, BioTime has 70,000 outstanding shares of Series A Convertible Preferred Stock ("Series A Preferred Stock"). The Series A Preferred Stock carries a cumulative annual 3% preferred dividend or \$1.50 per share, in preference to BioTime common shares. Each share of Series A Preferred Stock is convertible, at the election of the holder, into BioTime common shares at a conversion price of \$4.00 per share, a current conversion ratio of 12.5 common shares for each share of Series A Preferred Stock.

In addition to the preferred dividend, the Series A Preferred Stock will be entitled to participate with BioTime common shares in any dividends or distributions on common shares (other than dividends and distributions of common shares resulting in an adjustment of the conversion price) as if all shares of Series A Preferred Stock were then converted into common shares.

All outstanding Series A Preferred Stock will automatically be converted into common shares on March 4, 2019, or if holders of a majority of the outstanding shares of Series A Preferred Stock, voting as a class, approve or consent to a conversion. The conversion price is subject to prorata adjustment in the event of a subdivision or reclassification of the common shares into a greater number of shares, a stock dividend paid in common shares, or a stock combination or reclassification of the common shares into a smaller number of shares.

The Series A Preferred Stock will be entitled to vote with common shares on all matters submitted to common shareholders for approval. Each share of Series A Preferred Stock will be entitled to a number of votes equal to the number of common shares into which it could then be converted. The Series A Preferred Stock will also vote as a separate class on certain matters affecting those shares.

In the event of a liquidation or dissolution of BioTime, holders of Series A Preferred Stock will be entitled to receive payment of any accrued but unpaid preferred dividends before any assets may be distributed to holders of common shares. After payment of the accrued dividends, the Series A Preferred Stock will participate with the common shares in the distribution of any assets available to shareholders, as if the Series A Preferred Stock was then converted into common shares.

#### *Common Shares*

BioTime is authorized to issue 125,000,000 common shares with no par value. As of September 30, 2014, BioTime had 73,690,302 common shares issued and 68,291,760 common shares outstanding. The difference between the number of shares issued and the number of shares outstanding reflects 5,398,542 shares held by certain BioTime subsidiaries and treated as treasury shares for financial accounting purposes.

#### *Options and Warrants*

BioTime has an Equity Incentive Plan pursuant to which it may issue options to purchase, or may issue as “restricted stock,” up to a total of 4,000,000 common shares. During the nine months ended September 30, 2014 and 2013, BioTime granted 1,410,000 and 1,575,000 options, respectively, under its 2012 Equity Incentive Plan. At September 30, 2014, a total of 3,420,068 options were outstanding under the Equity Incentive Plan and BioTime’s 2002 Stock Option Plan.

At September 30, 2014, BioTime had warrants outstanding entitling the holders to purchase a total of 9,195,002 BioTime common shares at an exercise price of \$5.00 per share. At September 30, 2014 Asterias held 8,000,000 of the warrants that were scheduled for distribution to the holders of its Series A common stock on October 1, 2014. See Note 12.

During the nine months ended September 30, 2014, 2,060,400 options and no warrants were exercised. The options exercised included 1,470,400 options exercised by BioTime’s Chief Executive Officer, Michael D. West, and 475,000 options exercised by BioTime’s Senior Vice President, Chief Operating Officer, and Chief Financial Officer, Robert W. Peabody, at an exercise price of \$0.50 per share. Dr. West paid the exercise price of his options and a portion of his income tax withholding obligation through the delivery of 434,013 BioTime common shares to BioTime. Mr. Peabody paid the exercise price of his options through the delivery of 89,623 BioTime common shares to BioTime. The BioTime common shares had a market value of \$2.65 per share on the date that the options were exercised.

### **8. Asset Contribution Agreement**

On January 4, 2013, BioTime and Asterias entered into an Asset Contribution Agreement with Geron Corporation (“Geron”) pursuant to which BioTime and Geron agreed to concurrently contribute certain assets to Asterias in exchange for shares of Asterias common stock. The transaction closed on October 1, 2013.

#### *Transfer of BioTime Assets*

Under the Asset Contribution Agreement, BioTime contributed to Asterias 8,902,077 BioTime common shares registered for re-sale under the Securities Act of 1933, as amended, warrants to subscribe for and purchase 8,000,000 additional BioTime common shares (the “BioTime Warrants”) exercisable for a period of five years at a price of \$5.00 per share, subject to pro rata adjustment for certain stock splits, reverse stock splits, stock dividends, recapitalizations and other transactions; a 10% common stock interest in BioTime’s subsidiary OrthoCyte; a 6% ordinary share interest in BioTime’s subsidiary Cell Cure Neurosciences; and a quantity of certain hES cell lines produced under “good manufacturing practices” sufficient to generate master cell banks, and non-exclusive, world-wide, royalty-free licenses to use those cell lines and certain patents pertaining to stem cell differentiation technology for any and all purposes. In return, Asterias issued to BioTime 21,773,340 shares of its Series B common stock, par value \$0.0001 per share (“Series B Shares”), and warrants to purchase 3,150,000 Series B Shares, exercisable for a period of three years from the date of issue at an exercise price of \$5.00 per share. In addition, BioTime cancelled Asterias’ obligations to repay the principal amount of a loan in the amount of \$5,000,000 arising from cash financing provided to Asterias by BioTime during 2013 prior to the closing of the asset contribution transaction under the Asset Contribution Agreement.

Because Asterias is a subsidiary of BioTime, the transfer of assets from BioTime was accounted for as a transaction under common control. Non-monetary assets received by Asterias were recorded at their historical cost basis amounts with BioTime. Monetary assets were recorded at fair value. The difference between the value of assets contributed by BioTime and the fair value of consideration issued to BioTime was recorded as an additional contribution by BioTime, in additional paid-in capital.

The assets transferred by BioTime and the related consideration paid were recorded as follows:

Consideration transferred to BioTime:

Asterias Series B shares	\$ 52,164,568
Warrants to purchase Asterias Series B shares	2,012,481
Excess of contributed assets' value over consideration	4,800,063
Total consideration issued	<u>\$ 58,977,112</u>

Assets transferred by BioTime:

BioTime common shares, at fair value	\$ 34,985,163
BioTime Warrants, at fair value	18,276,406
Cancellation of outstanding obligation to BioTime	5,000,000
Investment in affiliates, at cost	415,543
Geron asset acquisition related transaction costs paid by BioTime	300,000
Total assets transferred	<u>\$ 58,977,112</u>

The fair value of the Asterias Series B shares issued was estimated at \$2.40 based on the Asterias enterprise value as determined on January 4, 2013, at the time the Asset Contribution Agreement was negotiated and executed by its parties, and as adjusted for subsequent changes in fair values of assets the parties agreed to contribute. The fair value of the warrants to purchase Asterias Series B shares was computed using a Black Scholes Merton option pricing model, which utilized the following assumptions: expected term equal to the contractual term of three years, which is equal to the contractual life of the warrants; risk-free rate of 0.63%; 0% expected dividend yield; 69.62% expected volatility based on the average historical common stock volatility of BioTime and Geron, which were used as Asterias' common stock does not have a trading history; a stock price of \$2.40; and an exercise price of \$5.00.

BioTime common shares were valued at \$3.93 using the closing price per BioTime common shares on the NYSE MKT on October 1, 2013. The fair value of the BioTime Warrants was computed using a Black Scholes Merton option pricing model, which utilized the following assumptions: expected term equal to the contractual term of five years, which is equal to the contractual life of the warrants; risk-free rate of 1.42%; 0% expected dividend yield; 77.63% expected volatility based on historical common stock volatility of BioTime; a stock price of \$3.93; and an exercise price of \$5.00.

The investment in OrthoCyte and Cell Cure Neurosciences stock represents a non-monetary asset and was recorded at BioTime's historical cost because BioTime is a common parent to Asterias and those two BioTime subsidiaries.

*Geron Assets Acquisition*

Under the Asset Contribution Agreement, Geron contributed to Asterias certain patents, patent applications, trade secrets, know-how and other intellectual property rights with respect to the technology of Geron directly related to the research, development and commercialization of certain products and know-how related to human embryonic stem ("hES") cells; certain biological materials, reagents, laboratory equipment; as well as clinical trial documentation, files and data, primarily related to GRNOPC1 clinical trials for spinal cord injury and VAC1 clinical trials for acute myelogenous leukemia. Asterias assumed all obligations related to such assets that would be attributable to periods, events or circumstances after the Asset Contribution closing date, including those related to certain patent interference proceedings and appeals in Federal District Court that have subsequently been settled.



As consideration for the acquisition of assets from Geron, Asterias issued to Geron 6,537,779 shares of Series A common stock, par value \$0.0001 per share ("Series A Shares"), which Geron had agreed to distribute to its stockholders, on a pro rata basis, subject to applicable legal requirements and certain other limitations (the "Series A Distribution"). Asterias agreed to distribute to the holders of its Series A Shares the 8,000,000 BioTime Warrants contributed to Asterias by BioTime (the "BioTime Warrants Distribution"). Geron gave notice to Asterias that the Series A Distribution was completed in August 2014. At September 30, 2014, the BioTime Warrants Distribution by Asterias was expected to be completed on October 1, 2014. See Note 12.

In addition, Asterias agreed to bear certain transaction costs in connection with the Geron asset acquisition. Such transaction costs were allocated to acquisition of assets in the amount of \$1,519,904 and issuance of equity in the amount of \$541,800.

The assets contributed to Asterias by Geron did not include workforce or any processes to be applied to the patents, biological materials, and other assets acquired, and therefore did not constitute a business. Accordingly, the acquisition of the Geron assets has been accounted for as an acquisition of assets in accordance with the relevant provisions of Accounting Standards Codification (ASC) 805-50. Total consideration payable by Asterias, including transaction costs, has been allocated to the assets acquired based on relative fair values of those assets as of the date of the transaction, October 1, 2013, in accordance with ASC 820, Fair Value Measurement.

The assets acquired from Geron and the related consideration were recorded as follows:

Consideration paid to Geron:	
Asterias Series A shares, net of share issuance costs of \$541,800	\$ 15,121,222
Obligation to distribute BioTime Warrants	18,276,406
Transaction and other costs	1,519,904
Total consideration paid	<u>\$ 34,917,532</u>
Assets acquired from Geron (preliminary allocation):	
Patents and other intellectual property rights related to hES cells	\$ 29,017,009
Deferred tax liability arising from difference in book versus tax basis on Geron intangible assets acquired	(11,558,243)
IPR&D expensed upon acquisition	17,458,766
Total assets and in-process research and development acquired	<u>\$ 34,917,532</u>

The fair value of the Asterias Series A shares issued was estimated at \$2.40 based on the estimated Asterias enterprise value as determined by parties at the time the Asset Contribution Agreement was negotiated and executed by its parties on January 4, 2013, as adjusted for subsequent changes in fair values of assets the parties agreed to contribute.

The difference between the fair value of assets contributed by Geron and the fair value of consideration issued to Geron was recorded as an additional contribution by Geron, in additional paid-in capital, because the fair value of the assets transferred by Geron was more reliably determined.

Assets acquired from Geron consist primarily of patents and other intellectual property rights related to hES cells which Asterias intends to license to various parties interested in research, development and commercialization of hES cells technologies, and IPR&D, which includes biological materials, reagents, clinical trial documentation, files and data related primarily to certain clinical trials previously conducted by Geron, which Geron discontinued in November 2011.

Intangible assets related to IPR&D represent the value of incomplete research and development projects which the company intends to continue. In accordance with the accounting rules in ASC 805, such assets, when acquired in conjunction with acquisition of a business, are considered to be indefinite-lived until the completion or abandonment of the associated research and development efforts and are capitalized as an asset. If and when development is complete, the associated assets would be deemed finite-lived and would then be amortized based on their respective estimated useful lives at that point in time. However, when acquired in conjunction with an acquisition of assets that do not constitute a business (such as the acquisition of assets from Geron), in accordance with the accounting rules in ASC 805-50, such intangible assets related to IPR&D are expensed upon acquisition.

The values of the acquired assets were estimated at October 1, 2013 based upon a preliminary review of those assets which took into account factors such as the condition of the cells, cell lines and other biological materials being contributed, the stage of development of particular technology and product candidates related to patents, patent applications, and know-how, the intended use of these assets and the priority assigned to the development of product candidates to which those assets relate, and the assessment of the estimated useful lives of patents. The amounts allocated to patents and other intellectual property rights that Asterias intends to license were capitalized as intangible assets and are being amortized over an estimated useful life period of 10 years. The amounts allocated to IPR&D were expensed at the time of acquisition of the related assets in accordance with the requirements of ASC 805-50. The allocation was based on the relative fair value of assets eligible for capitalization and the fair value of assets representing IPR&D before assessing the deferred tax liability arising from the difference in book versus tax basis on Geron intangible assets acquired, which management estimated to be approximately equal. Accordingly, \$17,458,766 was capitalized as of December 31, 2013, and \$17,458,766 was expensed. These amounts are preliminary as management has not yet completed a detailed assessment and valuation of the acquired assets. Such assessment and valuation is expected to be completed during the current fiscal year. Accordingly, the amounts included in capitalized intangible assets and expensed IPR&D as of December 31, 2013 are subject to adjustments which could be material.

Asterias is also obligated to pay Geron royalties on the sale of products, if any, that are commercialized in reliance upon patents acquired from Geron, at the rate of 4% of net sales.

*Stock and Warrant Purchase Agreement with Romulus*

On January 4, 2013, in connection with entering into the Asset Contribution Agreement, Asterias entered into a Stock and Warrant Purchase Agreement with Romulus Films, Ltd (“Romulus”) pursuant to which Romulus agreed to purchase 2,136,000 Series B Shares and warrants to purchase 350,000 additional Series B Shares for \$5,000,000 in cash upon the consummation of the acquisition of assets under the Asset Contribution Agreement. The warrants are exercisable for a period of three years from the date of issuance at an exercise price of \$5.00 per share. On October 1, 2013, the shares and warrants were issued in exchange for \$5,000,000 in cash.

**9. Unaudited Pro Forma Interim Financial Information – Nine months ended September 30, 2014 and 2013**

The following unaudited pro forma information gives effect to the asset acquisition through the Asset Contribution Agreement with Geron as if the transaction took place on January 1, 2013. The pro forma information does not necessarily reflect the results of operations that would have occurred had the entities been a single company during the periods presented.

	<b>Nine Months Ended September 30,</b>	
	<b>2014</b>	<b>2013</b>
Gross Profit	\$ 2,751,391	\$ 2,055,218
Net loss available to common shareholders	\$ (25,862,133)	\$ (41,904,064)
Net loss per common share – basic and diluted	\$ (0.41)	\$ (0.67)

## 10. Sales of BioTime Common Shares by Subsidiaries

Certain BioTime subsidiaries hold BioTime common shares that the subsidiaries received from BioTime in exchange for capital stock in the subsidiaries. The BioTime common shares held by subsidiaries are treated as treasury stock by BioTime and BioTime does not recognize a gain or loss on the sale of those shares by its subsidiaries. See also Note 12.

During June 2014, Asterias sold 5,000,000 of its BioTime common shares with warrants to purchase 5,000,000 shares of Asterias Series B common stock to two investors for \$12,500,000 in cash. Broadwood Partners, L.P., BioTime's largest shareholder, purchased 1,000,000 of the BioTime common shares with 1,000,000 Asterias warrants. One of BioTime's directors, Neal C. Bradsher, is President of Broadwood Partners, L.P., the investment manager of Broadwood Partners, L.P., and one of Asterias' directors, Richard T. LeBuhn, is Senior Vice President of Broadwood Capital, Inc. The other 4,000,000 BioTime common shares with 4,000,000 Asterias warrants were purchased by a trust previously established by George Karfunkel. Mr. Karfunkel beneficially owns more than 5% of the outstanding common shares of BioTime. Asterias allocated the proceeds received from the sale of the BioTime common stock and Asterias warrants based on their relative fair values resulting in \$9,316,109 and \$3,183,891 of the proceeds being allocated to the common shares and warrants, respectively.

## 11. Clinical Trial and Option Agreement

During September 2014, Asterias entered into a Clinical Trial and Option Agreement (the "CRUK Agreement") with Cancer Research UK (the "Charity") and Cancer Research Technology Limited, a wholly-owned subsidiary of the Charity, pursuant to which the Charity has agreed to fund Phase I/IIa clinical development of Asterias' AST-VAC2 product candidate. Asterias will, at its own cost, complete process development and manufacturing scale-up of the AST-VAC2 manufacturing process and will transfer the resulting cGMP-compatible process to the Charity. The Charity will, at its own cost, manufacture the clinical grade AST-VAC2 and will carry out the Phase I/IIa clinical trial of AST-VAC2 in cancer patients both resected early-stage and advanced forms of lung cancer. Asterias will have an exclusive first option to obtain a license to use the data from the clinical trial. If Asterias exercises that option it will be obligated to make payments upon the execution of the License Agreement, upon the achievement of various milestones, and then royalties on sales of products. In connection with the CRUK Agreement, Asterias sublicensed to CRUK for use in the clinical trials and product manufacturing process certain patents that have been licensed or sublicensed to Asterias by third parties. Asterias would also be obligated to make payments to those licensors and sublicensors upon the achievement of various milestones, and then royalties on sales of products if AST-VAC2 is successfully developed and commercialized.

## 12. Subsequent Events

On October 1, 2014, Asterias completed the BioTime Warrants Distribution by distributing 8,000,000 BioTime Warrants on a pro rata basis to the holders of Asterias Series A Shares.

On October 3, 2014 Asterias converted its Series B Shares into Series A Shares and began trading on the NYSE MKT under the ticker symbol "AST" on October 8, 2014.

On October 3, 2014, certain BioTime subsidiaries sold 504,600 BioTime common shares that they held. Those shares were sold through Cantor Fitzgerald & Co., as sales agent, at \$3.12 per share for aggregate gross proceeds of approximately \$1,574,352.

On October 8, 2014, BioTime sold 9,431,398 common shares for \$29,425,962 in a transaction registered under the Securities Act of 1933, as amended. The \$3.12 price per share was the closing price of BioTime common shares on the NYSE MKT on October 2, 2014, the date on which BioTime and the investors agreed upon the purchase price. BioTime paid no fees or commissions to broker-dealers or any finder's fees, and did not issue any stock purchase warrants, in connection with the offer and sale of the shares. Broadwood Partners, L.P., purchased 4,040,523 shares, and three of BioTime's current directors also purchased 96,150 shares in the offering.

On October 16, 2014, Asterias signed a Notice of Grant Award ("NGA") with the California Institute of Regenerative Medicine ("CIRM"), effective October 1, 2014, with respect to a \$14.3 million CIRM grant award for clinical development of Asterias' product, AST-OPC1. The NGA includes the terms under which CIRM will release grant funds to Asterias. Asterias received the first payment of grant funds in the amount of \$916,554 during October 2014.

We evaluated subsequent events through the issuance date of the financial statements. We are not aware of any significant events that occurred subsequent to the balance sheet date but prior to the filing of this Quarterly Report on Form 10-Q that would have a material impact on our financial statements.

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

The following Management's Discussion and Analysis of Financial Condition and Results of Operations is intended to provide information necessary to understand our condensed consolidated financial statements for the three and nine months ended September 30, 2014 and 2013, and highlight certain other information which, in the opinion of management, will enhance a reader's understanding of our financial condition, changes in financial condition and results of operations. In particular, the discussion is intended to provide an analysis of significant trends and material changes in our financial position and the operating results of our business during the quarter ended September 30, 2014 as compared to the quarter ended September 30, 2013. This discussion should be read in conjunction with our Condensed Consolidated Financial Statements for the three and nine months ended September 30, 2014 and 2013 and related notes included elsewhere in this Quarterly Report on Form 10-Q. These historical financial statements may not be indicative of our future performance. This Management's Discussion and Analysis of Financial Condition and Results of Operations contains a number of forward-looking statements, all of which are based on our current expectations and could be affected by the uncertainties and risks described throughout this filing, particularly in "Item 1A. Risk Factors," and in our Annual Report on Form 10-K for the year ended December 31, 2013.

### Overview

We are a biotechnology company focused on the emerging field of regenerative medicine. Our core technologies center on stem cells capable of becoming all of the cell types in the human body, a property called pluripotency. Products made from these "pluripotent" stem cells are being developed by us and our subsidiaries, for use in a variety of fields of medicine. Four of our subsidiaries, Asterias Biotherapeutics, Inc. ("Asterias"), Cell Cure Neurosciences, Ltd ("Cell Cure Neurosciences"), OrthoCyte Corporation ("OrthoCyte"), and ReCyte Therapeutics, Inc. ("ReCyte") are focused on developing cell based therapeutic products for diseases such as neurological disorders, cancer, age related macular degeneration, orthopedic disorders, and age-related cardiovascular disease. Our commercial strategy targets near-term opportunities such as: *Renevia*<sup>TM</sup> a product currently in clinical trials in Europe to facilitate cell transplantation; *ReGlyde*<sup>TM</sup> and *Premvia*<sup>TM</sup> for tendon and wound-management applications, respectively; *PanC-Dx*<sup>TM</sup>, a family of novel blood and urine-based cancer screens; our current line of research products including *PureStem*<sup>®</sup> human embryonic progenitor cell lines ("hEPSc"), associated *ESpan*<sup>TM</sup> culture media, human embryonic stem cell lines derived by our subsidiary ESI under current good manufacturing practices ("cGMP"); *HyStem*<sup>®</sup> hydrogel products; the LifeMap Database Suite and mobile health software products.

"Regenerative medicine" refers to an emerging field of therapeutic product development that may allow all human cell and tissue types to be manufactured on an industrial scale. This new technology is made possible by the isolation of human embryonic stem ("hES") cells, and by the development of "induced pluripotent stem ("iPS") cells" which are created from regular cells of the human body using technology that allows adult cells to be "reprogrammed" into cells with pluripotency similar to hES-like cells. These pluripotent hES and iPS cells have the unique property of being able to branch out into each and every kind of cell in the human body, including the cell types that make up the brain, the blood, the heart, the lungs, the liver, and other tissues. Unlike adult-derived stem cells that have limited potential to become different cell types, pluripotent stem cells may have vast potential to supply an array of new regenerative therapeutic products, especially those targeting the large and growing markets associated with age-related degenerative disease. Unlike pharmaceuticals that require a molecular target, therapeutic strategies in regenerative medicine are generally aimed at regenerating affected cells and tissues, and therefore may have broader applicability. Regenerative medicine represents a revolution in the field of biotechnology with the promise of providing therapies for diseases previously considered incurable.

The field of regenerative medicine includes a broad range of disciplines, including tissue banking, cellular therapy, gene therapy, and tissue engineering. Our commercial efforts in regenerative medicine include the development and sale of products designed for research applications in the near term as well as products designed for diagnostic and therapeutic applications in the medium and long term.

We have also developed and licensed manufacturing and marketing rights to *Hextend*<sup>®</sup>, a physiologically balanced blood plasma volume expander used for the treatment of hypovolemia in surgery, emergency trauma treatment, and other applications. Hypovolemia is a condition caused by low blood volume, often from blood loss during surgery or from injury. *Hextend*<sup>®</sup> maintains circulatory system fluid volume and blood pressure and helps sustain vital organs during surgery or when a patient has sustained substantial blood loss due to an injury. *Hextend*<sup>®</sup> is the only blood plasma volume expander that contains lactate, multiple electrolytes, glucose, and a medically approved form of starch called hetastarch. *Hextend*<sup>®</sup> is sterile, so its use avoids the risk of infection. Health insurance reimbursements and HMO coverage now include the cost of *Hextend*<sup>®</sup> used in surgical procedures.

*Hextend*<sup>®</sup> is manufactured and distributed in the United States by Hospira, Inc., and in South Korea by CJ Health Corporation (“CJ Health”), a subsidiary of Cheil Jedang Corp., under license from us.

The following table shows our subsidiaries, their respective principal fields of business, our percentage ownership as at September 30, 2014, and the country where their principal business is located:

Subsidiary	Field of Business	BioTime Ownership	Country
Asterias Biotherapeutics, Inc.	Research, development and commercialization of human therapeutic products from stem cells focused initially in the fields of neurology and oncology	70.6%	USA
BioTime Asia, Limited	Stem cell products for research	81%	Hong Kong
Cell Cure Neurosciences Ltd.	Age-related macular degeneration Multiple sclerosis Parkinson’s disease	62.5% <sup>(1)</sup>	Israel
ES Cell International Pte Ltd	Stem cell products for research, including clinical grade cell lines produced under cGMP	100%	Singapore
LifeMap Sciences, Inc.	Genetic, disease, and stem cell databases	74.52%	USA
LifeMap Sciences, Ltd.	Stem cell database	(2)	Israel
LifeMap Solutions, Inc.	Mobile health software	(2)	USA
OncoCyte Corporation	Cancer diagnostics	75.3%	USA
OrthoCyte Corporation	Orthopedic diseases, including chronic back pain and osteoarthritis	100% <sup>(3)</sup>	USA
ReCyte Therapeutics, Inc.	Vascular disorders, including cardiovascular-related diseases, ischemic conditions, vascular injuries. Stem cell-derived endothelial and cardiovascular related progenitor cells that have applications in research, drug testing, and therapeutics	94.8%	USA

(1) Includes shares owned by BioTime, Asterias, and ESI.

(2) LifeMap Sciences, Ltd. and LifeMap Solutions, Inc. are wholly-owned subsidiaries of LifeMap Sciences, Inc.

(3) Includes shares owned by BioTime and Asterias.

## Additional Information

*Espy*<sup>®</sup>, *HyStem*<sup>®</sup>, *Hextend*<sup>®</sup>, *PureStem*<sup>®</sup>, and *PentaLyte*<sup>®</sup> are registered trademarks of BioTime, Inc., and *Renevia*<sup>™</sup>, *ReGlyde*<sup>™</sup>, *Premvia*<sup>™</sup>, *Espan*<sup>™</sup> and *ESI BIO*<sup>™</sup> are trademarks of BioTime, Inc. *ACTCellerate*<sup>™</sup> is a trademark licensed to us by Advanced Cell Technology, Inc. *ReCyte*<sup>™</sup> is a trademark of ReCyte Therapeutics, Inc. *PanC-Dx*<sup>™</sup> is a trademark of OncoCyte Corporation. *OpRegen*<sup>®</sup> is a registered trademark of Cell Cure Neurosciences, Ltd. *GeneCards*<sup>®</sup> is a registered trademark of Yeda Research and Development Co. Ltd.

We were incorporated in 1990 in the state of California. Our principal executive offices are located at 1301 Harbor Bay Parkway, Alameda, California 94502. Our telephone number is (510) 521-3390.

## Critical Accounting Policies

*Revenue recognition* – We comply with ASC 605-10 and recognize revenue when persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered, the price is fixed or determinable, and collectability is reasonably assured. Grant income and the sale of research products are recognized as revenue when earned. Revenues from the sale of research products are primarily derived from the sale of hydrogels and stem cell products. Royalty revenues consist of product royalty payments. License fee revenues consist of fees under license agreements and are recognized when earned and reasonably estimable and also include subscription and advertising revenue from our online databases based upon respective subscription or advertising periods. We recognize revenue in the quarter in which the royalty reports are received rather than the quarter in which the sales took place. When we are entitled to receive up-front nonrefundable licensing or similar fees pursuant to agreements under which we have no continuing performance obligations, the fees are recognized as revenues when collection is reasonably assured. When we receive up-front nonrefundable licensing or similar fees pursuant to agreements under which we do have continuing performance obligations, the fees are deferred and amortized ratably over the performance period. If the performance period cannot be reasonably estimated, we amortize nonrefundable fees over the life of the contract until such time that the performance period can be more reasonably estimated. Milestone payments, if any, related to scientific or technical achievements are recognized in income when the milestone is accomplished if (a) substantive effort was required to achieve the milestone, (b) the amount of the milestone payment appears reasonably commensurate with the effort expended, and (c) collection of the payment is reasonably assured.

*Patent costs* – Costs associated with obtaining patents on products or technology developed are expensed as general and administrative expenses when incurred. This accounting is in compliance with guidance promulgated by the Financial Accounting Standards Board (“FASB”) regarding goodwill and other intangible assets.

*Intangible assets* – Intangible assets with finite useful lives are amortized over estimated useful lives and intangible assets with indefinite lives are not amortized but rather are tested at least annually for impairment. Acquired in-process research and development intangible assets are accounted depending on whether they were acquired as part of an acquisition of a business, or assets that do not constitute a business. When acquired in conjunction with acquisition of a business, these assets are considered to be indefinite-lived until the completion or abandonment of the associated research and development efforts and are capitalized as an asset. If and when development is complete, the associated assets would be deemed finite-lived and would then be amortized based on their respective estimated useful lives at that point in time. However, when acquired in conjunction with an acquisition of assets that do not constitute a business (such as Asterias’ acquisition of assets from Geron), in accordance with the accounting rules in ASC 805-50, such intangible assets related to IPR&D are expensed upon acquisition.

*Research and development* – We comply with FASB requirements governing accounting for research and development costs. Research and development costs are expensed when incurred, and consist principally of salaries, payroll taxes, consulting fees, research and laboratory fees, and license fees paid to acquire patents or licenses to use patents and other technology from third parties.

*Stock-based compensation* – We have adopted accounting standards governing share-based payments, which require the measurement and recognition of compensation expense for all share-based payment awards made to directors and employees, including employee stock options, based on estimated fair values. We utilize the Black-Scholes Merton option pricing model. Our determination of fair value of share-based payment awards on the date of grant using an option-pricing model is affected by our stock price as well as assumptions regarding a number of highly complex and subjective variables. These variables include, but are not limited to, expected stock price volatility over the term of the awards, and actual and projected employee stock option exercise behaviors. The expected term of options granted is derived from historical data on employee exercises and post-vesting employment termination behavior. The risk-free rate is based on the U.S. Treasury rates in effect during the corresponding period of grant. Although the fair value of employee stock options is determined in accordance with recent FASB guidance, changes in the subjective assumptions can materially affect the estimated value. In management’s opinion, the existing valuation models may not provide an accurate measure of the fair value of employee stock options because the option-pricing model value may not be indicative of the fair value that would be established in a willing buyer/willing seller market transaction.

*Treasury stock* – We account for BioTime common shares issued to subsidiaries for future potential working capital needs as treasury stock on the consolidated balance sheet. We have the intent and ability to register any unregistered shares to support the marketability of the shares.

*Impairment of long-lived assets* – Our long-lived assets, including intangible assets, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be fully recoverable. If an impairment indicator is present, we evaluate recoverability by a comparison of the carrying amount of the assets to future undiscounted net cash flows expected to be generated by the assets. If the assets are impaired, the impairment recognized is measured by the amount by which the carrying amount exceeds the estimated fair value of the assets.

*Royalty Obligation and Deferred license fees* – Deferred license and consulting fees consist of the value of warrants issued to third parties for services, and deferred license fees paid to acquire rights to use the proprietary technologies of third parties. The value of the warrants is being amortized over the lives of the warrants, and deferred license fees over the estimated useful lives of the licensed technologies or licensed research products. We are applying a 10 year estimated useful life to the technologies and products that we are currently licensing. The estimation of the useful life of any technology or product involves a significant degree of inherent uncertainty, since the outcome of research and development or the commercial life of a new product cannot be known with certainty at the time that the right to use the technology or product is acquired. We will review the continued appropriateness of the 10 year estimated useful life for impairments that might occur earlier than the original expected useful lives.



During September 2014, Asterias entered into a Clinical Trial and Option Agreement (the “CRUK Agreement”) with Cancer Research UK (the “Charity”) and Cancer Research Technology Limited, a wholly-owned subsidiary of the Charity, pursuant to which the Charity has agreed to fund Phase I/IIa clinical development of Asterias’ AST-VAC2 product candidate. Asterias will, at its own cost, complete process development and manufacturing scale-up of the AST-VAC2 manufacturing process and will transfer the resulting cGMP-compatible process to the Charity. The Charity will, at its own cost, manufacture the clinical grade AST-VAC2 and will carry out the Phase I/IIa clinical trial of AST-VAC2 in cancer patients both resected early-stage and advanced forms of lung cancer. Asterias will have an exclusive first option to obtain a license to use the data from the clinical trial. If Asterias exercises that option it will be obligated to make payments upon the execution of the License Agreement, upon the achievement of various milestones, and then royalties on sales of products. In connection with the CRUK Agreement, Asterias sublicensed to CRUK for use in the clinical trials and product manufacturing process certain patents that have been licensed or sublicensed to Asterias by third parties. Asterias would also be obligated to make payments to those licensors and sublicensors upon the achievement of various milestones, and then royalties on sales of products if AST-VAC2 is successfully developed and commercialized.

*Principles of consolidation* – Our consolidated financial statements include the accounts of our wholly-owned subsidiary ESI, and the accounts of our majority owned subsidiaries, Asterias, ReCyte Therapeutics, OncoCyte, OrthoCyte, BioTime Asia, Cell Cure Neurosciences, and LifeMap Sciences. All material intercompany accounts and transactions have been eliminated in consolidation. The consolidated financial statements are presented in accordance with accounting principles generally accepted in the U.S. and with the accounting and reporting requirements of SEC Regulation S-X.

## Results of Operations

For the three and nine months ended September 30, 2014, we recorded a net loss of \$8,267,925 and \$25,828,095, respectively.

### Revenues

	<b>Three Months Ended</b>		<b>\$ Increase/ Decrease</b>	<b>% Increase/ Decrease</b>
	<b>September 30,</b>			
	<b>2014</b>	<b>2013</b>		
License fees	\$ 285,157	\$ 382,767	\$ -97,610	-25.5%
Royalty from product sales	147,811	80,592	+67,219	+83.4%
Grant income	647,580	160,431	+487,149	+303.7%
Sales of research products and services	110,555	90,272	+20,283	+22.5%
<b>Total revenues</b>	<b>1,191,103</b>	<b>714,062</b>	<b>+477,041</b>	<b>+66.8%</b>
Cost of sales	(230,901)	(206,678)	+24,223	+11.7%
<b>Gross profit</b>	<b>960,202</b>	<b>507,384</b>	<b>452,818</b>	<b>+89.2%</b>

	<b>Nine Months Ended</b>		<b>\$ Increase/ Decrease</b>	<b>% Increase/ Decrease</b>
	<b>September 30,</b>			
	<b>2014</b>	<b>2013</b>		
License fees	\$ 880,740	\$ 1,094,843	\$ -214,103	-19.6%
Royalty from product sales	321,806	291,505	+30,301	+10.4%
Grant income	1,863,310	941,226	+922,084	+98.0%
Sales of research products and services	299,615	214,277	+85,338	+39.8%
<b>Total revenues</b>	<b>3,365,471</b>	<b>2,541,851</b>	<b>+823,620</b>	<b>+32.4%</b>
Cost of sales	(614,080)	(570,237)	+43,843	+7.7%
<b>Gross profit</b>	<b>2,751,391</b>	<b>1,971,614</b>	<b>+779,777</b>	<b>+39.6%</b>

Our license fee revenues for the three and nine months ended September 30, 2014 consist of subscription and advertising revenues of \$285,157 and \$880,740, respectively, from LifeMap Science’s online database business primarily related to its *GeneCards*<sup>®</sup> database. For the three and nine month periods ended September 30, 2013 our license fee revenues included LifeMap Sciences subscription and advertising revenue, and also included amortized license fees from certain licenses related to the development of our blood plasma volume expander products *Hexend*<sup>®</sup> and *PentaLyte*<sup>®</sup> in certain foreign countries, which have terminated.

Our royalty revenues from product sales for the three and nine months ended September 30, 2014 include \$84,515 and \$167,207, respectively, of royalties earned by Asterias and \$63,296 and \$154,599, respectively, of royalties on sales of *Hextend*<sup>®</sup> made by Hospira and CJ Health. Royalties on sales of *Hextend*<sup>®</sup> have been decreasing as hospitals have shifted their purchases of blood volume expanders to albumin products, leading to a decline in the number of units sold and the price per unit. Sales of *Hextend*<sup>®</sup> also declined following the implementation of certain new safety labeling changes mandated by the FDA during November 2013 for the entire class of hydroxyethyl starch products, including *Hextend*<sup>®</sup>. In addition, during June 2014, we entered into an amendment of our license agreement with CJ Health that extended the term of the license and CJ Health's royalty payment obligation beyond the expiration date of our Korean patents but reduced the royalty rate by 50%. We expect royalty revenues from sales of *Hextend*<sup>®</sup> to continue to decline as a percentage of total revenue.

Under our license agreements with Hospira and CJ Health, our licensees report sales of *Hextend*<sup>®</sup> and pay us the royalties due on account of such sales within 90 days after the end of each calendar quarter. We recognize such revenues in the quarter in which the sales report is received, rather than the quarter in which the sales took place. For example, our royalties on sales made during the second quarter 2014 were recognized in our financial statements for the third quarter.

Total grant revenue for the three and nine months ended September 30, 2014 were \$647,580 and \$1,863,310, respectively, representing increases of approximately 303.7% and 98.0% over grant revenues for the respective periods of the prior year. Grant revenue for the three and nine months ended September 30, 2014 included \$457,705 and \$1,338,999, respectively, recognized through Cell Cure Neurosciences, and \$189,875 and \$524,311, respectively from various grants awarded to us by the National Institutes of Health ("NIH") that will expire at various times during the current year.

While revenues increased by 32.4% during the nine months ended September 30, 2014, cost of sales increased by only 7.7%, reflecting the fact that grant revenues and license fees, which do not give rise to costs of sales, increased by \$707,981 which is approximately 86% of the total increase in revenues.

### Expenses

The following tables show our operating expenses for the three and nine month periods ended September 30, 2014 and 2013.

	Three Months Ended		\$ Increase/ Decrease	% Increase/ Decrease
	September 30,			
	2014	2013		
Research and development expenses	\$ (8,836,341)	\$ (6,441,462)	\$ +2,394,879	+37.2%
General and administrative expenses	(4,261,450)	(4,267,875)	-6,425	-0.2%
Interest (expense)/income, net	(7,632)	509	-8,141	-1,599.4%
Other income/(expense), net	(118,796)	(60,704)	+58,092	+95.7%
	Nine Months Ended		\$ Increase/ Decrease	% Increase/ Decrease
	September 30,			
	2014	2013		
Research and development expenses	\$ (26,267,792)	\$ (17,389,409)	\$ +8,878,383	+51.1%
General and administrative expenses	(12,764,324)	(11,273,948)	+1,490,376	+13.2%
Interest (expense)/income, net	(29,786)	2,033	-31,819	-1,565.1%
Other income/(expense), net	165,135	(169,512)	+334,647	+197.4%

*Research and development expenses* – Research and development expenses for the three and nine months ended September 30, 2014 increased to \$8,836,341 and \$26,267,792, respectively, from \$6,441,462 and \$17,389,409 for the same periods of 2013. The increase is largely due to the amortization of intangible assets acquired by Asterias from Geron and BioTime in October 2013 and the ramp-up of the Asterias and LifeMap Solutions product development programs. OncoCyte’s clinical trial work to develop its *PanC-Dx™* cancer diagnostics and our continued clinical development of *Renovia™* also contributed to the increase in research and development expense. For the three months ended September 30, 2014, compared to the same period of 2013, amortization of intangible assets increased by \$725,425, employee compensation, including stock-based compensation and related costs allocated to research and development expenses increased by \$581,288, outside research and services primarily related to our clinical trials of *Renovia™* increased by \$324,049, contract manufacturing related expenses increased by \$310,609, patent, license, and trademark related fees increased by \$289,154, depreciation expenses allocated to research and development increased by \$94,117, clinical trials related expenses increased by \$72,930, and rent and facilities maintenance related expenses allocated to research and development increased by \$71,083. These increases are in part offset by a decrease of \$168,828 in preclinical trial related expenses in our *Renovia™* program and a decrease of \$70,250 in Cell Cure Neurosciences’ research and development expenses.

The increase in research and development expenses during the nine months ended September 30, 2014 is generally attributable to the same factors that contributed to the increase during the third quarter, including an increase of \$3,149,160 in employee compensation, stock-based compensation, employee bonus accruals, and related costs allocated to research and development expenses, an increase of \$2,176,276 in amortization of intangible assets, an increase of \$1,053,160 in license, trademark, and patent fees and patent related litigation fees, an increase of \$781,473 in outside research and services, and increase of \$749,507 in contract manufacturing related expenses, an increase of \$473,614 in consulting services, an increase of \$354,703 in depreciation expenses allocated to research and development, an increase of \$262,554 in laboratory expenses and supplies, an increase of \$252,999 in rent and facilities maintenance related expenses allocated to research and development, an increase of \$186,666 in Cell Cure Neurosciences’ research and development expenses, an increase of \$129,568 in insurance premiums allocated to research and development, and an increase of \$85,584 in travel, lodging, and meals allocated to research and development. These increases are in part offset by a decrease of \$642,818 in preclinical trial related expenses of *Renovia™* and a decrease of \$85,396 in ESI’ research and development expenses.

The following table shows the amount of our total research and development expenses allocated to our primary research and development programs during the nine months ended September 30, 2014 and 2013.

Company	Program	Nine Months Ended September 30,	
		2014	2013
Asterias	hESC-based cell therapeutic programs	\$ 7,910,097	\$ 1,931,048
BioTime and ESI	<i>PureStem®</i> hEPCs, cGMP hES cell lines, and related research products	2,397,018	2,001,047
BioTime	<i>PureStem®</i> technology	-	227,429
BioTime	Hydrogel therapeutic products and <i>HyStem®</i> research	4,487,274	3,813,658
BioTime	<i>Hextend®</i>	48,549	72,894
BioTime	<i>HyStem®</i> 3D cell culture platform for cancer drug discovery	128,392	47,017
BioTime Asia	Stem cell products for research	-	23,787
Cell Cure Neurosciences	<i>OpRegen®</i> , <i>OpRegen®-Plus</i> , and neurological disease therapeutics	4,182,470	3,986,790
LifeMap Sciences	Database development and sales and mobile health software development	2,754,015	1,881,822
OncoCyte	Cancer diagnostics	2,743,655	1,964,173
OrthoCyte	Orthopedic therapeutics	551,685	718,874
ReCyte Therapeutics	Cardiovascular therapeutics	1,064,637	720,870
Total research and development expenses		\$ 26,267,792	\$ 17,389,409

The following table shows the approximate percentages of our total research and development expenses of \$8,836,341 and \$26,267,792 allocated to our primary research and development projects during the three and nine months ended September 30, 2014, respectively, and \$6,441,462 and \$17,389,409 for the same periods in 2013, respectively.

Company	Program	Three Months Ended September 30,		Nine Months Ended September 30,	
		2014	2013	2014	2013
Asterias	hESC-based cell therapeutic programs	29.1%	17.9%	30.1%	11.1%
BioTime and ESI	<i>PureStem</i> <sup>®</sup> hEPCs, cGMP hES cell lines, and related research products	8.6%	8.7%	9.1%	11.5%
BioTime	<i>PureStem</i> <sup>®</sup> technology	–%	0.4%	–%	1.3%
BioTime	Hydrogel therapeutic products and <i>HyStem</i> <sup>®</sup> research	16.6%	23.4%	17.1%	22.0%
BioTime	<i>Hextend</i> <sup>®</sup>	0.2%	0.5%	0.2%	0.4%
BioTime	<i>HyStem</i> <sup>®</sup> 3D cell culture platform for cancer drug discovery	0.1%	0.7%	0.5%	0.3%
BioTime Asia	Stem cell products for research	–%	0.1%	–%	0.1%
Cell Cure Neurosciences	Age related macular degeneration ( <i>OpRegen</i> <sup>®</sup> and <i>OpRegen</i> <sup>®</sup> -Plus ), and neurological disease therapeutics	18.9%	26.6%	15.9%	23.0%
LifeMap Sciences	Database development and sales and mobile health software development	12.2%	9.9%	10.5%	10.8%
OncoCyte	Cancer diagnostics	9.7%	8.7%	10.4%	11.3%
OrthoCyte	Orthopedic therapeutics	1.6%	1.8%	2.1%	4.1%
ReCyte Therapeutics	Cardiovascular therapeutics	3.0%	1.3%	4.1%	4.1%

*General and administrative expenses* – General and administrative expenses for the three and nine months ended September 30, 2014 were \$4,261,450 and \$12,764,324, respectively, compared to \$4,267,875 and \$11,273,948 for the same periods in 2013. The changes in general and administrative expenses reflect a decrease of \$6,425 and increase of \$1,490,376, respectively, for the three and nine months ended September 30, 2014 compared to the same periods in 2013. The changes reflect in part the ramp-up of operations of LifeMap Solutions and Asterias and a decline in operations by ESI.

The largest components of the decline in general and administrative expenses during the third quarter of 2014 were decreases of \$144,715 in legal expense, and a decrease of \$120,634 in stock-based compensation to our independent directors. The decrease in stock-based compensation expense reflects, in part, a decline in the number of outside directors, the timing of resignations and appointments of independent directors. Other components of the decrease in general and administrative costs for the three months ended September 30, 2014 were: a decrease of \$78,856 in office expenses and supplies and computer supplies, and a decrease of \$56,969 in ESI and Cell Cure Neurosciences general and administrative expenses. These decreases were in part offset by an increase of \$159,043 in employee compensation, including employee bonus accruals and related costs allocated to general and administrative expenses, an increase of \$106,236 in general consulting expenses, an increase of \$70,674 in marketing and advertisement related expenses, and an increase of \$62,169 in investor and public relations expenses, transfer agent, stock listing and registration fees.

The increase in total general and administrative costs on a consolidated basis for the nine months ended September 30, 2014 are primarily attributable to an increase of \$1,299,878 in employee compensation, including employee bonus accruals, stock-based compensation and related costs allocated to general and administrative expenses, an increase of \$414,614 in general consulting expenses, an increase of \$283,904 in marketing and advertisement related expenses, an increase of \$230,312 in accounting, audit and tax related expense, an increase of \$170,658 in Asterias' state corporation and franchise taxes, an increase of \$94,829 in rent and facilities maintenance related expenses allocated to general and administrative expenses, and an increase of \$84,154 in travel, lodging and meals allocated to general and administrative expenses. These increases are in part offset by decreases of \$685,160 in legal fees generally reflecting non-recurring expenses that we incurred in 2013 related to the Asset Contribution Agreement transactions, including preparing registration statements for filing with the SEC and a proxy statement for a special meeting of our shareholders, a decrease of \$298,705 in stock-based compensation to consultants and our independent directors, and a decrease of \$110,257 in office expenses and supplies and computer supplies.

General and administrative expenses include employee and director compensation allocated to general and administrative expenses, consulting fees other than those paid for science-related consulting, insurance costs allocated to general and administrative expenses, stock exchange-related costs, depreciation expense, shipping expenses, marketing costs, legal and accounting costs, and other miscellaneous expenses which are allocated to general and administrative expense.

The following table shows the amount of our general and administrative expenses and those related to our subsidiaries during the nine months ended September 30, 2014 and 2013.

Company	Nine Months Ended September 30,	
	2014	2013
BioTime	\$ 4,788,669	\$ 5,292,735
Asterias	\$ 4,107,888	\$ 2,888,028
BioTime Asia	\$ 11,915	\$ 127,920
Cell Cure Neurosciences	\$ 534,058	\$ 549,233
ES Cell International Pte Ltd	\$ 153,451	\$ 209,214
LifeMap	\$ 1,986,244	\$ 1,302,827
OncoCyte	\$ 568,062	\$ 310,809
OrthoCyte	\$ 304,100	\$ 296,820
ReCyte Therapeutics	\$ 309,937	\$ 296,362
Total general and administrative expenses	\$ 12,764,324	\$ 11,273,948

*Other income/(expense)* – Other income/(expense) during the three and nine months ended September 30, 2014 consist primarily of foreign currency transaction loss of \$87,533 and gain of \$91,686, respectively from ESI and Cell Cure Neurosciences upon remeasurement of amounts owed to BioTime in US dollars. Other income during the nine months ended September 30, 2014 also includes \$110,097 earned by Cell Cure Neurosciences on embedded derivatives related to a research contract, based in U.S. dollars, with an Israeli company. This income was offset in part by charitable donations of \$32,261 made during the nine months ended September 30, 2014. Other expense during the same periods in 2013 consists primarily of \$9,145 and \$124,298, respectively, of foreign currency transaction loss.

*Income Taxes* – A deferred income tax benefit of approximately \$5,175,000 was recorded for the nine months ended September 30, 2014, of which approximately \$3,580,000 was related to federal and \$1,595,000 was related to state taxes. A deferred income tax benefit of approximately \$3,280,000 was recorded for the year ended December 31, 2013, of which approximately \$2,800,000 was related to federal and \$480,000 was related to state taxes. No tax benefit had been recorded through September 30, 2013 because of the net operating losses incurred and a full valuation allowance had been provided.

In June 2014, Asterias sold a portion of the BioTime common shares it held, resulting in a taxable gain of approximately \$10.3 million and a tax payable of \$3.6 million. This payable, however, is expected to be fully offset by available net operating losses. As of September 30, 2014, Asterias recorded a \$4.1 million deferred tax liability for the temporary taxable difference in the basis of the investment still held by Asterias in BioTime stock. Both transactions were treated as a deemed distribution by Asterias and recorded against equity. BioTime's net operating losses may not be used to offset Asterias' gains for federal income tax purposes as the companies file separate federal tax returns and may not use each other's tax attributes.

## Liquidity and Capital Resources

At September 30, 2014, we had \$7,416,235 of cash and cash equivalents on hand, of which \$5,025,499 was held by Asterias. During October 2014, we raised \$29,425,962 of cash through the issue and sale of 9,431,398 BioTime common shares for \$3.12 per share in a transaction registered under the Securities Act. The \$3.12 price per share was the closing price of BioTime common shares on the NYSE MKT on the date on which we and the investors agreed upon the purchase price. In addition, during October 2014 certain of our subsidiaries received approximately \$1,574,352 of gross proceeds from the sale of 504,600 BioTime common shares that they held. The subsidiaries sold those shares through Cantor Fitzgerald & Co., as sales agent. The capital raised by our subsidiaries through those stock sales belongs to the subsidiaries and not to BioTime. See “Cash generated by financing activities” below.

Asterias has been awarded a \$14.3 million Strategic Partnership III grant by the California Institute for Regenerative Medicine (“CIRM”) to help fund Asterias’ clinical development of its AST-OPC1 product candidate. The grant will provide funding for Asterias to conduct a Phase 1/2a clinical trial of AST-OPC1 in subjects with complete cervical 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. CIRM will disburse the grant funds to Asterias over four years in accordance with a quarterly disbursement schedule, subject to Asterias attaining certain progress and safety milestones. Asterias received the first payment during October 2014 in the amount of \$916,554.

During September 2014, Asterias entered into a Clinical Trial and Option Agreement with Cancer Research UK (the “Charity”) and Cancer Research Technology Limited, a wholly-owned subsidiary of the Charity, pursuant to which the Charity has agreed to fund Phase I/IIa clinical development of the AST-VAC2 product candidate. Asterias will, at its own cost, complete process development and manufacturing scale-up of the AST-VAC2 manufacturing process and will transfer the resulting cGMP-compatible process to the United Kingdom organization. The Charity will, at its own cost, manufacture the clinical grade AST-VAC2 and will carry out the Phase I/IIa clinical trial of AST-VAC2 in cancer patients both resected early-stage and advanced forms of lung cancer. Asterias will have an exclusive first option to obtain a license to use the data from the clinical trial. If Asterias exercises that option it will be obligated to make payments upon the execution of the License Agreement, upon the achievement of various milestones, and then royalties on sales of products if AST-VAC2 is successfully developed and commercialized.

### ***Cash generated by operations***

During the nine months ended September 30, 2014, we received \$3,201,664 of cash in our operations. Our sources of that cash primarily consisted of \$904,993 from the sale of research products and subscription and advertisement revenues, \$1,475,856 in foreign research grants to Cell Cure Neurosciences, \$499,008 of research grant payments from the NIH, and \$321,806 in royalty revenues on product sales by licensees. During the same nine month period in 2013, we received \$3,280,659 of cash in our operations. Our sources of that cash primarily consisted of \$1,429,932 in foreign research grants, \$1,080,328 from the sale of research products and subscription and advertisement revenues, \$ 291,223 of royalty revenues from sales of *Hextend*<sup>®</sup>, the final payment of \$392,664 from a research grant from CIRM, and a \$85,207 research grant payment from the NIH.

### ***Cash used in operations***

During the nine months ended September 30, 2014, our total research and development expenditures were \$26,267,792 and our general and administrative expenditures were \$12,764,324. Net loss for the nine months ended September 30, 2014 amounted to \$25,828,095. Net cash used in operating activities during this period amounted to \$29,744,008. The net loss for the period includes the following non-cash items: amortization of \$4,103,994 in intangible assets; \$3,320,773 in stock-based compensation paid to employees, consultants and directors; \$794,414 in depreciation expenses; and \$82,125 in amortization of deferred license fees. This overall difference was offset to some extent by net loss of \$5,151,013 allocable to the non-controlling interest in our subsidiaries, \$5,174,977 in deferred income tax benefit; \$1,544,520 in accounts payable and accrued liabilities; \$113,635 in prepaid expenses and other current assets; \$124,442 in other long-term liabilities; and \$86,124 in accounts receivables.

### ***Cash flows from investing activities***

During the nine months ended September 30, 2014, we used \$799,363 for investing activities. The primary components of this cash were approximately \$497,119 used in the purchase of equipment, and a lease security deposit of \$300,000 for Asterias' facilities in Fremont, California.

### ***Cash generated by financing activities***

During the nine months ended September 30, 2014, we raised gross proceeds of \$15,806,316 from the sale of 5,040,560 BioTime common shares by us and our subsidiaries at a weighted average price of \$3.14 per share in "at-the-market" transactions through Cantor Fitzgerald & Co. ("Cantor"), as the sales agent. Offers and sales of our common shares for our account through Cantor were made under a *Controlled Equity Offering*<sup>SM</sup> Sales Agreement and have been registered under the Securities Act of 1933, as amended (the "Securities Act"). Under the sales agreement, Cantor sold our common shares in transactions that constituted an "at-the-market" offering as defined in Rule 415 under the Securities Act, including, but not limited to, sales made directly on NYSE MKT, and in privately negotiated transactions. Cantor has also acted as a sales agent for our subsidiaries Asterias, LifeMap Sciences, OncoCyte, and Cell Cure Neurosciences that have sold BioTime common shares to raise capital for their operations. The offer and sale of those shares has also been registered under the Securities Act. We contributed the BioTime common shares to the subsidiaries in exchange for subsidiary capital stock. The proceeds of the sale of BioTime shares by our subsidiaries belong to those subsidiaries. There is no assurance that we or our subsidiaries will be able to sell additional common shares through Cantor at prices acceptable to us.

On March 4, 2014, BioTime received \$3,500,000 from the sale of 70,000 shares of a newly authorized Series A Convertible Preferred Stock ("Series A Preferred Stock"). The Series A Preferred Stock carries a cumulative annual 3% preferred dividend or \$1.50 per share, in preference to BioTime common shares. Each share of Series A Preferred Stock is convertible, at the election of the holder, into BioTime common shares at a conversion price of \$4.00 per share, a current conversion ratio of 12.5 common shares for each share of Series A Preferred Stock. See Note 7 to the Condensed Consolidated Interim Financial Statements.

On June 16, 2014, Asterias sold 200,000 shares of its Series B common stock to its President and Chief Executive Officer, Pedro Lichtinger, for \$468,000 in cash, and on June 16, 2014 Asterias sold 5,000,000 of its BioTime common shares with warrants to purchase 5,000,000 shares of Asterias' Series B common stock to two private investors for \$12,500,000 in cash. The warrants are exercisable until June 15, 2015 at an exercise price of \$2.34 per share. The exercise price of the warrants and the number of shares issuable upon the exercise of the warrants are subject to adjustment in the case of stock splits, stock dividends, or certain other transactions. See Note 10 to the Condensed Consolidated Interim Financial Statements.

During the nine months ended September 30, 2014, Cell Cure Neurosciences received \$466,690 under a convertible debt arrangement from current investors in the company.

During the nine months ended September 30, 2014, BioTime received \$219,500 in cash from the exercise of options by an employee and three directors at a weighted average exercise price of \$1.91 per share.

Subsequent to September 30, 2014, we and our subsidiaries raised \$31,000,314 of additional equity capital through the sale of BioTime common shares. See Note 12 to the Condensed Consolidated Interim Financial Statements.

## Contractual obligations

As of September 30, 2014, our contractual obligations for the next five years and thereafter were as follows:

Contractual Obligations <sup>(1)</sup>	Principal Payments Due by Period				
	Total	Less Than 1 Year	1-3 Years	4-5 Years	After 5 Years
Operating leases <sup>(2)</sup>	\$ 11,378,686	\$ 560,174	\$ 2,976,392	\$ 2,579,280	\$ 5,262,840
Capital lease <sup>(3)</sup>	\$ 116,425	\$ 15,876	\$ 100,549	\$ -	\$ -

- 1) This table does not include payments to key employees that could arise if they were involuntary terminated or if their employment terminated following a change in control.
- 2) Includes the lease of our principal office and laboratory facilities in Alameda, California, and leases of the offices and laboratory facilities of our subsidiaries Asterias, LifeMap Sciences, and Cell Cure Neurosciences. Also includes three operating leases for lab equipment.
- 3) Includes one capital lease for lab equipment.

## Future capital needs

The operations of our subsidiary Asterias will continue to result in an increase in our operating expenses and losses on a consolidated basis compared to 2013, and will increase our need for additional capital on an ongoing basis. Asterias' research and development efforts will involve substantial expenses that will add to our losses on a consolidated basis for the near future. Also, Asterias is now a public company. As a public company, Asterias will incur costs associated with audits of its financial statements, filing annual, quarterly, and other periodic reports with the SEC, holding annual shareholder meetings, and public relations and investor relations. These costs will be in addition to those incurred by us for similar purposes.

We and our subsidiaries will need to continue to sell BioTime common shares from time to time, and our subsidiaries may also seek to raise capital through the sale of their capital stock. We and our subsidiaries will also seek funding for our research and development programs from other sources such as research grants and other arrangements with third parties.

We have consolidated the sales and marketing of our research products in a new ESI BIO division. As part of this plan, we have shifted our sales and marketing efforts from a website based effort to one that utilizes more sales personnel who may be employees or independent sales representatives. We also plan to expand our product offerings. This effort will require additional expenditures for the development of new research products and the addition of assets and personnel for sales and marketing purposes.

The amount and pace of research and development work that we and our subsidiaries can do or sponsor, and our ability to commence and complete the clinical trials that are required in order for us to obtain FDA and foreign regulatory approval of products, depend upon the amount of money we and our subsidiaries have. Future research and clinical study costs are not presently determinable due to many factors, including the inherent uncertainty of these costs and the uncertainty as to timing, source, and amount of capital that will become available for our projects.

The market value and the volatility of our stock price, as well as general market conditions, could impact our ability to raise capital on favorable terms, or at all. Any equity financing that we or our subsidiaries obtain may further dilute or otherwise impair the ownership interests of our current shareholders. If we and our subsidiaries fail to generate positive cash flows or fail to obtain additional capital when required, we and our subsidiaries could modify, delay or abandon some or all of our respective research and development programs.

Because our revenues are not presently sufficient to cover our operating expenses, we will continue to need to obtain additional equity capital or debt in order to finance our operations. The future availability and terms of equity or debt financing are uncertain. The unavailability or inadequacy of financing or revenues to meet future capital needs could force us to modify, curtail, delay, or suspend some or all aspects of our planned operations. Sales of additional equity securities by us or our subsidiaries could result in the dilution of the interests of present shareholders.



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

#### *Foreign Currency Exchange Risk*

We are exposed to some foreign exchange currency risks because we have subsidiaries that are located in foreign countries. We do not engage in foreign currency hedging activities. Because we translate foreign currencies into United States dollars for reporting purposes, currency fluctuations have an impact on our financial results. We believe that our exposure to currency exchange fluctuation risk is mitigated by the fact that our foreign subsidiaries pay their financial obligations almost exclusively in their local currency. As of September 30, 2014 and as of December 31, 2013, currency exchange rates did not have a material impact on our intercompany transactions with our foreign subsidiaries. However, a weakening of the dollar against the foreign exchange used in the home countries of our foreign subsidiaries could increase our cost of providing additional financing to our foreign subsidiaries in the future. Conversely, a strengthening of the dollar would decrease our cost of making additional investments in those subsidiaries.

#### *Credit Risk*

We place some of our cash in U.S. banks and invest most of our cash in money market funds. Deposits with banks may temporarily exceed the amount of insurance provided on such deposits. We will monitor the cash balances in the accounts and adjust the cash balances as appropriate, but if the amount of a deposit at any time exceeds the federally insured amount at a bank, the uninsured portion of the deposit could be lost, in whole or in part, if the bank were to fail. Our investments in money market funds are not insured or guaranteed by the United States government or any of its agencies.

Our foreign subsidiaries deposit their cash in local banks, but if the amount of a deposit at any time exceeds the amount at a bank under the national banking insurance laws, the uninsured portion of the deposit could be lost, in whole or in part, if the bank were to fail.

#### *Interest Rate Risk*

We invest most of our cash in money market funds. The primary objective of our investments will be to preserve principal and liquidity while earning a return on our invested capital, without incurring significant risks. Our future investment income is not guaranteed and may fall short of expectations due to changes in prevailing interest rates, or we may suffer losses in principal if the net asset value of a money market fund falls below \$1 per share.

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

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

It is management's responsibility to establish and maintain adequate internal control over all financial reporting pursuant to Rule 13a-15 under the Securities Exchange Act of 1934 ("Exchange Act"). Our management, including our principal executive officer, our principal operations officer, and our principal financial officer, have reviewed and evaluated the effectiveness of our disclosure controls and procedures as of the end of our third quarter. Following this review and evaluation, management collectively 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 chief executive officer, our chief operations officer, and our chief 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.

**Item 1. Legal Proceedings.**

From time to time, we and our subsidiaries may be involved in routine litigation incidental to the conduct of our business. We and our subsidiaries are presently not parties to any litigation.

**Item Risk Factors  
1A.**

Our business is subject to various risks, including those described below. You should consider the following risk factors, together with all of the other information included in this report and the risks described in our Annual Report on Form 10-K for the year ended December 31, 2013, which could materially adversely affect our proposed operations, our business prospects, and financial condition, and the value of an investment in our business. There may be other factors that are not mentioned here or of which we are not presently aware that could also affect our business operations and prospects.

**Risks Related to Our Business Operations****We have incurred operating losses since inception and we do not know if we will attain profitability**

Our comprehensive net losses for the nine months ended September 30, 2014 and for the fiscal years ended December 31, 2013, 2012, and 2011 were \$26,044,426, \$43,760,366, \$21,362,524, and \$17,535,587, respectively, and we had an accumulated deficit of \$171,606,642 as of September 30, 2014 and \$145,778,547, \$101,895,712, and \$80,470,009, as of December 31, 2013, 2012, and 2011, respectively. We primarily finance our operations through the sale of equity securities, licensing fees, royalties on product sales by our licensees, research grants, and subscription fees and advertising revenue from database products. Ultimately, our ability to generate sufficient operating revenue to earn a profit depends upon our and our subsidiaries' success in developing and marketing or licensing products and technology.

**We will spend a substantial amount of our capital on research and development but we might not succeed in developing products and technologies that are useful in medicine**

- We are attempting to develop new medical products and technologies.
- Many of our experimental products and technologies have not been applied in human medicine and have only been used in laboratory studies *in vitro* or in animals. These new products and technologies might not prove to be safe and efficacious in the human medical applications for which they were developed.
- The experimentation we are doing is costly, time consuming, and uncertain as to its results. We incurred research and development expenses amounting to \$26,267,972, during the nine months ended September 30, 2014, and \$26,609,423, \$18,116,688, and \$13,699,691 during the fiscal years ended December 31, 2013, 2012, and 2011, respectively, excluding \$17,458,766 charged as in process research and development expenses during 2013 in accordance with ASC 805-50 on account of Asterias' acquisition of certain assets from Geron. See Note 8 to condensed consolidated interim financial statements.
- If we are successful in developing a new technology or product, refinement of the new technology or product and definition of the practical applications and limitations of the technology or product may take years and require the expenditure of large sums of money. Future clinical trials of new therapeutic products, particularly those products that are regulated as drugs or biological, will be very expensive and will take years to complete. We may not have the financial resources to fund clinical trials on our own and we may have to enter into licensing or collaborative arrangements with larger, well-capitalized pharmaceutical companies in order to bear the cost. Any such arrangements may be dilutive to our ownership or economic interest in the products we develop, and we might have to accept a royalty payment on the sale of the product rather than receiving the gross revenues from product sales.

## **We may increase our investment in LifeMap Sciences to provide funding for the development of new software products**

Our subsidiary LifeMap Sciences has formed a new subsidiary, LifeMap Solutions, to develop the new personal mobile health software products intended to connect users with their complex personal health information and other big data. We have invested \$5,000,000 in LifeMap Sciences to provide funding for the project, and unless additional financing can be obtained from third parties, we may need to increase our investment significantly during the next few calendar years to fund the development and commercialization of the planned products.

The field of mobile health products, including both hardware and software products, is new, and there is no certainty that LifeMap Solutions will be successful in developing its planned new products or that it will be successful in commercializing any products that it does develop.

The field of mobile health products is subject to increasing competition, including from large computer and internet technology companies that have much greater financial and marketing resources than we and LifeMap Solutions have.

The FDA has also taken an interest in the field of on-line or mobile health products and there is a risk that the FDA could determine that LifeMap Solutions' products should be regulated as medical devices under existing laws and regulations, or the FDA could promulgate new regulations that might subject LifeMap Solutions' products to FDA clinical trial and approval procedures, as a prerequisite for permission to use and market the new mobile health products in the United States. Foreign regulatory authorities could make similar determinations or could adopt their own rules regulating the use and marketing of LifeMap Solution's products.

## **Sales of *Hextend*<sup>®</sup> have been be adversely affected by safety and use labeling changes required by the FDA**

Sales of *Hextend*<sup>®</sup> have been adversely affected by certain safety labeling changes required by the FDA for the entire class of hydroxyethyl starch products, including *Hextend*<sup>®</sup>. The labeling changes were approved by the FDA in November 2013 and include a boxed warning stating that the use of hydroxyethyl starch products, including *Hextend*<sup>®</sup>, increases the risk of mortality and renal injury requiring renal replacement therapy in critically ill adult patients, including patients with sepsis, and that *Hextend*<sup>®</sup> should not be used in critically ill adult patients, including patients with sepsis. New warning and precaution information is also required along with new information about contraindications, adverse reactions, and information about certain recent studies. The new warning and precautions include statements to the effect that the use of *Hextend*<sup>®</sup> should be avoided in patients with pre-existing renal dysfunction, and the coagulation status of patients undergoing open heart surgery in association with cardiopulmonary bypass should be monitored as excess bleeding has been reported with hydroxyethyl starch solutions in that population and use of *Hextend*<sup>®</sup> should be discontinued at the first sign of coagulopathy. The liver function of patients receiving hydroxyethyl starch products, including *Hextend*<sup>®</sup> should also be monitored. The approved revised label may adversely affect *Hextend*<sup>®</sup> sales since some users of plasma volume expanders might elect to abandon the use of all hydroxyethyl starch products, including *Hextend*<sup>®</sup>.

## **The amount and pace of research and development work that we and our subsidiaries can do or sponsor, and our ability to commence and complete clinical trials required to obtain regulatory approval to market our therapeutic and medical device products, depends upon the amount of money we have**

- At September 30, 2014, we had \$7,416,235 of cash and cash equivalents on hand. There can be no assurance that we or our subsidiaries will be able to raise funds on favorable terms or at all, or that any funds raised will be sufficient to permit us or our subsidiaries to develop and market our products and technology. Unless we and our subsidiaries are able to generate sufficient revenue or raise additional funds when needed, it is likely that we will be unable to continue our planned activities, even if we make progress in our research and development projects.
- We may have to postpone or limit the pace of our research and development work and planned clinical trials of our product candidates unless our cash resources increase through a growth in revenues or additional equity investment or borrowing.

**The condition of certain cells, cell lines and other biological materials that Asterias acquired from Geron could impact the time and cost of commencing Asterias' research and product development programs**

The cells, cell lines and other biological materials that Asterias acquired are being stored under cryopreservation protocols intended to preserve their functionality. Asterias has successfully completed the verification of the viability of the clinical grade lots of OPC1 cells that it intends to use in clinical trials. However, the functional condition of the other materials cannot be certified until they are tested in an appropriate laboratory setting by qualified scientific personnel using validated equipment. Asterias intends to perform that testing on the cells that it intends to use in its research and development programs as the need arises.

To the extent that the cells Asterias plans to use are not sufficiently functional for its purposes, Asterias would need to incur the time and expense of regenerating cell lines from cell banks, or regenerating cell banks from cell stocks, which could delay and increase the cost of its research and development work using those cells.

**We and our subsidiaries will have certain obligations and may incur liabilities arising from clinical trials, and we do not yet know the scope of any resulting expenses that might arise**

We or our subsidiaries that conduct clinical trials of product candidates face the risk of incurring liabilities to patients if they incur any injuries as a result of their participation in the clinical trials. We or our subsidiaries will also be obligated to obtain information and prepare reports about the health of the clinical trial patients. In addition, Asterias has assumed Geron's obligations to obtain information and prepare reports about the health of patients, and has assumed any liabilities to those patients that might arise from any injuries they may have incurred, as a result of their participation in the clinical trials of Geron's GRNOPC1 cell replacement therapy for spinal cord damage and its GRNVAC1 immunological therapy for certain cancers. We are not aware of any claims by patients alleging injuries suffered as a result of any of our clinical trials or the Geron clinical trials, but if any claims are made and if liability can be established, the amount of any liability that we or our subsidiaries may incur, depending upon the nature and extent of any provable injuries, could exceed any insurance coverage that we or our subsidiaries may obtain, and the amount of the liability could be material to our financial condition.

**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
3.1	Articles of Incorporation with all amendments.(1)
3.2	By-Laws, As Amended. (2)
4.1	Specimen of Series A Convertible Preferred Stock Certificate (3)
4.2	Certificate of Determination of Series A Convertible Preferred Stock (3)
4.3	Warrant Agreement, dated October 1, 2013, as amended September 19, 2014, between BioTime, Inc. and American Stock Transfer & Trust Company, LLC (4)
4.4	Form of Warrant (included in Exhibit 4.3) (4)
10.1	Clinical Trial and Option Agreement, dated September 8, 2014, between Asterias Biotherapeutics, Inc. and Cancer Research UK and Cancer Research Technology Limited(Portions of this exhibit have been omitted pursuant to a request for confidential treatment) *
31	Rule 13a-14(a)/15d-14(a) Certification.*
32	Section 1350 Certification.*
101	Interactive Data File
101.INS	XBRL Instance Document *
101.SCH	XBRL Taxonomy Extension Schema *
101.CAL	XBRL Taxonomy Extension Calculation Linkbase *
101.LAB	XBRL Taxonomy Extension Label Linkbase *
101.PRE	XBRL Taxonomy Extension Presentation Linkbase *
101.DEF	XBRL Taxonomy Extension Definition Document *

(1) Incorporated by reference to BioTime's Annual Report on Form 10-K/A-1 for the year ended December 31, 2013 filed with the Securities and Exchange Commission on April 30, 2014

(2) Incorporated by reference to Registration Statement on Form S-1, File Number 33-48717 and Post-Effective Amendment No. 1 thereto filed with the Securities and Exchange Commission on June 22, 1992, and August 27, 1992, respectively.

(3) Incorporated by reference to BioTime's Current Report on Form 8-K filed with the Securities and Exchange Commission on March 5, 2014

(4) Incorporated by reference to BioTime's Current Report on Form 8-K filed with the Securities and Exchange Commission on September 23, 2014.

\* Filed herewith

**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.

Date: November 7, 2014

BIOTIME, INC.

*/s/ Michael D. West*

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Michael D. West  
Chief Executive Officer

Date: November 7, 2014

*/s/ Robert W. Peabody*

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Robert W. Peabody  
Chief Financial Officer

Exhibit Numbers	Description
3.1	Articles of Incorporation with all amendments.(1)
3.2	By-Laws, As Amended. (2)
4.1	Specimen of Series A Convertible Preferred Stock Certificate (3)
4.2	Certificate of Determination of Series A Convertible Preferred Stock (3)
4.3	Warrant Agreement, dated October 1, 2013, as amended September 19, 2014, between BioTime, Inc. and American Stock Transfer & Trust Company, LLC (4)
4.4	Form of Warrant (included in Exhibit 4.3) (4)
<a href="#">10.1</a>	Clinical Trial and Option Agreement, dated September 8, 2014, between Asterias Biotherapeutics, Inc. and Cancer Research UK and Cancer Research Technology Limited (Portions of this exhibit have been omitted pursuant to a request for confidential treatment) *
<a href="#">31</a>	Rule 13a-14(a)/15d-14(a) Certification.*
<a href="#">32</a>	Section 1350 Certification.*
101.INS	XBRL Instance Document *
101.SCH	XBRL Taxonomy Extension Schema *
101.CAL	XBRL Taxonomy Extension Calculation Linkbase *
101.LAB	XBRL Taxonomy Extension Label Linkbase *
101.PRE	XBRL Taxonomy Extension Presentation Linkbase *
101.DEF	XBRL Taxonomy Extension Definition Document *

- (1) Incorporated by reference to BioTime's Annual Report on Form 10-K/A-1 for the year ended December 31, 2013 filed with the Securities and Exchange Commission on April 30, 2014
- (2) Incorporated by reference to Registration Statement on Form S-1, File Number 33-48717 and Post-Effective Amendment No. 1 thereto filed with the Securities and Exchange Commission on June 22, 1992, and August 27, 1992, respectively.
- (3) Incorporated by reference to BioTime's Current Report on Form 8-K filed with the Securities and Exchange Commission on March 5, 2014
- (4) Incorporated by reference to BioTime's Current Report on Form 8-K filed with the Securities and Exchange Commission on September 23, 2014.

\* Filed herewith

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

**CANCER RESEARCH UK**

and

**CANCER RESEARCH TECHNOLOGY LIMITED**

and

**ASTERIAS BIOTHERAPEUTICS, INC.**

**CLINICAL TRIAL AND OPTION AGREEMENT**





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Schedule 9	Additional Studies
Schedule 10	Form of Progress Report
Schedule 11	Clinical Protocol Summary

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**THIS AGREEMENT** is made the 8th day of September, 2014

**BETWEEN:**

**CANCER RESEARCH UK** a company limited by guarantee registered under number 4325234 and a charity registered under number 1089464 of Angel Building, 407 St. John Street, London, EC1V 4AD, England (the “**Charity**”);

**CANCER RESEARCH TECHNOLOGY LIMITED** a company registered in England and Wales with number 1626049 and registered office at Angel Building, 407 St. John Street, London, EC1V 4AD, England (“**CRT**”); and

**ASTERIAS BIOTHERAPEUTICS, INC.**, a Delaware company with principal place of business at 230 Constitution Drive, Menlo Park, CA94025, USA (the “**Company**”).

**WHEREAS:**

- (A) The Company has the right to conduct research and clinical testing on the IMP (as defined below). At this time, the Company does not intend to undertake any further development of the Product except as provided in this Agreement.
- (B) The Charity's charitable objects are to protect and promote the health of the public in particular by research into the nature, causes, diagnosis, prevention, treatment and cure of cancer, including development of findings of research into practical applications.
- (C) The Charity has expertise in the clinical evaluation of novel anti-cancer agents and considers that the Product has the potential to be a valuable drug that could be applied for the treatment of cancer. Accordingly, the Charity is interested in undertaking the development of the Product at its own cost. As the development is to be undertaken in pursuance of the Charity's charitable objects, the Charity will have the right to publish the results of such development work.
- (D) On completion of the Charity's development work, the Company will have the option to take a licence to the results thereof with a view to the Company developing the Product further. If the Company does not wish to take a licence to such results, then CRT shall have the right to take a licence to the Company's rights in and to the Product and Related Products to enable it to find an alternative partner to develop them further.
- (E) CRT is a wholly owned subsidiary of the Charity and is, by arrangement with the Charity, responsible for the management, exploitation and commercialisation of intellectual property generated by the Charity or using funding from the Charity and the Charity has assigned and will assign such intellectual property to CRT for such purpose. CRT remits all its taxable profits to the Charity.
- (F) The Company, CRT and the Charity have therefore agreed to enter into this Agreement to enable the Charity to undertake the development of the IMP subject to the following terms and conditions:

**NOW IT IS HEREBY AGREED** as follows:

## **1. DEFINITIONS AND INTERPRETATION**

1.1 In this Agreement the words and phrases set out below shall, unless the context requires otherwise, have the corresponding meaning attributed to them below. In addition, any words and phrases in this Agreement which are not defined below, but which are defined in the CTD, shall have the meaning attributed to them in the CTD.

**“Additional Studies”** means any biomarker, manufacturing, purity, toxicology, imaging or combination studies, or any other exploratory or pre-clinical *in vitro* or *in vivo* studies commenced after the Effective Date and associated with any part of the Product, or carried out in support of the clinical trial conducted pursuant to this Agreement, where such studies are performed by or on behalf of the Charity, including those described in Schedule 9 (as the same may be amended from time to time by the Charity).

**“Affiliate”** means an entity that, whether now or in the future, Controls, is Controlled by or is under common Control with a Party. For the purpose of this definition only, “Control” means the possession (directly or indirectly) of fifty per cent or more of the voting stock or other equity interest of a subject entity with the power to vote, or the power in fact to control the management decisions of such entity through the ownership of securities or by contract or otherwise and “Controls” and “Controlled by” shall be construed accordingly.

**“this Agreement”** means this agreement and each of the Schedules to it as amended from time to time in accordance with Clause 19.

**“Case Report Forms”** means a record of the data and other information gathered on each Clinical Trial Subject pursuant to the Protocol.

**“Cell Line”** means \*\*\*.

**“Charity’s Standard Operating Procedures”** means the documents in use by the Drug Development Office of the Charity from time to time that are designated as standard operating procedures and which describe the procedures that must be followed to complete various tasks.

**“Chief Investigator”** means the person who will lead and co-ordinate the work of the Clinical Trial overall where the Clinical Trial is to be carried out at more than one site.

**“Clinical Trial”** means the Phase I/II clinical trial described in the Protocol to be conducted under the Sponsorship of the Charity, the manufacture of IMP to be conducted by the Charity, and any Additional Studies.

**“Clinical Trial Database Lock Date”** means the date when the clinical research database relating to the Clinical Trial is locked (after the Clinical Trial Results have been cleaned but excluding any Long Term Survival Data) in accordance with the Charity’s Standard Operating Procedures.

<b>“Clinical Trial Legislation”</b>	means all laws and regulations from time to time in force applicable to the performance of the Clinical Trial, including the CTD, the Human Rights Act 1998, the Data Protection Act 1998, the Medicines Act 1968, the Medicines for Human Use (Clinical Trials) Regulations 2004, and the Human Tissue Act 2004.
<b>“Clinical Trial LPFV Date”</b>	means the date when the final Clinical Trial Subject in the Clinical Trial attends their first study visit. The Clinical Trial LPFV Date may be further defined in the Protocol.
<b>“Clinical Trial Results”</b>	means all Know-How, data, information and results Controlled by the Charity or CRT and arising from the Clinical Trial, including the contents of each Progress Report, the Final Report, Case Report Forms and associated Data Listings and any other updates that may be agreed by the Parties from time to time.
<b>“Clinical Trial Subject”</b>	means any person who is enrolled in the Clinical Trial either as a recipient or planned recipient of the Investigational Medicinal Product or as a control.
<b>“Commencement Date”</b>	means the date first written above.
<b>“Company Combination Patent Rights”</b>	means those Patent Rights owned by or licensed to the Company which claim the use of the Product in combination with one or more other anti-cancer agents or therapies and all Patent Rights deriving priority from them.
<b>“Company Intellectual Property”</b>	means the Company Patent Rights, and all rights in the Company Know-How, the Investigational Medicinal Product and the Company Materials.
<b>“Company Know-How”</b>	means such Know-How in the Company’s possession relating to the Product and/or Investigational Medicinal Product (and any constituents thereof), including: (i) any safety and toxicological data; (ii) information relating to the manufacturing/production; (iii) information relating to quality; (iv) information relating to safe and proper handling, storage and use; (v) information that the Company is required to disclose to the Charity pursuant to the Technology Transfer Plan; and (vi) any other data which is relevant to the efficient performance of the Clinical Trial and/or would make the Investigational Medicinal Product in any way easier to make; and (vii) any other data that would make the Product more useful, more valuable or in any way improve its prospects for development or commercialisation.
<b>“Company Materials”</b>	means the Cell Line and other Materials to be provided by the Company to the Charity pursuant to this Agreement including those set out the Technology Transfer Plan.

<b>“Company Owned Intellectual Property”</b>	means the Company Owned Patent Rights, and the Company’s rights in the Company Materials, Investigational Medical Product and the Company Know-How
<b>“Company Owned Patent Rights”</b>	means (i) those Patent Rights listed in Schedule 1A; (ii) those Patent Rights owned by the Company (including those arising after the Commencement Date) which would be infringed by the unauthorised manufacture, use or sale in, or importation into, the relevant country of the Product, Related Products and/or Investigational Medicinal Product; and (iii) all Patent Rights deriving priority from (i) and (ii).
<b>“Company Patent Rights”</b>	means (i) those Patent Rights listed in Schedule 1; (ii) those Patent Rights owned by or licensed to the Company (including those arising after the Commencement Date) which would be infringed by the unauthorised manufacture, use or sale in, or importation into, the relevant country of the Product, Related Products and/or Investigational Medicinal Product; and (iii) all Patent Rights deriving priority from (i) and (ii).
<b>“Confidential Information”</b>	means all information designated as confidential by any Party in writing, together with all other information which relates to the business, affairs, technology, products, developments, trade secrets, Know-How, manufacturing methods, product specifications personnel, customers, agents, distributors and suppliers of any Disclosing Party, or information which may reasonably be regarded as the confidential information of the Disclosing Party. Subject to the terms of any licence agreement entered into in relation to them, the Clinical Trial Results shall be the Confidential Information of the Charity and CRT.
<b>“Control”</b>	means, with respect to Intellectual Property Rights, possession of the ability (whether through ownership or licence, other than a licence granted under this Agreement) to grant the licences or sublicences or make the assignments as provided herein without violating the terms of any agreement or other arrangement with any third party.
<b>“Contributors”</b>	means the Chief Investigator, the Principal Investigator(s), the Sub-Investigators, the Experts, the NHS Trust(s) involved in the Clinical Trial, any sub-contractor of the Charity and/or any academic or not-for-profit entity involved in the Clinical Trial.

<b>“Costs”</b>	means all actual prepaid and committed costs and expenses incurred from time to time in connection with the Clinical Trial, including, for the avoidance of doubt, the internal personnel costs of the Charity and the Charity’s Biotherapeutics Development Unit (BDU).
<b>“CTD”</b>	means the European Clinical Trials Directive (Directive 2001/20/EC) and national legislation implementing such Directive, as the same may be amended from time to time.
<b>“Data Listings”</b>	means the computer generated data listings produced by the Charity detailing all anonymised patient data collected under the Clinical Trial other than the Long Term Survival Data.
<b>“Declaration of Helsinki”</b>	means the 2008 version of the Helsinki Declaration of the World Medical Association.
<b>“Development Work”</b>	means the process development and manufacturing scale-up work to be carried out by the Company to determine a Product Manufacturing Process.
<b>“Development Work Plan”</b>	means the work plan in Schedule 8 setting out the Development Work along with the projected timelines for that work and any amendments to the same made in accordance with Clause 2.3.
<b>“Disclosing Party”</b>	has the meaning specified in Clause 5.1.
<b>“Duke Licence”</b>	means the License Agreement between Duke University and Merix Bioscience, effective January 10, 2000, as amended effective July 28, 2003,
<b>“Ethics Committee”</b>	has the meaning given to it in the CTD.
<b>“Exclusive Results”</b>	means those Clinical Trial Results and the Intellectual Property Rights therein that directly relate to and only to the Product and Related Products. Exclusive Results shall not include any assay methodology, formulation-related results or biomarker results which do not directly relate to and only to the Product and/or Related Products.
<b>“Exercise Notice”</b>	has the meaning specified in Clause 7.1.
<b>“Expert”</b>	means any member of the Charity’s expert committees or any other person not being an employee of the Charity whom the Charity may engage from time to time to advise the Charity on the Clinical Trial or to assist with the Product Manufacturing Process at the Charity’s Biotherapeutics Development Unit.
<b>“Field”</b>	means use of the Product in immunotherapy applications using ***

<b>“Final Report”</b>	means a Report Synopsis, unless, pursuant to Clause 3.11, a Full Clinical Study Report is prepared by the Charity instead of a Report Synopsis.
<b>“Financial Year”</b>	means the period commencing on January 1 and ending on December 31.
<b>“Full Clinical Study Report”</b>	means a full clinical study report in relation to the Clinical Trial written by or on behalf of the Charity in accordance with the Charity’s Standard Operating Procedures and which meets the standards of the ICH Guidelines for Structure and Content of Clinical Study reports as per ICH Topic E3 dated July 1996 except that Long Term Survival Data will not be included in the report.
<b>“Full CS Report Fee”</b>	has the meaning given to it in Clause 3.11.
<b>“Good Manufacturing Practice”</b>	means the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use as defined in: (i) the CTD; (ii) European Community Directive 2003/94/EC; (iii) European Community Directive 2005/28/EC; (iv) Eudralex Volume 4: ‘EU Guidelines to Good Manufacturing Practice, Medicinal Products for Human and Veterinary Use, Part II Basic Requirements for Active Substances used as Starting Materials’, ICHQ7a Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients and ‘EU Guidelines to Good Manufacturing Practice Medicinal Products for Human and Veterinary Use, Annex 13: Investigational Medicinal Products’; and (v) any national legislation implementing the aforementioned Directives and any relevant guidance relating thereto.
<b>“hTERT Antigen”</b>	means a human telomerase antigen.
<b>“hTERT Licensed Patents”</b>	means the patent rights listed in Schedule 1B, which were licensed to Company under the hTERT Licence.
<b>“hTERT Licence”</b>	means the Exclusive Sublicense Agreement between Geron Corporation and Company, effective October 1, 2013, a copy of which has been provided to the Charity.
<b>“ICH GCP”</b>	means the latest version from time to time of the International Conference on Harmonisation (ICH) Tripartite Guidelines, Good Clinical Practice (CPMP/ICH/135/95) together with such other good clinical practice requirements as are specified in the CTD and in Commission Directive 2005/28/EC and in any other regulations relating to medicinal products for human use and in any guidance published by the European Commission pursuant to such Directives or regulations.

<b>“Immunomic/JHU Licensed Patents”</b>	means the patent rights listed in Schedule 1G, which were licensed to Immunomic Therapeutics under the JHU License, and subsequently sublicensed to Company as result of the Immunomic License.
<b>“Immunomic Licence”</b>	means the Exclusive License Agreement between Geron Corporation and Immunomic Therapeutics Inc effective October 31, 2006, which was subsequently assigned by Geron Corporation to Company effective October 1, 2013, a copy of which has been provided to the Charity.
<b>“Independent Opinion”</b>	means the opinion of an independent expert in the field of valuation of intellectual property in a similar field to the Company Intellectual Property, appointed by agreement between the Parties or in default of such agreement within twenty one (21) days of a Party seeking in writing to the others to appoint such expert, by the President for the time being of the Association of the British Pharmaceutical Industry (ABPI) in England and Wales, referred to at Clause 13.1.
<b>“Intellectual Property Rights”</b>	means all Patent Rights, Know-How, copyright, database rights, design rights, moral rights, rights in trade names, logos and trade and service marks, domain names, rights in Materials and all rights or forms of protection of a similar nature or having equivalent or similar effect to any of them which may subsist anywhere in the world, whether or not any of them are registered, including any application for registration of any of them.
<b>“Investigational Medicinal Product” or “IMP”</b>	means the pharmaceutical formulation of the Product suitable for use in the Clinical Trial.
<b>“Investigational Medicinal Product Dossier”</b>	means a dossier relating to the Investigational Medicinal Product which accompanies a request for clinical trial authorisation to conduct the Clinical Trial from a Regulatory Authority. The Investigational Medicinal Product Dossier shall include a specification of the IMP.
<b>“Isis Licensed Patents”</b>	means the patent rights listed in Schedule 1D, which were licensed to Company under the Isis Licence.
<b>“Isis Licence”</b>	means the Exclusive License Agreement between Geron Corporation and Isis Innovation Limited effective March 23, 2006, which was subsequently assigned by Geron Corporation to Company effective October 1, 2013, a copy of which has been provided to the Charity.



<b>“JHU Licence”</b>	means the Exclusive License Agreement between Johns Hopkins University and Immunomic Therapeutics effective September 26, 2006.
<b>“Know-How”</b>	means all technical and other information which is not in the public domain, including information comprising or relating to concepts, discoveries, data, designs, formulae, ideas, inventions, methods, models, designs for experiments and tests and results of experimentation and testing, processes, specifications and techniques, laboratory records, clinical data, reports, manufacturing data and information contained in submissions to Regulatory Authorities.
<b>“Licence”</b>	means a licence to the Clinical Trial Results and any Intellectual Property Rights therein in the form attached at Schedule 4. Such licence shall be exclusive in respect of the Exclusive Results, and non-exclusive in relation to the Non-Exclusive Results. For the avoidance of doubt, neither CRT nor the Charity shall have any obligation to supply any Materials to the Company pursuant to any Licence.
<b>“Long Term Survival Data”</b>	means any ongoing survival data for Clinical Trial Subjects that the Charity collects after the completion of the interventional component of the Clinical Trial.
<b>“Losses”</b>	means losses, damages, costs and expenses (including reasonable legal costs and expenses).
<b>“Materials”</b>	means any chemical or biological substances including any: organic or inorganic element or compound; nucleotide or nucleotide sequence including DNA and RNA sequences gene; vector or construct including plasmids, phages, bacterial vectors, bacteriophages and viruses; host organism including bacteria, fungi, algae, protozoa and hybridomas; eukaryotic or prokaryotic cell line or expression system or any development strain or product of that cell line or expression systems; protein including any peptide or amino acid sequence, enzyme, antibody or protein conferring targeting properties and any fragment of a protein or a peptide enzyme or antibody; drug or pro-drug; assay or reagent; any plasma or tissue; or any other genetic or biological material or micro-organism or any transgenic animal.
<b>“Merix/Duke Licensed Patents”</b>	means the patent rights listed in Schedule 1E, which were licensed to Merix Bioscience under the Duke License, and were subsequently sublicensed to Company under the Merix License.
<b>“Merix/Rockefeller Licensed Patents”</b>	means the patent rights listed in Schedule 1F, which were licensed to Merix Bioscience under the Rockefeller License, and were subsequently sublicensed to Company under the Merix License.

<b>“Merix Licence”</b>	means the Exclusive License Agreement between Geron Corporation and Merix Bioscience (now Argos Therapeutics) effective March 6, 2004, and subsequently assigned by Geron Corporation to Company effective October 1, 2013, a copy of which has been provided to the charity.
<b>“Non-Exclusive Results”</b>	means those Clinical Trial Results that are not Exclusive Results (and all Intellectual Property Rights therein), including all assay methodology, formulation-related results or biomarker results.
<b>“Option”</b>	has the meaning specified in Clause 7.1.
<b>“Option Fee”</b>	means the sum of *** less the amount of any Full CS Report Fee actually paid by the Company to CRT under Clause 3.11 and excluding VAT or other applicable sales tax.
<b>“Option Period”</b>	has the meaning specified in Clause 7.1.
<b>“Party”</b>	means any party to this Agreement and <b>“Parties”</b> means all of them.
<b>“Patent Rights”</b>	means any patent applications, patents, author certificates, inventor certificates, utility models, and all foreign counterparts of them and includes all divisionals, renewals, continuations, continuations-in-part, extensions, reissues, substitutions, confirmations, registrations, revalidations and additions of or to them, as well as any Supplementary Protection Certificate, or any like form of protection (including any pediatric, orphan drug or other exclusivity granted by a Regulatory Authority beyond the expiry of the original patent expiration date).
<b>“Principal Investigator”</b>	means the person who will lead and co-ordinate the work of the Clinical Trial at a particular Clinical Trial site.
<b>“Post Development Meeting”</b>	has the meaning given in Clause 2.7.
<b>“Product”</b>	means the Company’s cell based therapeutic agent known as AST-VAC2 which comprises ***.
<b>“Product Manufacturing Process”</b>	means a reproducible process for the manufacture and quality testing of the IMP in accordance with Good Manufacturing Practice and which meets the requirements in the Transfer Criteria and the process specifications in the Technology Transfer Plan on a scale and standard suitable to enable the Charity to produce sufficient quantities of IMP to conduct the Clinical Trial.
<b>“Progress Report”</b>	means a report on the status of the Clinical Trial in the format set out in Schedule 10, or in such other format as is the Charity’s standard practice at the relevant time in respect of a clinical trial at the same stage, and of the same scope, as the Clinical Trial.

<b>“Protocol”</b>	means the clinical trial protocol to be prepared by the Charity and the Chief Investigator in accordance with the criteria described in Schedule 11, as may be amended from time to time by the Charity in accordance with Clause 3.6.
<b>“Recipient Party”</b>	has the meaning specified in Clause 5.2.
<b>“Regulatory Authority”</b>	means any local, national or supra-national agency, authority, department, inspectorate, minister, ministry official or public or statutory person (whether autonomous or not) or any government of any country as shall have jurisdiction over the Clinical Trial or any part of it or over any activity of the Parties in connection with the Clinical Trial. Regulatory Authority includes, but is not limited to, the United Kingdom Medicines and Healthcare products Regulatory Agency (MHRA), the United States Food and Drug Administration (FDA) and the European Medicines Agency (EMA).
<b>“Related Product”</b>	means a cell based therapeutic agent which is not a Product but which ***.
<b>“Report Synopsis”</b>	a summary of the results of the Clinical Trial written by or on behalf of the Charity in accordance with the Charity’s Standard Operating Procedures in a form substantially similar to the format set out in Schedule 2 and the format of the clinical study synopsis set out in Annex I of ICH Topic E3 of the ICH Guidelines for Structure and Content of Clinical Study reports dated July 1996. The Report Synopsis shall not include or contain any additional documents or any appendices, exhibits or annexes nor shall it include or contain any Data Listings, Case Report Forms or any raw data comprised within the Clinical Trial Results or cover any Long Term Survival Data.
<b>“Rockefeller Licence”</b>	means the License Agreement between Rockefeller University and Merix Bioscience, effective June 27, 2001, as amended June 29, 2001.
<b>“Specification”</b>	means the specification of the IMP detailed in the Investigational Medicinal Product Dossier.
<b>“Signature Period”</b>	means the period of *** commencing on:  (i) in the event that the Charity does not prepare a Full Clinical Study Report pursuant to Clause 3.11, the Company’s receipt of the Data Listings pursuant to Clause 7.3; or  (ii) in the event that the Charity prepares a Full Clinical Study Report pursuant to Clause 3.11, the date of the Exercise Notice.

<b>“Sub-Investigator”</b>	means a clinician appointed and supervised by the Chief Investigator or Principal Investigator to assist in the carrying out of the Clinical Trial at the same trial site as the Principal Investigator.
<b>“Supplementary Protection Certificate”</b>	means a right based on a patent pursuant to which the holder of the right is entitled to exclude third parties from using, making, having made, selling or otherwise disposing or offering to dispose of, importing or keeping the product to which the right relates, such as supplementary protection certificates in Europe, and any similar right anywhere in the world.
<b>“Technology Transfer Plan”</b>	has the meaning given in Clause 2.6.
<b>“Third Party Licences”</b>	means those licences listed in Schedule 7
<b>“Third Party Licence Payments”</b>	means those milestone, royalty and other payments listed in Schedule 7B in respect of the Third Party Licences.
<b>“Tobacco Party”</b>	means: (i) any entity who develops, sells or manufactures tobacco products; and/ or (ii) any entity which makes the majority of its profits from the importation, marketing, sale or disposal of tobacco products. Furthermore, Tobacco Party shall include any entity that is an Affiliate of any entity referred to in (i) or (ii);
<b>“Transfer Approval Notice”</b>	has the meaning given in Clause 2.7.
<b>“Transfer Criteria”</b>	means criteria to be agreed between the Parties as described in Clause 2.1 that if met thereby demonstrate to the Charity that the Product Manufacturing Process for the IMP that is to be developed by the Company under the Development Work has been scaled-up to the required level and meets the required quality, validation, price and other technical, scientific and quality requirements as further described in Clause 2.1.
<b>“University of Western Ontario Licensed Patents”</b>	means the patent rights listed in Schedule 1C, which were licensed to Company under the University of Western Ontario Licence.
<b>“University of Western Ontario Licence”</b>	means the Exclusive License Agreement between Geron Corporation and The University of Western Ontario effective January 30, 2009, and subsequently assigned by Geron Corporation to Company effective October 1, 2013, a copy of which has been provided to the Charity.
<b>“WARF Intellectual Property”</b>	means the rights in the WARF Patents and Wisconsin Materials listed in Schedule 1H, which were licensed to the Company in the WARF Licence.

**“WARF Licence”** means the Non-Exclusive License Agreement between Company and the Wisconsin Alumni Research Foundation, effective October 7, 2013, a redacted copy of which has been provided to the Charity.

1.2 In this Agreement:

- 1.2.1 unless the context requires otherwise, all references to a particular Clause, paragraph or Schedule shall be references to that clause, paragraph or schedule, of or to this Agreement;
- 1.2.2 the table of contents and headings are inserted for convenience only and shall be ignored in construing this Agreement;
- 1.2.3 unless the contrary intention appears, words importing the masculine gender shall include the feminine and vice versa and words in the singular include the plural and vice versa;
- 1.2.4 unless the contrary intention appears, words denoting persons shall include any individual, partnership, company, corporation, joint venture, trust, association, organisation or other entity, in each case whether or not having separate legal personality;
- 1.2.5 reference to any statute or regulation includes any modification or re-enactment of that statute or regulation, provided that the modification or re-enactment does not diminish the rights or extend the obligations of any Party; and
- 1.2.6 references to the words “include” or “including” shall be construed without limitation to the generality of the preceding words.

**2. PROCESS DEVELOPMENT WORK**

- 2.1 As soon as is reasonably practicable (and within thirty (30) days of the Commencement Date), the Parties shall meet (either in person or by teleconference) to introduce the key members of their respective teams and to discuss the initial Development Work Plan and agree the actions and timeline for formulating the Transfer Criteria. The Parties shall endeavour to have the Transfer Criteria in an agreed form as soon as practicable, but in any event by no later than three months before the date when the Development Work is anticipated to be completed as shown in the Development Work Plan (as that may be amended from time to time). Without intending this to be an exhaustive list, the scope of the Transfer Criteria shall include specific and measurable criteria for: adequate documentation of processes and conditions for product manufacture, QA and quality control; process reproducibility and success rates; cost of manufacture; process yields; process timelines and staffing requirements; GMP compliance at each stage of the Product Manufacturing Process through to preparing the IMP for patient use; IMP purity levels and ranges; and cost and availability of any special equipment or facilities required for performance of the Product Manufacturing Process, preparation of the prepared dose, and/or product release testing. The Company will carry out the Development Work at its own cost and in accordance with the Development Work Plan and the terms of this Agreement. It is understood that the Development Work Plan is likely to evolve as the Company moves through the Development Work and that the Company may need to update the Development Work Plan including the projected timings that form part of the same. The Development Work Plan, including all drafts, iterations, and revisions of the Development Work Plan, shall be the Company’s Confidential Information.

- 2.2 The Company shall provide to the Charity written monthly updates on progress against the Development Work Plan (for clarity, such updates may be in the form of presentation slides from joint project team meetings) and any necessary updates to the Development Work Plan along with any information or data which is reasonably necessary for the Charity to fully understand the then current status of the Development Work and the steps being taken to achieve the desired outcomes. The Company shall give due consideration to any comments or suggestions provided by the Charity on updates to the Development Work Plan (including making any amendments to the updated Development Work Plan which are reasonably requested by the Charity and which would impact on the Charity's ability to carry out the Product Manufacturing Process at its Biotherapeutics Development Unit).
- 2.3 As the Company carries out the Development Work the Parties may also wish to amend or refine the Transfer Criteria to reflect the results of the Development Work. Either the Charity or the Company may propose changes to the Transfer Criteria with the objective of ensuring that the Transfer Criteria represent a fair and measurable set of standards that it would be reasonable for the Charity to expect to be met to show that the Product Manufacturing Process is fit for purpose prior to transfer to the Charity. Each of the Charity and the Company will consider changes to the Transfer Criteria requested by the other in good faith and shall not unreasonably withhold its agreement to a change. Any agreed changes to the Transfer Criteria will be recorded in writing and signed by the Charity and the Company.
- 2.4 The Company may sub-contract activities to be performed under the Development Work Plan provided that:
- 2.4.1 the Company informs the Charity of the identity of any proposed sub-contractor and, in the event that the Charity (acting reasonably) expresses any concerns with the proposed sub-contractor, takes such concerns into consideration prior to entering into a formal agreement with the sub-contractor to carry out any Development Work;
  - 2.4.2 the Company will remain fully responsible for the performance of all of the Company's obligations under this Agreement;
  - 2.4.3 the terms of any sub-contract will allow the Company to fulfill its obligations under this Agreement, including with respect to acquiring necessary Intellectual Property Rights and confidentiality obligations;
  - 2.4.4 no Tobacco Party shall be permitted to conduct any activities under the Development Work or otherwise in connection with the Clinical Trial; and
  - 2.4.5 within twenty (20) days of entering into any subcontract, the Company shall provide the Charity with a true copy of the statement of work of that subcontract (which may be redacted as to terms not applicable to the Company's compliance hereunder).
- 2.5 As the Development Work progresses and prior to the Post Development Meeting the Company will work with the Charity to develop a "**Technology Transfer Plan**" setting out how the Parties will transfer the Product Manufacturing Process from the Company to the Charity's Biotherapeutics Development Unit and the responsibilities of each Party during and after that transfer and will include (to the extent not already covered by the Transfer Criteria):

- 2.5.1 A description of the scope of the Technology Transfer Plan that includes a table setting out the roles, responsibilities and deliverables to be supplied by each of the Company and the Charity;
- 2.5.2 Documentation requirements (define which stages require a technical or analytical summary report, documents required for importation into the UK/EU of the Cell Line, certificates of analysis and compliance, etc);
- 2.5.3 A process description with operating parameters for the Product Manufacturing Process (this needs to be detailed with each manipulation described);
- 2.5.4 A sampling plan for use during the Product Manufacturing Process and for the final IMP with quality control test acceptance criteria (define success of tech transfer);
- 2.5.5 Transfer of Company Know-How and training requirements for Charity staff including:
  - (a) the Charity making suitably qualified employees available to spend such time at the Company prior to transfer of the Product Manufacturing Process as reasonably required to learn the how the Product Manufacturing Process is carried out at the Company (anticipated at the Commencement Date to be in the region of two (2) Charity staff working on site with the Company for up to eight (8) weeks);
  - (b) The Company making suitably qualified employees available to provide such on-site scientific and technical guidance at the Charity's Biotherapeutics Development Unit during and/or after transfer of the Product Manufacturing Process as reasonably required to ensure that the Product Manufacturing Process can be carried out at Biotherapeutics Development Unit on a scale and standard suitable to enable the Charity to produce sufficient quantities of IMP to conduct the Clinical Trial (anticipated at the Commencement Date to be in the region of one (1) Company staff member working on site with the Charity for four up to (4) weeks);
- 2.5.6 The Company Materials to be provided by the Company as part of the transfer of the Product Manufacturing Process, along with the quantities and specifications of such Company Materials and timing for provision;
- 2.5.7 A list of equipment requirements to enable the Charity to carry out the Product Manufacture Process;

The first draft of the Technology Transfer Plan was provided to the Charity by the Company on 5<sup>th</sup> August 2014.

- 2.6 The Company will notify the Charity in writing on completion of the Development Work. Within thirty (30) days after the Company provides such notice the Parties shall meet either in person or by teleconference (the "**Post Development Meeting**") to review whether the Transfer Criteria have been achieved and the Company has demonstrated to the Charity's reasonable satisfaction that the Product Manufacturing Process can be carried out on a scale and standard suitable to enable the Charity to produce sufficient quantities of IMP to conduct the Clinical Trial. Where this is the case the Charity will promptly provide the Company with written notice of approval of the Product Manufacturing Process ("**Transfer Approval Notice**") and the Charity and the Company will finalise the Technology Transfer Plan. Without intending to affect the generality of foregoing it is agreed that as part of the joint review by the Parties, the Company shall make available to the Charity a report including data and conclusions generated by the Company in undertaking the Development Work. Once agreed by both the Company and the Charity the Technology Transfer Plan shall be circulated for approval and signature by the Company and the Charity.

- 2.7 If the Parties decide at the Post Development Meeting that the Transfer Criteria have not been met (or waived by the Charity) or the Company has otherwise not demonstrated to the Charity's reasonable satisfaction that the Product Manufacturing Process can be carried out on a scale and standard suitable to enable the Charity to produce sufficient quantities of IMP to conduct the Clinical Trial, then the Parties shall record that decision in writing and agree what further Development Work is required. On notice by the Company that it has completed any such further Development Work the Charity and Company will hold a further Post Development Meeting in accordance with Clause 2.6.
- 2.8 Once signed by each Party pursuant to Clause 2.6 the Charity and the Company will use commercially reasonable efforts to carry out the Technology Transfer Plan.
- 2.9 The Product Manufacturing Process, including all drafts, iterations, and revisions, shall be the Company's Confidential Information.

### **3. CONDUCT OF THE CLINICAL TRIAL AND SPONSORSHIP**

- 3.1 Subject to: (i) the Company's compliance with its obligations hereunder including the successful completion of the Development Work; and (ii) the Ethics Committee and the Regulatory Authority granting consent for the Clinical Trial, the Charity will use its reasonable endeavours to carry out or procure the carrying out of the Clinical Trial in accordance with the Protocol.
- 3.2 Once the Clinical Trial has been opened to Clinical Trial Subjects, the Charity shall use reasonable endeavours to provide to the Company at least one Progress Report per month (or with the frequency that is the Charity's standard practice at the relevant time in respect of a clinical trial at the same stage, and of the same scope, as the Clinical Trial, but no less frequently than quarterly). The Company may use the Progress Reports for the purpose of determining whether or not to exercise the Option. All Progress Reports and any supplementary information provided under them shall be the Confidential Information of the Charity and the provisions of Clause 5 shall apply. The Company acknowledges that information or data provided under this Clause 3.2 may not be verified, clean or accurate, and is provided "as is". Without prejudice to the generality of Clause 8.7, neither CRT nor the Charity make any representation or warranty (express or implied) of any nature in respect of such data or information, including as to its accuracy, quality, usefulness or comprehensiveness.
- 3.3 The Charity may, at its sole discretion: (i) sub-contract to third parties including Contributors any part of the Clinical Trial; and (ii) engage such Experts and such persons to fulfil the roles of Chief Investigator and/or Principal Investigator or to assist with the Product Manufacturing Process at the Charity's Biotherapeutics Development Unit as the Charity deems appropriate.
- 3.4 The Charity shall, at its own expense, be responsible for seeking approval of the Clinical Trial and the Protocol from the Regulatory Authority and Ethics Committee prior to commencing the Clinical Trial. For the avoidance of doubt, the Charity shall not be held liable or responsible for any failure and/or refusal by the Ethics Committee or the Regulatory Authority to grant consent for the Clinical Trial or any change required therein.



- 3.5 The Charity shall use reasonable endeavours to carry out, or procure the carrying out of, the Clinical Trial in accordance with relevant aspects of:
- 3.5.1 Clinical Trial Legislation; and
  - 3.5.2 ICH GCP and the Declaration of Helsinki.
- 3.6 The Charity shall have control of the preparation and approval of the Protocol, which shall conform in scope with the provisions of Schedule 11 unless otherwise mutually agreed between the Parties. The Charity may acting reasonably amend the Protocol and/or change the third party undertaking any part of the Clinical Trial in accordance with the provisions of Clauses 3.6.1 and 3.6.2, provided that such Protocol or change to the Protocol has first been approved by the Ethics Committee and, if required by law or regulation, the Regulatory Authority and further provided that;
- 3.6.1 prior to submission for Ethics Committee approval, the Charity shall provide to the Company a copy of the first final version of the Protocol at least fourteen (14) days before seeking Ethics Committee approval and give due consideration to any comments received from the Company by the Charity within such time.
  - 3.6.2 the Charity shall notify the Company in writing of any proposed changes to the Protocol that has been approved by the Ethics Committee at least fourteen (14) days before seeking Ethics Committee approval for such changes, and shall give due consideration to any comments that the Company might make within such time. In an emergency (such as patient safety needs) the said fourteen (14) day time period may be reduced to such time period as the Charity is actually able to give to the Company in the circumstances and the Charity may, if in its reasonable opinion it is required, submit such changes to the Ethics Committee prior to notifying the Company of such;  
  
The Charity will try to reach a consensus with the Company on all issues arising out of the Company's review of any Protocol pursuant to this Clause 3.6.2, but the Charity shall have the final decision save in the case where the Charity proposes to change the cancerindication, primary endpoints, to remove the monitoring of immune responses to hTERT antigen or HLA alloantigens, or to reduce the patient numbers, number of administrations per patient or dose per administration in any such case by more than \*\*\* as compared to the Protocol that has been approved by the Ethics Committee or if at the relevant time none has been approved by the Ethics Committee then the Protocol Summary in Schedule 11 in which circumstances (acting reasonably) the approval of Company shall be required.
  - 3.6.3 in the event that the Ethics Committee and/or the Regulatory Authority does not approve the original Protocol, or if the Company, the Ethics Committee and/or the Regulatory Authority disapprove of any amendment to the Protocol, the Charity shall have the right to terminate this Agreement forthwith upon written notice to the Company.
- 3.7 The Charity shall have sole responsibility for the conduct and control of the Clinical Trial and shall accept the obligations of the sponsor of the Clinical Trial in accordance with the requirements of the Medicines for Human Use (Clinical Trials) Regulations 2004.

- 3.8 The Charity shall use reasonable endeavours to procure that Clinical Trial Subjects are recruited in accordance with the selection procedures and criteria set out in the Protocol.
- 3.9 The Charity shall provide the Company with safety information in accordance with the procedures and timeframes set out in Schedule 3. For the avoidance of doubt the Charity shall also be permitted to provide all safety information to CRT.
- 3.10 The Charity shall promptly advise the Company, in writing, of the occurrence of the Clinical Trial LPFV Date.
- 3.11 The Company may elect to receive a Full Clinical Study Report instead of a Report Synopsis by:
  - 3.11.1 providing the Charity with written notice of its election to receive a Full Clinical Study Report, which written notice must be received by the Charity before the expiration of fourteen (14) days from the date the Charity advised the Company of the occurrence of the Clinical Trial LPFV Date; and
  - 3.11.2 paying the Charity the sum of \*\*\* excluding VAT or other applicable sales tax (the “**Full CS Report Fee**”) within twenty one (21) days after service of such notice.

If the Company does not serve a written notice and pay the Full CS Report Fee as specified in this Clause 3.11, the Charity shall prepare a Report Synopsis and shall have no obligation to prepare or provide the Company with a Full Clinical Study Report.

- 3.12 The Charity shall provide the Final Report to the Company and CRT within \*\*\* after the Clinical Trial Database Lock Date.
- 3.13 The Charity shall only use the Investigational Medicinal Product for the purposes of carrying out the Clinical Trial and shall not permit any third party to use the Investigational Medicinal Product except as required for the purpose of carrying out the Clinical Trial or as set out in this Agreement.

#### 4. COMPANY'S OBLIGATIONS

- 4.1 The Company shall, at the Company's sole cost, provide the Charity with:
  - 4.1.1 such quantities of the Company Materials as are specified in Technology Transfer Plan or, where no quantities are specified, such quantities as the Charity may reasonably request to enable the Charity to carry out the Clinical Trial;
  - 4.1.2 all Company Know-How that it deems reasonably relevant to the Charity's efforts hereunder as soon as practicable following the Commencement Date;
  - 4.1.3 any other information in the Company's Control pertaining to the safety of the IMP or which in the reasonable opinion of the Company may have a bearing on the conduct of the Clinical Trial as soon as the same comes to the attention of the Company;
  - 4.1.4 such scientific and technical guidance as the Charity may reasonably request to enable the Charity and the Contributors to conduct and manage the Clinical Trial in a safe and proper manner, provided however, that Company shall not without its prior consent be obligated to provide scientific and technical guidance other than that described in the Tech Transfer Plan in excess of \*\*\* in total cost;

- 4.1.5 all information (including information for inclusion in the Investigational Medicinal Product Dossier) and co-operation reasonably requested by the Charity at any time from the Commencement Date to enable the Charity to compile an Investigational Medicinal Product Dossier; provided that such requested information is in the Company's Control. In the case of co-operation requested under this Clause 4.1.5, the Company shall procure (at its own cost) that any subcontractor which has performed activities or produced documents on its behalf under this Agreement is made available to the Charity on such notice, for such time and with such frequency as may be reasonably requested by the Charity. The Company shall provide information requested by the Charity within fourteen (14) days of request (or such other period as may be reasonable given the nature of the request);
- 4.1.6 all data and documentation to be provided by the Company to the Charity pursuant to the Technology Transfer Plan in the manner, and at the times, set out in the Technology Transfer Plan. If the Technology Transfer Plan does not set out specific times for certain categories of data and documentation to be provided, the Company shall provide all such data and documentation in its possession or Control at the Commencement Date (to the extent not already provided), within thirty (30) days of the Commencement Date and thereafter shall provide all such data and documentation on an ongoing basis in accordance with Clause 4.2.
- 4.2 The Company shall provide to the Charity any and all data, documentation, information and Know-How described in Clauses 4.1.1 to 4.1.6 on an ongoing basis within a reasonable time after the same comes to the Company's attention (if already in the Company's Control), or into the Company's Control, after the Commencement Date.
- 4.3 The Company shall provide the Charity with safety information in accordance with the procedures and timeframes set out in Schedule 3. For avoidance of doubt, the Charity shall be entitled to pass such safety information to CRT.
- 4.4 The Company will keep the Charity informed of the scope and results of any pre-clinical or other non-clinical studies being undertaken by or with third parties in relation to the Product. If the Company is intending to transfer the Product or undertake any new research in relation to the Product with a third party it will consult with the Charity on the scope of the intended research and the identity of the third party and take into good faith consideration any comments the Charity may have in respect to the same. This Clause should not be interpreted to limit any restrictions on the Company's use of the Product or any Related Product under Clause 6.1 or elsewhere in this Agreement.
- 4.5 The Company shall submit to CRT:
- 4.5.1 a copy of its detailed operating budget (including a quarterly cash flow and expenditure forecast) for development of the Product in respect of each Financial Year as adopted by the Company's board (the "**Annual Budget**"), at least thirty (30) days prior to the commencement of the Financial Year to which the Annual Budget relates;
- 4.5.2 quarterly management accounts of the Company (to include, inter alia, a (consolidated) profit and loss account, balance sheet and cash flow statement and shall indicate where such management accounts differ to any material extent from the Annual Budget for such period), within five (5) business days after the date by which such financial statements are filed with the United States Securities and Exchange Commission for such period, but in no event later than fifty (50) days after quarter close for the first three financial quarters and ninety five (95) days after close of the financial year. Such quarterly management accounts shall be prepared in accordance with United States generally accepted accounting principles consistently applied.

- 4.6 The Company will maintain and will not terminate the Third Party Licences and will be solely responsible for any and all payments due under the Third Party Licences that may become due as a result of the grant of rights to the Charity under this Agreement or the carrying out the Clinical Trial in accordance with this Agreement.

## 5. CONFIDENTIALITY/PUBLICATION

- 5.1 Subject to Clause 5.5, each Party shall keep confidential and not disclose to any third party (other than the Experts, Contributors, Ethics Committee, Regulatory Authority, and staff involved in carrying out the Clinical Trial on a need to know basis) any Confidential Information disclosed to it by another Party (the “**Disclosing Party**”) without the prior written consent of the Disclosing Party. For the avoidance of doubt, the Charity shall be permitted to disclose Confidential Information disclosed to it to CRT and CRT shall be permitted to disclose Confidential Information disclosed to it to the Charity. Any party to whom Confidential Information is disclosed in accordance with this Clause 5.1 shall be:

5.1.1 subject to no less onerous obligations than those contained in this Clause 5 to keep such information confidential; and

5.1.2 advised of its confidential nature.

- 5.2 The obligations of confidence referred to in Clause 5.1 shall not apply to any part of the Confidential Information which can be proved by evidence in writing:

5.2.1 was known to the recipient Party (the “**Recipient Party**”) before its disclosure by the Disclosing Party;

5.2.2 was available to the public before that date or was otherwise in the public domain;

5.2.3 becomes available to the public or enters the public domain after that date otherwise than as a result of an act or default of the Recipient Party;

5.2.4 is received by the Recipient Party from a third party not bound to the Disclosing Party by any obligation of secrecy;

5.2.5 is independently developed or generated by the Recipient Party in circumstances where it has not been derived directly or indirectly from the Disclosing Party’s Confidential Information; or

5.2.6 is required to be disclosed by: (i) any law or statute or any rule or regulation of any Regulatory Authority or other government or administrative agency or authority, (ii) a Regulatory Authority; or (iii) an order of any court, provided however, that in each such event the Recipient Party required to disclose the Confidential Information shall give prompt notice to the Disclosing Party of such requirement so that such Disclosing Party may seek a protective order or other appropriate remedy to the extent of such disclosure.

- 5.3 The obligations of the Parties under Clause 5.1 shall survive the expiry or termination of this Agreement for whatever reason for a period of ten (10) years from the date of such expiry or termination.
- 5.4 Each of the Parties agrees that the provisions of this Clause 5 are fair and reasonable and that money damages are not a sufficient remedy for any breach of this Clause 5 and therefore, in addition to all other remedies, all Parties shall be entitled to seek injunctive or other equitable relief as a remedy for such breach.
- 5.5 Notwithstanding any confidentiality obligations assumed by the Parties hereunder, the Parties acknowledge the importance of publications to the academic standing of the Charity and the Contributors and the capital raising, transactional, and licensing prospects and reporting and disclosure obligations of the Company under United States and other securities laws, and progress reporting obligations to licensors and sublicensors under Third Party Licences. Accordingly, the Parties have agreed as follows as regards publication of Clinical Trial Results and Progress Reports:
- 5.5.1 The Charity shall use reasonable endeavours to publish, or procure the publication by the Contributors of, the Clinical Trial Results in a timely manner in accordance with generally accepted academic practice, whether during the course of or after completion of the Clinical Trial;
- 5.5.2 The Company may disclose the content of Progress Reports only to the extent required for (a) satisfying mandatory reporting and disclosure obligations under United States and other securities laws; or (b) to existing licensors or sublicensors of the Company in order to comply with reporting obligations in existence as at the date of this agreement under Third Party Licences, provided that in the case of (b) the disclosure will exclude all information regarding clinical responses and shall be limited to only information regarding the clinical indication, anticipated timelines of the trial, the number of patients dose, and such other information of a similar nature as may be reasonably required by the Third Party Licence;
- 5.5.3 In the event that the Company wishes to disclose the content of Progress Reports to a third party in connection with capital raising, financing, transactional, and/or licensing activities or prospects for the benefit of the Company, it shall give notice to the Charity, including details of the content of the proposed disclosure and the reason for wishing to make such disclosure, and obtain the Charity's approval before proceeding with the disclosure. The Company shall inform Charity of the identity of the third party in its notice unless it is prevented from doing so due to express confidentiality restrictions owed to the third party, in which case the Company shall state the main business area within which the third party operates; and
- 5.5.4 It is further provided that any disclosure of the content of Progress Reports by the Company shall be subject to the following conditions: (a) all recipients shall be informed in writing beforehand of the confidential nature of the information being disclosed and shall have agreed in writing to obligations of confidentiality in favour of the Company no less onerous than those contained in this Clause 5 (but without any right of further disclosure) to keep such information confidential; and (b) only the content of the documents containing the relevant information which has been processed into a suitable format may be disclosed but not copies of the actual documents themselves. Condition (a) above shall not apply to a disclosure by the Company for the purpose mentioned in Clause 5.5.2(a).

- 5.6 The Charity will include provisions in its contracts with the Contributor(s) that require such Contributor(s) to notify the Charity in advance of submission of any abstract, presentation or manuscript incorporating Clinical Trial Results that the Contributor(s) wish to publish or have published or to present or have presented.
- 5.7 Upon receipt of such notification from a Contributor or if the Charity wishes itself to publish or have published or to present or have presented an abstract, presentation or manuscript incorporating Clinical Trial Results the Charity shall so notify the Company and CRT and provide (in so far as it is able to do so in the case of a Contributor's notification) in response to the Company's and/or CRT's reasonable request a copy or summary thereof at least seven (7) days prior to submission for publication of an abstract or presentation or at least thirty (30) days prior to submission for publication of a manuscript (or twenty one (21) days prior to submission for publication of a manuscript in the case of a Contributor's notification). Any such copy or summary shall provide sufficient details to enable the Company and CRT to ascertain whether it contains Confidential Information of the Company or CRT respectively or whether Patent Rights or other proprietary protection should be sought.
- 5.8 The Company and CRT shall review and make any comments on such intended publication or presentation of an abstract to the Charity within seven (7) days and/or shall review and make any comments on such intended publication or presentation of a manuscript within thirty (30) days. The Company and/or CRT may request that:
  - 5.8.1 Confidential Information of the Company (not including Clinical Trial Results nor information directly relating to the Investigational Medicinal Product) or Confidential Information of CRT (not including Clinical Trial Results) be removed from the proposed publication or presentation; and/or
  - 5.8.2 any such publication or presentation be delayed if in the Company's or CRT's reasonable opinion it is necessary to delay publication or presentation in order to file a patent application or application for other proprietary protection in respect of any invention made in the course of the Clinical Trial. Any such delay will be kept to the minimum period practicable and will in no event extend beyond thirty (30) days from the date the proposed publication or presentation was provided to the Company.

In the event of a request pursuant to Clauses 5.8.1 or 5.8.2, the Company or CRT (as the case may be) shall provide the Charity with a written explanation of the reasons why it believes information should be removed or a delay is necessary. For the avoidance of doubt, any Patent Rights filed pursuant to Clause 5.8.2 shall be filed in CRT's name.

- 5.9 The Charity and CRT shall be entitled to publish information in relation to the proposed Clinical Trial, including that it is or will be a trial conducted by the Clinical Development Partnerships initiative set up by the Charity and CRT, the pre-requisites for patient recruitment, a brief description of the Clinical Trial, including the name of the Company, the reference number and class of the Investigational Medicinal Product and the location(s) at which the trial is taking place.

## **6. INTELLECTUAL PROPERTY RIGHTS**

- 6.1 The Company hereby grants to the Charity:

- 6.1.1 a \*\*\* in the Field under the Company Owned Intellectual Property; and
- 6.1.2 a \*\*\* in the Field under the hTERT Licensed Patents; and
- 6.1.3 a \*\*\* in the Field under the University of Western Ontario Licensed Patents; and
- 6.1.4 a \*\*\* in the Field under the Isis Licensed Patents; and
- 6.1.5 a \*\*\* in the Field under the Merix/Duke Licensed Patents; and
- 6.1.6 a \*\*\* in the Field on consent of Johns Hopkins University (as described in Section 2.2 of the JHU License) under the Immunomic/JHU Licensed Patents; and
- 6.1.7 a \*\*\* in the Field under the WARF Intellectual Property

in each case subject to the terms and conditions for such sub-licence described in Schedule 7A, on a royalty-free basis, and for the purpose of preparing for and carrying out (and having prepared or carried out for the Charity) the Clinical Trial. In addition the Company hereby grants to the Charity a non-exclusive, royalty free licence under the Company Intellectual Property (including the right to use Company Materials), subject to the terms and conditions for each sub-licence described in Schedule 7A, for the Charity and scientists funded by the Charity to adapt and use the Product Manufacturing Process and make and have made Products and Related Products for non-commercial research purposes, provided that such research will not include clinical research without the prior written consent of the Company on a case-by-case basis. Such license under the Immunomic/JHU Licensed Patents shall include only rights relating to use of \*\*\*.

In the event the Charity reasonably determines that its Contributors require any additional sub-licence under any Third Party Licence in order to perform their activities in support of the Clinical Trial, at the Charity's request the Company agrees to use its reasonable endeavours to obtain the necessary consents under the relevant Third Party Licences to enable the Charity to grant the additional sub-licences to the Contributors or if such consent is refused in any case or in the Company's reasonable opinion is unlikely to be granted then, if it is so permitted under the relevant Third Party Licence, the Company agrees to directly sublicense the Contributors as appropriate.

During the term of this Agreement, the Company shall not be entitled to (and shall not authorise any of its Affiliates or any other third party to) conduct any clinical trials in respect of the Product or, save as the Parties may agree otherwise pursuant to Clause 6.2 below, any Related Product.

If, within \*\*\* of the Effective Date, the licensor or sublicensor of a Third Party Licence requires that a provision of a Third Party Licence be added to this Agreement on the basis that the Third Party Licence requires that the provision be included in a sublicense, the Charity, CRT and the Company shall so amend this Agreement; provided, however that if the Charity reasonably determines that the provision, if added to this Agreement, would impose upon the Charity an obligation that is not acceptable to the Charity or an obligation that would be illegal for the Charity to perform under the laws of England, then the Charity may terminate this Agreement upon \*\*\* written notice to the Company.

Notwithstanding anything to the contrary above in this Clause 6.1, or elsewhere in this Agreement, the Company acknowledges, agrees and warrants that the Charity is entitled to lawfully sub-contract in accordance with Clause 3.3 above any of the work that is contemplated by this Agreement (including work that is preparatory to any such work) without requiring any further or other consents from the Company or any third party.

As regards the Intellectual Property Rights that have been licensed to the Charity under clauses 6.1.4, 6.1.6 and 6.1.7 above, the Parties acknowledge the consent letters set out in the table at the top of Schedule 7 that have been obtained from the relevant head licensors. Without affecting the Charity's rights above in this Clause 6.1:

- (a) if at any time the Charity wishes to additionally obtain a consent letter from the University of Western Ontario that provides freedom or greater freedom in favour of the Charity to sub-license the Intellectual Property Rights that have been licensed to the Charity under Clause 6.1.3, then upon being requested to do so, Asterias shall cooperate with the Charity and use its commercial reasonable endeavours to obtain such consent letter in the form reasonably requested by the Charity at the time; and
- (b) for clarity Asterias hereby represents and warrants to and for the benefit of the Charity that Asterias is entitled to grant direct sub-licences to Contributors (and any other third parties) under the Intellectual Property Rights that have been licensed to the Charity under Clause 6.1.3 and that upon being requested to do so by the Charity at any time, Asterias shall promptly enter into such direct sub-licences with such Contributors or other third parties so as to enable the Charity to properly perform its obligations and enjoy its rights under the main body of this Agreement by means of selective sub-contracting and sub-licensing as the Charity may desire. The terms of such direct sub-licence shall be non-exclusive and free of charge and otherwise similar to the licence terms set out above in this Clause 6.1 avoiding (so far as is lawful) any restrictions or other terms that are of no relevance to the main purposes of the sub-contract or sub-licence and excluding any right to further sub-licence.

6.2 If at any time during the Clinical Trial the Company desires to commence a clinical study in respect of a Related Product, it shall give as much notice of this as practicable to CRT and the Charity and the Parties shall endeavour to agree and enter into a separate agreement within ninety (90) days detailing the terms on which the desired clinical study may be commenced and carried out by the Company in respect of the Related Product. The Parties shall act in good faith to negotiate an agreement that facilitates clinical development of the Related Product while minimizing any potential negative impact on the ongoing Clinical Trial and commercial prospects for the Product.

6.3 The Company shall use commercially reasonable endeavours to continue to prosecute and maintain, at its own cost, all of the Company Patent Rights and to procure that where this is the responsibility of the licensor under a Third Party Licence, that the licensor similarly does so; subject to this Clause 6.3. If the Company intends to substantially narrow the scope of the claims of any patent or patent application within the Company Patent Rights it will first consult with CRT and take into good faith consideration any concerns or views expressed by CRT. If the Company elects not to prosecute or maintain any part of the Company Patent Rights, the Company shall notify CRT in writing within a reasonable period and no less than ninety (90) days prior to the expiration of any applicable time bars. After receipt of such notice, and if and to the extent permitted by the terms of the applicable Third Party Licence in the case of Company Patent Rights under a Third Party Licence, CRT may elect, before the expiry of any such time bars, by written notice to the Company, to take an assignment of any Company Patent Rights identified in such notice at CRT's sole discretion and for consideration not exceeding one pound (£1). In the event that CRT elects to take such an assignment, the Company shall promptly transfer to CRT (or any person nominated by CRT) copies of any and all documents in the Company's control relating to the filing, prosecution, maintenance, enforcement and defence of such Company Patent Rights. The Company shall not assign, charge, encumber or dispose of any interest in any of the Company Patent Rights in a manner that limits or impairs CRT's rights under the licence of Company Patent Rights pursuant to this Agreement without CRT's prior written consent or to or in favour of a Tobacco Party.



- 6.4 As between the Company and the Charity, \*\*\*. The Charity hereby \*\*\*. CRT hereby \*\*\*.
- 6.5 Subject to \*\*\*, and to the exceptions allowed for under \*\*\*, the Company shall \*\*\*.
- 6.6 Solely in connection with the Charity's and the Contributors' activities performed pursuant to the Clinical Trial, where carried out in accordance with the terms of this Agreement, the Company shall not, and shall procure that its Affiliates shall not, anywhere in the world, institute or prosecute (or, other than as required by law, in any way aid any third party in instituting or prosecuting) any claim, demand, action or cause of action for damages, costs, expenses or compensation, or for an injunction, or any other equitable remedy, alleging the infringement by the Charity and/or any Contributors of any Patent Rights of the Company and/or any Patent Rights of the Company's Affiliates. For the avoidance of doubt, the foregoing shall not apply in respect of: (i) development, at any time, of products other than the IMP, Products or Related Products in accordance with the provisions of Clause 6.1; or (ii) any activity in relation to Products, Related Products or the IMP which constitutes a breach of the terms of this Agreement.
- 6.7 Any breach of Clause 6.6 shall be a material breach and shall accordingly entitle the Charity to terminate this Agreement under Clause 11.2.
- 6.8 CRT hereby reserves and excludes from the Option, the worldwide, perpetual and irrevocable right in and to the Exclusive Results for the Contributors and the Charity (including scientists funded and/or employed by the Charity) to:
- 6.8.1 use the Exclusive Results for the purpose of non-commercial scientific research carried out by or for or under their respective direction in accordance with their respective charitable and/or academic status, whether alone or in collaboration with a third party or third parties; and
  - 6.8.2 grant licences under, and make available, the Exclusive Results solely to the extent necessary to exercise the rights under Clause 6.8.1, but not otherwise.

- 6.9 For the avoidance of doubt, CRT shall be entitled, at its discretion, at any time (including during the Option Period) to grant non-exclusive licences to the Non-Exclusive Results to any person and for any purpose.
- 6.10 In the event that the Charity is prevented or materially restricted from carrying out the Clinical Trial in accordance with this Agreement due to an actual or potential infringement of third party Intellectual Property Rights, the Charity shall have right to terminate this Agreement under Section 11.3.4 if the Company does not, within \*\*\* after the Company's receipt of notice of a claimed infringement from the third party, obtain a licence from the third party permitting the use of the third party's infringed Intellectual Property Rights by the Charity in the Clinical Trial.

## 7. OPTION

- 7.1 CRT grants to the Company the option, exercisable by notice to CRT in writing (the "**Exercise Notice**") at any time during the \*\*\* (the "**Option Period**"), to enter into the Licence (the "**Option**"). Subject to Clause 6.8, the Option shall be \*\*\*.
- 7.2 Upon exercise of the Option, the Company shall pay the Option Fee to CRT within the Option Period.
- 7.3 Save where the Charity has provided a Full Clinical Study Report, CRT shall procure the provision of the Data Listings to the Company following the exercise of the Option and the receipt by CRT of the Option Fee.
- 7.4 If the Company exercises the Option, CRT and the Company shall execute the Licence within the Signature Period.
- 7.5 If either: (i) the Company does not exercise the Option within the Option Period; or (ii) following the exercise of the Option, the Company does not enter into the Licence within the Signature Period, then at any time within the period of \*\*\* following the expiry of the Option Period or Signature Period (as applicable), at CRT's request the Company shall:
- 7.5.1 provide CRT with such assistance as CRT may reasonably request to enable CRT to carry out in-depth due diligence on the Company Patent Rights and the Third Party Licences, including by providing access to true copies of the Third Party Licences and any freedom to operate searches conducted by or in the possession or control of the Company in respect of the Company Patent Rights;
  - 7.5.2 provide CRT with such assistance as CRT may reasonably request in liaising with the licensors under the Third Party Licences for the purpose of obtaining direct contractual rights with such licensors;
  - 7.5.3 in respect of Third Party Licences under which the Company would retain a right to use some or all of the relevant Intellectual Property Rights after entering into the CRT Licence, \*\*\*; and
  - 7.5.4 promptly license the Company Intellectual Property (including by granting sub-licences under the Third Party Licences to the extent laid out in Schedule 6, and subject to the terms and conditions of, the Third Party Licences) to CRT by executing an agreement in the form attached at Schedule 6 (the "**CRT Licence**"), and CRT shall be free to license or otherwise grant rights in respect of the Clinical Trial

Results and the Intellectual Property Rights in the Clinical Trial Results on such terms and to such third parties as it shall see fit. Further Company agrees, at CRT's sole discretion (but subject to any sublicensing limitations in the underlying Third Party Licence), to issue a direct sublicense to third parties of CRT's choosing under those Third Party Licences for which Company is unable to award CRT a further sublicensable sublicense. Any disagreement between CRT and the Company as to: (i) categorisation of Company Intellectual Property as "Company Background Intellectual Property" or "Company Foreground Intellectual Property" under the CRT Licence; or (ii) a fair and reasonable apportionment of Third Party Licence Payments under Clause 7.5.3, will be resolved by Independent Opinion in accordance with Clause 13.

## **8. WARRANTIES AND LIMITS OF LIABILITY**

8.1 The Charity warrants that:

8.1.1 it will procure the discharge of its obligations hereunder with reasonable care and skill; and

8.1.2 it will use its reasonable endeavours to procure that each Contributor that carries out part of the Clinical Trial ensures that where applicable the relevant Chief Investigator and/or the Principal Investigator discharge their obligations in respect of that part of the Clinical Trial in accordance with applicable ICH GCP provisions.

8.2 The Company warrants and represents that:

8.2.1 it is entitled to make the Company Materials available to the Charity for the purposes of this Agreement;

8.2.2 to the best of its knowledge the use and possession of the Company Materials and/or the use, possession and manufacture (in accordance with the Product Manufacturing Process) of IMP by the Charity and/or the Contributors shall not infringe the rights (including without limitation any Intellectual Property Rights) of any third party;

8.2.3 the Company Materials have been manufactured, handled and stored at all times in accordance with the regulatory standards agreed between the parties in the Technology Transfer Plan;

8.2.4 it has the full right, power and authority, and has obtained all approvals or consents necessary to grant the rights under the Third Party Licences as provided under this Agreement;

8.2.5 the Third Party Licences:

(a) are the only third party licences held by the Company or to which the Company is entitled to acquire under options or otherwise in respect of the manufacture, possession and use of the IMP and the rights granted to the Charity under this Agreement;

(b) that have been copied to CRT prior to the date of this Agreement (save for redactions that are apparent on the face of the documents) are complete and accurate and are not in the course of being varied; and

(c) shall not be materially varied during this Agreement without the prior written approval of CRT, such approval not to be unreasonably withheld or delayed.

- 8.2.6 the Third Party Licence Payments are the only payments that could become payable under the Third Party Licences, excepting only patent maintenance and prosecution costs, costs arising from the defence or prosecution of any infringement or alleged infringement of any patents or other intellectual property, and indemnification costs;
- 8.2.7 to the best of its knowledge and belief there are no outstanding breaches of the Third Party Licences by the Company; and
- 8.2.8 to the best of its knowledge and belief no acts or omissions have occurred which would give one or more of its licensors the right to terminate a Third Party Licence, either now or at a later date

8.3 The Company warrants and represents that all information and Know-How supplied to the Charity and/or CRT pursuant to this Agreement (including any safety information) shall be accurate and complete and shall be supplied as soon as practicable following the Commencement Date (or as otherwise specified herein) to enable the Charity to conduct and manage the Clinical Trial in a safe and proper manner.

8.4 Nothing in this Agreement shall exclude or limit the liability of any Party for death or personal injury resulting from its negligence or the negligence of its employees while acting in the course of their employment or shall exclude or limit the liability of any Party for fraud.

8.5 Subject to Clause 8.4, the entire aggregate liability for any loss or damage arising from any act or omission relating to this Agreement or its subject matter regardless of the form of action, whether in contract or tort (including in each case negligence), strict or statutory liability or otherwise,:

8.5.1 of the Charity and CRT to the Company excluding the liability of the Charity or CRT under Clause 9.1.1, shall be limited to \*\*\* in aggregate and the liability of the Charity or CRT under Clause 9.1.1 shall be limited to \*\*\* in aggregate;

8.5.2 of the Company to CRT and the Charity excluding the liability of the Company under Clause 9.2.1, shall be limited to \*\*\* in aggregate and the liability of the Company under Clause 9.2.1 shall be limited to \*\*\* in aggregate.

8.6 To the fullest extent permissible by law, no Party shall under any circumstances be liable to any other for any loss of revenue, business, contracts, anticipated savings, profits, data or information, or any indirect or consequential loss howsoever arising whether from negligence, breach of contract or otherwise.

8.7 Save to the extent otherwise provided in this Agreement, each Party specifically excludes to the extent permitted by law all warranties, representations, and conditions regarding the performance of its obligations under this Agreement including those implied by law, whether as to suitability, quality or fitness for any purpose or otherwise.

## 9. INDEMNITIES

9.1 Subject to Clause 8.5, the Charity shall indemnify and hold the Company its officers, and employees and its licensors and sub-licensors under Third Party Licences (the “**Company Indemnitees**”) harmless from and against:

9.1.1 \*\*\*; and

9.1.2 \*\*\*

9.1.3 in either case under Clauses 9.1.1 and 9.1.2 above arising out of the conduct of the Clinical Trial by the Charity;

9.1.4 save in either case where such claims and proceedings, losses, damages, costs or expenses arise as a consequence of (i) any wrongful act or omission and/or negligence of any of the Company Indemnitees; (ii) a breach of this Agreement by the Company; or (iii) a misrepresentation by the Company. It is a condition of this indemnity that the Company hands over or procures the hand over (as the case may be) of control of the matter to the Charity, gives or procures (as the case may be) such information and assistance as the Charity may reasonably request in connection with the matter, and allows or procures, (as the case may be) that the Charity has exclusive conduct of the matter and any ensuing legal proceedings;

9.1.5 and provided always that the foregoing indemnity given in respect of liability owed by the Company to its licensors and sub-licensors under Third Party Licences shall apply only to the extent that the relevant Third Party Licence contractually requires the Company to indemnify the licensor or sublicensee against such liability.

9.2 Notwithstanding the provisions of Clause 9.1 above and any other restrictions on liability contained in this Agreement, but subject to Clause 8.5 above, the Company shall indemnify and hold the Charity, CRT, the Contributors, the Experts and their respective officers, employees and agents harmless from and against all:

9.2.1 \*\*\*; and

9.2.2 \*\*\*;

9.2.3 in either case under Clauses 9.2.1 and 9.2.2 above arising out of: (i) any failure or delay on the part of the Company to provide relevant or accurate Company Know-How and other information relating to the storage, manufacture, quality assurance, use and safety of any of the Company Materials; and/or (ii) any wrongful act or omission and/or negligence of the Company (or any third party engaged by the Company) \*\*\*; and

9.2.4 alleging infringement of a third party's Patent Rights or other Intellectual Property Rights resulting from use of Company Intellectual Property or Company Materials in the course of or in consequence of the performance of the Clinical Trial or by importation, storage, manufacture, supply or use of any of the Company Materials and/or Product as permitted by this Agreement; provided always that

9.2.5 it is a condition of the indemnity that the Charity and CRT hand over or procure the hand over (as the case may be) of control of the matter to the Company, and give or procure (as the case may be) such information and assistance as the Company may reasonably request in connection with the matter, and allow or procure, (as the case may be) that the Company has exclusive conduct of the matter and any ensuing legal proceedings.

- 9.3 The indemnities set out in Clauses 9.1 and 9.2 shall survive the expiration or termination of this Agreement for whatever reason.
- 9.4 The Charity shall ensure that all Clinical Trial Subjects receive the benefit of a no-fault compensation scheme substantially in the form attached at Schedule 5 hereto. Subject to the indemnity in Clause 9.2, the Charity shall bear all costs associated with the provision of such compensation scheme including in relation to all claims received pursuant to such scheme.
- 9.5 The Company shall to the extent reasonably possible carry liability insurance coverage for potential liabilities which the Company may directly or indirectly have to Clinical Trial Subjects or under Clause 9.2.1 of this Agreement in amounts equal to at least \*\*\* per occurrence combined single limit and \*\*\* annual aggregate coverage. The Company shall maintain such insurance in full force throughout the term of the Agreement and shall upon request of the Charity provide such evidence of compliance as the Charity deems sufficient.

## 10. ASSIGNMENT

- 10.1 No Party shall assign its rights under this Agreement or any part thereof; provided that the Company may assign its rights and obligations to a third party in connection with any merger or consolidation of the Company with another business entity, or in connection with the sale of all or a substantial part of its business and related assets that includes its business in relation to the Product, other than a merger or consolidation with or a sale of assets to a Tobacco Party and provided that the Company obtains a direct covenant from the acquiring party to CRT and the Charity undertaking to be bound by the terms of this Agreement. Save as set out in this Agreement, no Party shall sub-contract the performance of all or any of its obligations under this Agreement without the prior written consent of the other Parties.

## 11. TERM AND TERMINATION

- 11.1 Unless terminated earlier pursuant to the provisions hereunder, and except as otherwise provided hereunder, this Agreement shall remain in full force and effect from the Commencement Date until the earlier of the date that:
- 11.1.1 The Company enters into the Licence pursuant to Clause 7.4; or
  - 11.1.2 The Company licenses the Company Intellectual Property to CRT pursuant to Clause 7.5; or
  - 11.1.3 The \*\*\* period following the expiry of the Option Period or Signature Period described in Clause 7.5 has expired without request from CRT to execute the CRT Licence.
- 11.2 Any of the Parties hereto may at any time terminate this Agreement, but shall not be obliged to do so, upon written notice to the other Party (being the Charity and CRT where the terminating Party is the Company, or the Company where the terminating Party is the Charity or CRT) under the following circumstances:
- 11.2.1 in the event that the other Party commits a material breach of this Agreement and does not fully remedy, if capable of remedy, the same within sixty (60) days of its receipt of written notice of the breach from any other Party;
  - 11.2.2 in the event, in respect of a Party, a voluntary arrangement is proposed or approved or an administration order is made, or a receiver or administrative receiver is appointed of any of such Party's assets or undertakings or a winding-up resolution or petition is passed (otherwise than for the purpose of solvent reconstruction or amalgamation) or if any circumstances arise which entitle a court or a creditor to appoint a receiver, administrative receiver or administrator or make a winding-up order or similar or equivalent action is taken against or by such Party by reason of its insolvency; or

11.2.3 If the required approval of the Ethics Committee or applicable Regulatory Authority for the commencement of the Clinical Trial is not obtained within \*\*\* of both the Technology Transfer Plan being completed and the Parties agreeing that the Transfer Criteria have been met, or if any approval granted is revoked, withdrawn, or otherwise terminated, or if an applicable Regulatory Authority orders a halt or hold on the Clinical Trial of greater than \*\*\* in duration. No right of termination arising under this Clause 11.2.3 may be exercised by a Party unless it has first notified the other Parties of its wish to terminate and entered into good faith discussions over a period of not less than thirty (30) days with the other Parties to review and discuss the circumstances with a view to avoiding a termination without affecting the purposes contemplated by this Agreement.

11.3 The Charity shall have the right to terminate this Agreement forthwith, upon written notice to the Company:

11.3.1 in accordance with Clause 3.6;

11.3.2 if the Charity is not satisfied that the Product Manufacturing Process can be carried out on a scale and standard suitable to enable the Charity to produce sufficient quantities of IMP to conduct the Clinical Trial including an inability for technical or other reasons to produce the desired quantity of IMP;

11.3.3 if the Charity faces budget constraints that require a reduction in its development portfolio; or

11.3.4 if the Charity reasonably believes that proceeding with the Clinical Trial would: (i) be unsafe or otherwise counter to the best interests of Clinical Trial Subjects; ii) be counter to changes in the business plan or research strategy of the Charity iii) be counter to recommendations made by the committee established by the Charity to regularly review the Charity's clinical portfolio; (iv) involve increases of more than \*\*\* to anticipated timelines, including due to difficulties with patient recruitment or unforeseen regulatory hurdles; (v) be unlikely to achieve the primary and/or secondary endpoints of the Protocol; (vi) fail to reach such defined go/no-go criteria as have been previously agreed upon by the Company and the Charity; or (vii) infringe any third party Intellectual Property Rights and the Company does not obtain a licence entitling the Charity to use such Intellectual Property Rights in the Clinical Trial as provided in Clause 6.10; or

11.3.5 in accordance with the last sentence of Clause 6.1.

11.4 The Charity shall have the right to terminate this Agreement forthwith, upon written notice to the Company If, by way of merger, acquisition or otherwise, the Company becomes a Tobacco Party.

- 11.5 The Parties may by mutual written agreement terminate this Agreement for any reason, including, if in their opinion the objectives of the Clinical Trial cannot be achieved.

## 12. CONSEQUENCES OF TERMINATION

- 12.1 In the event of termination of this Agreement by the Company:

- 12.1.1 subject to Clause 12.1.3 and 12.8, the Charity shall, within thirty (30) days, return to the Company or destroy (by a method specified by the Company) and at the Company's cost and expense any remaining quantities of the Company Materials and/or Confidential Information of the Company in the Charity's possession or control;
- 12.1.2 where the Charity has commenced the Clinical Trial, the Charity shall within thirty (30) days of finalisation of the last Case Report Form submit to the Company copies of all completed Case Report Forms and Data Listings for the Clinical Trial. The Charity shall be entitled to retain the original Case Report Forms for its own records; and
- 12.1.3 where the Charity has commenced the Clinical Trial, the Charity shall nonetheless be entitled to continue to manufacture the Investigational Medicinal Product and continue to provide such Investigational Medicinal Product to: (i) any particular Clinical Trial Subject who has commenced treatment; and/or (ii) any Clinical Trial Subject where the Regulatory Authority and/or Ethics Committee request or require that such provision occurs, unless, in either case, termination occurs under Clause 11.2.3 or 11.5.

- 12.2 In the event of any termination of this Agreement pursuant to Clause 11.2.1 or Clause 11.2.2 by CRT or the Charity:

- 12.2.1 the Option shall lapse forthwith;
- 12.2.2 the Company shall within thirty (30) days of the date of such termination reimburse the Charity all Costs; and
- 12.2.3 the Charity shall be entitled to (as applicable) commence and complete the Clinical Trial and the Company shall provide the Charity with the necessary assistance to allow the Charity to do so. For the avoidance of doubt, the licence granted by the Company under Clause 6.1 shall continue to the extent necessary to allow the Charity to commence and complete the Clinical Trial; provided, that upon completion or termination of the Clinical Trial the Charity shall, within thirty (30) days return to the Company or destroy (by a method specified by the Company) and at the Company's cost and expense any remaining quantities of the Company Materials and/or Confidential Information of the Company in the Charity's possession or control.

- 12.3 In the event of termination of this Agreement pursuant to Clause 11.3 by the Charity or pursuant to Clause 11.5:

- 12.3.1 subject to Clause 12.3.2 and 12.8, the Charity shall, within thirty (30) days, return to the Company or destroy (by a method specified by the Company) and at the Company's cost and expense any remaining quantities of the Company Materials and/or Confidential Information of the Company in the Charity's possession or control;



- 12.3.2 except for termination under Clause 11.3.4, where the Charity has commenced the Clinical Trial, the Company shall nonetheless continue to permit the Charity to continue to provide Investigational Medicinal Product to: (i) any particular Clinical Trial Subject who has commenced treatment; and/or (ii) any Clinical Trial Subject where the Regulatory Authority and/or Ethics Committee request or require that such provision occurs;
- 12.3.3 where the Charity and CRT consider it appropriate to do so in light of the reason for termination, for a period of thirty (30) days from the date of termination (or such longer period as CRT may notify) CRT will offer the Company the option, exercisable by written notice to CRT, to enter into the Licence in respect of those Clinical Trial Results in existence at the date of termination and subject to agreement between CRT and the Company on amended financial and other terms for the Licence to reflect that the Clinical Trial was not completed. If the Parties have not been able to agree amended financial terms within thirty (30) days of the date CRT receives the Company's exercise notice the Parties at their joint cost and expense shall obtain an Independent Opinion on a fair and reasonable reduction to the financial terms.

- 12.4 In the event of termination of this Agreement pursuant to Clause 11.2.3, the Charity shall, within thirty (30) days, return to the Company or destroy (by a method specified by the Company) and at the Company's cost and expense any remaining quantities of the Company Materials and/or Confidential Information of the Company in the Charity's possession or control.
- 12.5 Termination of this Agreement for whatever reason shall not affect the accrued rights of the Parties arising out of this Agreement as at the date of its termination.
- 12.6 The provisions of the following Clauses shall survive the expiration or termination of this Agreement 5 (Confidentiality/Publication), 6.3 (Assignment of Clinical Trial Results to CRT), 6.5 (Covenant not to sue), 8.4 to 8.6 inclusive (Limits or exclusion of liability), 8.7 (Exclusion of other warranties), 9 (Indemnities), 10 (Assignment), 12 (Consequences of termination), 13 to 23 inclusive (Dispute Resolution to Third Party Rights inclusive).
- 12.7 The Charity shall retain copies of the Company's Confidential Information and the Clinical Trial Results in accordance with ICH GCP and as otherwise required under the Charity's obligations as Sponsor of the Clinical Trial.

### 13. DISPUTE RESOLUTION

- 13.1 Insofar as this Agreement provides that a matter shall be resolved by Independent Opinion, the opinion of the appointed independent expert (who shall act as an expert and not as an arbitrator) shall be final and binding on the Parties. In the event of a Party seeking an Independent Opinion under this Agreement, each Party shall make written submissions to the expert and to the other Parties within fourteen (14) days of the appointment. Each Party shall have seven (7) days to respond to the others' submissions. The expert shall be requested to deliver his Independent Opinion within a further thirty (30) days. The costs of any Independent Opinion shall be borne in such proportions as the expert may determine in his Independent Opinion to be fair and reasonable in all the circumstances or, if no such determination is made in the Independent Opinion, by the Parties in equal proportions.
- 13.2 It shall be a condition precedent to the commencement of any action in court or other tribunal (save an action for an interim injunction or an Independent Opinion sought under Clause 13.1) in respect of any dispute relating to this Agreement that the Parties have sought to resolve the dispute by one Party notifying the others in writing for resolution to the Chief Executive Officer of CRT, the Director of Drug Development of the Charity and the CEO of the Company (or their express delegates) (the "**Representatives**") who shall meet (whether in person or via teleconference) within twenty one (21) days of such notice to seek resolution in good faith. If the Representatives are unable to resolve the dispute at such meeting, any Party may pursue any remedy available to such Party at law or in equity, subject to the terms and conditions of this Agreement and the other agreements expressly contemplated hereunder.

- 13.3 This Agreement shall be governed by and construed in accordance with English Law and, subject to the provisions of Clause 13.1 and 13.2, each Party agrees to submit to the exclusive jurisdiction of the English Courts (except in respect of disputes under Clause 5 where jurisdiction is non-exclusive).

#### 14. NOTICES

- 14.1 Any notice or other document to be given under this Agreement shall be in writing and shall be deemed to have been given:

14.1.1 upon delivery if given in person; or

14.1.2 upon confirmation of receipt if sent by facsimile (or other similar means of electronic communication such as email); or

14.1.3 (if posted to an inland destination) three (3) business days after deposit into First Class post;

14.1.4 (If posted to an overseas destination) five (5) days after deposit into airmail post; or

14.1.5 upon delivery by air delivery service;

to a Party at the address or fax number set out below for such Party or such other address as the Party may from time to time designate by written notice to the other Parties.

Address of the Company

Asterias Biotherapeutics  
230 Constitution Dr  
Menlo Park, CA 94025  
Contact: Legal/contracts  
Fax: 001 650 433 2900

Address of the Charity

Cancer Research UK  
Angel Building  
407 St. John Street  
London EC1V 4AD  
England  
Contact: Director of Drug Development  
Fax: +44 (0) 20 7121 6700

With a copy to:  
Cancer Research UK  
Angel Building  
407 St. John Street  
London EC1V 4AD  
England  
Contact: Hayley Farmer  
Fax: +44 (0) 20 7121 6700

Address of CRT  
Cancer Research Technology Limited  
Angel Building  
407 St. John Street  
London  
EC1V 4AD  
United Kingdom  
Contact: Chief Executive Officer  
Fax: +44 (0) 20 3014 8633

**15. WAIVER**

- 15.1 No failure or delay on the part of any Party hereto to exercise any right or remedy under this Agreement shall be construed as or operate as a waiver thereof nor shall any single or partial exercise of any right or remedy under this Agreement preclude the exercise of any other right or remedy or preclude the further exercise of such right or remedy as the case may be.

**16. FORCE MAJEURE**

- 16.1 No Party shall be liable to any other Party or shall be in default of its obligations hereunder if such default is the result of any cause beyond the reasonable control of the Party affected including war, hostilities, revolution, civil commotion, strike, epidemic, accident, fire, wind, flood or because of any act of God . The Party affected by such circumstances shall promptly notify the other Parties in writing when such circumstances cause a delay or failure in performance (a “**Delay**”) and where they cease to do so. In the event of a Delay lasting for twenty six (26) weeks or more either of the non-affected Parties shall have the right to terminate this Agreement immediately by notice in writing to the affected Party.

**17. SEVERABILITY**

- 17.1 If and to the extent that any court or tribunal of competent jurisdiction holds any of the terms, provisions or conditions or parts thereof of this Agreement, or the application hereof to any circumstances, to be invalid or to be unenforceable in a final non-appealable order, the remainder of this Agreement and the application of such term, provision or condition or part thereof to circumstances other than those as to which it is held invalid or unenforceable shall not be affected thereby, and each of the other terms, provisions and conditions of this Agreement shall be valid and enforceable to the fullest extent permissible by law.

**18. ENTIRE AGREEMENT**

- 18.1 This Agreement embodies and sets forth the entire agreement and understanding of the Parties and supersedes all prior oral or written agreements, understandings or arrangements relating to the subject matter of this Agreement. No Party shall be entitled to rely on any agreement, understanding or arrangement which is not expressly set forth in this Agreement unless otherwise agreed between the Parties and recorded in writing. In the event of any inconsistency between this Agreement and the Protocol, the terms of this Agreement shall govern.

**19. AMENDMENT**

- 19.1 This Agreement shall not be amended, modified, varied or supplemented except in writing signed by duly authorised representatives of the Parties.
- 19.2 The Charity shall at all times be free to amend, modify, vary or supplement any of the Charity's Standard Operating Procedures.

**20. PUBLIC ANNOUNCEMENTS**

- 20.1 The text of any press release, shareholders' report or other communication to be published or disclosed in any way by or on behalf of the Company by or in the media concerning the Charity, the Contributors or the Experts, the subject matter of this Agreement or concerning this Agreement itself, other than as required by law or by any regulatory or government authority or the rules of any securities exchange, shall be submitted to the Charity and CRT at least seven (7) days in advance of publication or disclosure for approval, such approval not to be unreasonably withheld; provided, that disclosure that repeats or restates prior public disclosure permitted by this Agreement need not be submitted to the Charity or CRT for approval.

**21. PAYMENTS**

- 21.1 All payments due to CRT and the Charity under this Agreement shall be made in cleared funds in pounds sterling to the bank accounts nominated by CRT and the Charity respectively from time to time. All costs of transmission shall be borne by the Company.
- 21.2 All payments under this Agreement are expressed to be exclusive of value added tax howsoever arising, which the Company shall pay in addition to those payments.
- 21.3 Save as expressly set out in Clause 7.2, all amounts due under this Agreement shall be paid in full without any deduction or withholding other than as required by law and the Company shall not be entitled to assert any credit, set-off or counterclaim against CRT or the Charity in order to justify withholding payment of any such amount in whole or in part.

21.4 Where a Party does not receive payment of any sums due to it by the due date, interest shall accrue both before and after any judgement on the sum due and owing to such Party at the rate equivalent to an annual rate of four percent (4%) over the then current base rate of Natwest Bank, calculated on a daily basis, until the full amount is paid, without prejudice to such Party's right to receive payment on the due date.

**22. DATA PROTECTION**

22.1 The Parties' attention is drawn to the Data Protection Act 1998, Directive 95/46/EC of the European Parliament and any national or European legislation and/or regulations implementing them or made in pursuance of them (all referred to together as the "**Data Protection Requirements**").

22.2 Each Party warrants that it will observe all its obligations under the Data Protection Requirements which arise in connection with the performance of this Agreement and in particular that it will process and use any personal data fairly and lawfully.

**23. THIRD PARTY RIGHTS**

23.1 Save for the third parties identified in Clauses 5.5 (Contributors' right to publish), 6.5 (Covenant not to sue), 9.1 and 9.2 (Indemnities) and 9.3 (No fault compensation scheme), who shall have the benefit of those respective Clauses, this Agreement shall not create any rights that shall be enforceable by anyone other than the Parties to this Agreement. The rights created in Clauses 5.5, 6.5, 9.1, 9.2 and 9.3 may be altered or extinguished by the Parties without consent of any third party beneficiary of such rights.

**24. EXECUTION**

24.1 This Agreement may be executed in any one or more number of counterpart agreements, and as scanned email attachments, and all signatures and counterparts so exchanged shall be considered as original and shall be deemed to form part of and together constitute this Agreement.

**IN WITNESS** whereof this Agreement has been executed by duly authorised officers of the Parties on the day first above written.

Signed by: \*\*\*  
\_\_\_\_\_

Name: \*\*\*  
\_\_\_\_\_

Title: \*\*\*  
\_\_\_\_\_

For and on behalf of  
**CANCER RESEARCH TECHNOLOGY  
LIMITED**

Signed by: \*\*\*

Name: \*\*\*

Title: \*\*\*

For and on behalf of  
**CANCER RESEARCH UK**

Signed by: /s/ Pedro Lichtinger

Name: /s/ Pedro Lichtinger

Title: CEO

For and on behalf of  
**ASTERIAS BIOTHERAPEUTICS, INC.**

**Schedule 1**  
**Company Patent Rights**

**Schedule 1A: Company Owned Patent Rights**

File #	Title	Country	App # / Patent #	Status	Filing date	Expiration date
***	***	***	***	***	***	***

**Schedule 1B: hTERT Licensed Patents**

<b>File #</b>	<b>Title</b>	<b>Country</b>	<b>App #/ Patent #</b>	<b>Status</b>	<b>Filing date</b>	<b>Expiration date</b>
***	***	***	***	***	***	***



**Schedule 1C: University of Western Ontario Licensed Patents**

<b>File #</b>	<b>Title</b>	<b>Country</b>	<b>App #/ Patent #</b>	<b>Status</b>	<b>Filing date</b>	<b>Expiration date</b>
***	***	***	***	***	***	***

**Schedule 1D: Isis Licensed Patents**

<b>File #</b>	<b>Title</b>	<b>Country</b>	<b>App #/ Patent #</b>	<b>Status</b>	<b>Filing date</b>	<b>Expiration date</b>
***	***	***	***	***	***	***

**Schedule 1E: Merix/Duke Licensed Patents**

<b>File #</b>	<b>Title</b>	<b>Country</b>	<b>App #/ Patent #</b>	<b>Status</b>	<b>Filing date</b>	<b>Expiration date</b>
***	***	***	***	***	***	***

**Schedule 1F:**  
**(intentionally blank)**

**Schedule 1G: Immunomic/JHU Licensed Patents**

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**Schedule 1H: WARF Intellectual Property**

**WARF Patents**

<b>WARF REFERENCE NUMBER</b>	<b>COUNTRY</b>	<b>APPLICATION SERIAL NUMBER</b>	<b>FILING DATE</b>	<b>PATENT NUMBER</b>
***				

**Wisconsin Materials**

\*\*\*

**Schedule 2  
Report Synopsis Headings**

Name of Sponsor/Company:	Individual Study Table Referring to Part of the Dossier
Name of Finished Product:	Volume:
Name of Active Ingredient:	Page:
Title of Study:	
Investigators:	
Study Centre(s):	
Publication (reference):	
Studied period (years): (date of first enrolment)  (date of last completed)	Phase of development:
Objectives:	
Methodology:	
Number of Patients (planned and analysed):	
Diagnosis and main criteria for inclusion:	
Test product, dose and mode of administration, batch number:	
Duration of treatment:	
Reference therapy, dose and mode of administration, batch number:	

Name of Sponsor/Company:	Individual Study Table Referring to Part of the Dossier
Name of Finished Product:	Volume:
Name of Active Ingredient:	Page:
Criteria for evaluation:	
<b>Efficacy:</b>	
<b>Safety:</b>	
Statistical methods:	
SUMMARY – CONCLUSIONS	
<b>EFFICACY RESULTS:</b>	
<b>SAFETY RESULTS:</b>	
<b>CONCLUSION:</b>	
Date of the report:	



### Schedule 3 Safety Information

- A. Cancer Research UK and Asterias Biotherapeutics Inc. have entered into a clinical trial agreement (the “Clinical Trial Agreement”) (of which this document is Schedule [3]) under which they agreed to collaborate in connection with a Phase [I/II] clinical trial of the Investigational Medicinal Product in accordance with the Protocol.
- B. The procedure in this Schedule describes how safety information regarding the Investigational Medicinal Product (“IMP”) will be communicated as it becomes known.

#### 1 DEFINITIONS

“**Adverse Event**” (or “**AE**”) means any untoward medical occurrence in a patient or clinical trial subject administered a medicinal product, which does not necessarily have a causal relationship with this treatment.

An AE can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding, for example), symptom or disease temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product.

An AE includes but is not limited to:

- a clinically significant worsening of a pre-existing condition. This includes conditions which may resolve completely and then become abnormal again;
- an AE occurring from an overdose of an IMP, whether accidental or intentional; and
- an AE occurring as a result of a quality issue with a batch of IMP.

Other reportable events which must be treated as AEs include:

- pregnancy exposure to an IMP. Any pregnancy occurring in a patient or a patient’s partner during treatment with an IMP or occurring within six months of the last dose of study drug administration, must be reported within the same timelines as a Serious Adverse Event (as defined below), even if the patient has been withdrawn from the clinical trial;
- overdose with or without an AE;
- inadvertent or accidental exposure to an IMP with or without an AE; and
- any adverse event which is serious and which could be related to the protocol procedures, and which could modify the conduct of the clinical trial.

“**Development International Birth Date**” (or “**DIBD**”) means the first date that clinical trial authorisation is given by a Regulatory Authority for an interventional clinical trial using the IMP anywhere in the world.

“**Development Safety Update Report**” (or “**DSUR**”) means a periodic safety report in relation to use of the IMP in the Clinical Trial which: (i) is written by or on behalf of the Charity in accordance with the Charity’s Standard Operating Procedures; (ii) meets the standards of the ICH Guidelines for Development Safety Update Reports as per ICH Topic E2F; and (iii) is required to be submitted annually to the Regulatory Authority in each ICH member state in which the clinical trial is conducted (and to the applicable Ethics Committee) within 60 days of the anniversary of the date of the DIBD.

**“Global Development Safety Update Report” (or “GDSUR”)** means a periodic safety report in relation to use of the IMP in two or more clinical trials which: (i) meets the standards of the ICH Guidelines for Development Safety Update Reports as per ICH Topic E2F; and (ii) is required to be submitted annually to the Regulatory Authority in each ICH member state in which the clinical trial is conducted (and to the applicable Ethics Committee) within 60 days of the anniversary of the date of the DIBD.

**“Investigator’s Brochure” (or “IB”)** means a compilation of the clinical and non-clinical data on the Investigational Medicinal Product or products which are relevant to the clinical trial of the product or products in human subjects.

**“Medically Important Event” (or “MIE”)** means any event that may jeopardise the patient or may require intervention to prevent one of the outcomes listed above. The Charity may identify certain events which must be treated as medically important by both Parties, and subject to expedited reporting.

**“Serious Adverse Event” (or “SAE”)** means any untoward medical occurrence or effect (an adverse event) that at any dose, regardless of causality or expectedness, results in:

- death;
- is life-threatening;
- requires in-patient hospitalisation or prolongs existing in-patient hospitalisation;
- results in persistent or significant incapacity or disability;
- is a congenital anomaly or birth defect; or
- is any other Medically Important Event (as defined below).

These characteristics/consequences have to be considered at the time of the event. For example, regarding a life-threatening event, this refers to an event in which the subject was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe.

**“Suspected Unexpected Serious Adverse Reaction” (or “SUSAR”)** means all serious adverse events that are suspected to be related to an investigational medicinal product and that are unexpected.

**“Sponsor”** means an individual, company, institution or organisation which takes responsibility for the initiation, management and/or financing of a clinical trial.

All capitalised words shall have the same meaning as in the Clinical Trial Agreement unless expressed otherwise.

## 2. PROCEDURE

### 2.1 Reporting of SAEs

#### 2.1.1 Reporting of SAEs by the investigational sites to the Company or the Charity, as the case may be

The Company shall, if it (or any of its licensees or sub-licensees) is carrying out clinical trials on Related Products, use all reasonable endeavours to

- monitor, and ensure that it receives from the investigational site within twenty four (24) hours of the investigator or any member of the study team becoming aware of the event) initial reports on SAEs from clinical trials of the Related Products; and
- actively seek follow-up information from the investigational site on SAEs from clinical trials of the Related Products until full details (including diagnosis if available, causality, outcome and cause of death if fatal) are reported.

The Charity shall use all reasonable endeavours to:

- monitor, and ensure that it receives from the investigational site within twenty four (24) hours of the Principal Investigator or any member of the study team becoming aware of the event) reports on SAEs from the Clinical Trial; and
- actively seek follow-up up information from the investigational site on SAEs from the Clinical Trial until full details (including diagnosis if available, causality, outcome, and cause of death if fatal) are reported.

#### 2.1.2 Reporting of SAEs to the other Party

Within seven (7) calendar days of receipt by the Company for fatal and life-threatening SUSARs (where day 0 is the day the Company became aware of the event) and within fifteen (15) calendar days of receipt by the Company for all other SUSARs, the Company shall report to the Charity all initial and follow-up information on all SUSARs from clinical trials with the Related Products for which the Company is the Sponsor.

The reports shall be in the form of a CIOMS or MedWatch form.

The Company shall send reports preferably as e-mail attachments, or alternatively by fax, to:

Pharmacovigilance Group  
Drug Development Office  
Cancer Research UK

E-mail: [SAE@cancer.org.uk](mailto:SAE@cancer.org.uk)  
Fax +44 20 7983 9547

Within seven (7) calendar days of receipt by the Charity for fatal and life-threatening SUSARs (where day 0 is the day the Charity became aware of the event) and within fifteen (15) calendar days of receipt by the Charity for all other SUSARs, the Charity shall report to the Company all initial and follow-up information on all SUSARs from clinical trials with the IMP for which the Charity is the Sponsor.

The reports shall be in the form of a CIOMS form.

The Charity shall send reports preferably as e-mail attachments, or alternatively by fax, to:

Asterias Biotherapeutics  
Attn: Medical Monitor  
230 Constitution Dr.  
Menlo Park, CA 94025  
Fax: (650)433-2998  
medicalmonitor@asteriasbio.com

### 2.1.3 Late Reports

If either Party fails to provide reports to the other Party within the timelines described above, they must provide to the other Party a legitimate reason for lateness and immediately provide evidence of corrective action taken.

## 2.2 **Expedited Reporting to Regulatory Authorities and Ethics Committee(s)**

Each Party shall fulfil its local regulatory obligations in relation to the clinical trials it Sponsors.

The Company will report to the appropriately all SUSARs originating from clinical trials with the Related Products for which it is the Sponsor.

The Charity will report to appropriately all SUSARs originating from clinical trials with the Investigational Medicinal Product for which it is the Sponsor.

## 2.3 **Quarterly Exchange of Line Listings**

During the currency of the clinical trials, with a view to reconciling SAEs between the Parties, a line listing of all SAEs received during the previous quarter originating from clinical trials with the IMP for which the Party is the Sponsor shall be exchanged between the Parties on a quarterly basis

Each line listing shall include sufficient information to identify the patient and the event, i.e., case reference, study ID, patient ID, (Number, age and gender) SAE (verbatim term), date event(s) became serious, investigator causality to IMP, maximum grade using NCI CTCAE criteria, and outcome of event.

Each Party shall send line listings preferably as e-mail attachments, or alternatively by fax, to the contact details specified in 2.1.2.

## 2.4 **Trials of Related Product(s)**

The Company shall keep the Charity informed about clinical trials in which the Related Products are being used. The Company shall do this by providing to the Charity for each clinical trial a summary protocol and a summary of all protocol amendments relating to safety on an ongoing basis. The Company will be open to questions on safety issues arising from these documents.

## **2.5 Development Safety Update Report**

2.5.1 In the event that the Clinical Trial is the only clinical trial being conducted on the IMP anywhere in the world, the Charity will be responsible for the preparation and submission of the DSUR.

The Development International Birth Date (DIBD) to be used will be [DD-MMM-YYYY].

The Party responsible for the Development Safety Update Report or Global Development Safety Update Report shall provide the other Party with a draft for review. The reviewing Party shall have fourteen (14) calendar days to comment on the draft. The responsible Party shall give due consideration to any comments that the reviewing Party might make, and provide the reviewing Party with a copy of the final report.

## **2.6 Investigator's Brochure ("IB")**

The Charity will produce the Investigator Brochure. The Charity will provide an annual update to the IB or provide confirmation that an annual review of safety data has been carried out and no update is required.

The Charity must promptly provide the Company with a copy of each version of the IB within fourteen (14) calendar days of the IB version being issued. Should the Charity disallow photocopying, it shall provide the other Party with sufficient copies of each version of the IB to allow at least one copy to be distributed to each of the Company's investigational sites, plus two copies for the Company's own use. If requested, the Company will distribute and document numbered copies of the IB.

## **2.7 Safety Information from Other Sources**

Each Party shall promptly review all information concerning safety of the IMP or Related Products that is obtained or otherwise received from any source, foreign or domestic, including data derived from clinical trials, epidemiological studies, animal experiments, commercial marketing experience, reports as part of scientific literature and unpublished scientific papers.

Any such information that is deemed important, i.e. could result in changes to protocols, patient information sheets or IB, shall be communicated within seven (7) calendar days to the other Party using the same means as for expedited SAE reports.

## **2.8 Developments and Enquiries**

Each Party shall advise the other of any regulatory or other developments affecting the safety of the IMP or Related Products, e.g., proposed recalls, labelling and other registration dossier change, any proposed changes to manufacturing, IMP quality complaints or quality issues.

Each Party shall advise the other Party of any enquires from Regulatory Authorities and Ethics Committees concerning the safety of the IMP or Related Products. The Parties shall collaborate fully, and in a timely manner, in providing a response to such enquiry.

## **2.9 Language**

The Parties agree to communicate with each other and prepare documents on the Investigational Medicinal Product or Related Products in English.

**Schedule 4  
Licence**

**THIS AGREEMENT is made the \_\_\_\_\_ day of \_\_\_\_\_ 20[●●]**

**BETWEEN:**

- (1) **CANCER RESEARCH TECHNOLOGY LIMITED**, a company registered in England and Wales under number 1626049 with registered office at Angel Building, 407 St. John Street, London, EC1V 4AD, England] (“**CRT**”); and
- (2) **ASTERIAS BIOTHERAPEUTICS, INC.**, a Delaware company with principal place of business at 230 Constitution Drive, Menlo Park, CA94025, USA (the “**Company**”).

**RECITALS**

- (A) CRT is a wholly owned subsidiary of Cancer Research UK (the “**Charity**”) and is, by arrangement with the Charity, responsible for the management, exploitation and commercialisation of intellectual property generated by the Charity or using funding from the Charity.
- (B) Pursuant to a Clinical Trial and Option Agreement between CRT, the Charity and the Company dated [●●●] attached at Appendix 2 (the “**CTOA**”) the Charity has conducted the Clinical Trial (as defined below) and assigned the results of such Clinical Trial and all intellectual property therein to CRT.
- (C) CRT has agreed to grant the Company a licence under the Licensed Intellectual Property (as defined below) upon the terms and conditions set out in this Agreement.

**OPERATIVE PROVISIONS**

**1. INTERPRETATION**

1.1 In this Agreement except where the context requires otherwise, the following words and expressions shall have the following meanings:

“**Accountancy Opinion**” means the opinion of an independent United Kingdom chartered accountant appointed by agreement between the Parties or in default of such agreement within twenty one (21) days of either Party seeking in writing to the other to appoint such accountant, at the request of either Party, by the President for the time being of the Institute of Chartered Accountants in England and Wales, referred to in Clauses 1, 6.3 and 24.1.

“**Affiliate**” has the same meaning as that ascribed to that phrase in the CTOA.

“**Affordable Price**” means in relation to a Licensed Product: (i) a determination by the UK Pricing Authority that such Licensed Product should be used within the NHS; and/or (ii) approval by the UK Pricing Authority of the price proposed by the Company or its Sub-Licensee in relation to sales of that Licensed Product in the United Kingdom (or one or more constituent countries thereof).

<b>“Agreement”</b>	means this agreement and each of the Appendices as amended from time to time in accordance with Clause 21.
<b>“BLA”</b>	means, in relation to any Licensed Product, a biologics licence application, supplementary biologics licence application or any of their equivalents filed with the United States Food and Drugs Administration (FDA) or any successor to it, a marketing authorisation application or its equivalent filed with the European Medicines Agency (EMA) or any successor to it, or a marketing authorisation application or a product licence application or equivalent filed with the relevant Regulatory Authority in any one or more countries or regions within the Territory.
<b>“Clinical Trial”</b>	has the same meaning as that ascribed to that phrase in the CTOA.
<b>“Clinical Trial Results”</b>	has the same meaning as that ascribed to that phrase in the CTOA.
<b>“Commencement”</b>	means the first dosing of a human subject in a Phase I Clinical Trial, Phase II Clinical Trial or Phase III Clinical Trial (as context requires).
<b>“Company Combination Patent Rights”</b>	has the same meaning as that ascribed to that phrase in the CTOA.
<b>“Company Foreground Patent Rights”</b>	Means those of the Company Patent Rights with applications solely or primarily related to the Product and Related Products.
<b>“Company Intellectual Property”</b>	has the same meaning as that ascribed to that phrase in the CTOA.
<b>“Company Patent Rights”</b>	has the same meaning as that ascribed to that phrase in the CTOA.
<b>“Competing Programme”</b>	means a research and development programme, other than one conducted by the Charity or CRT or any of their Affiliates under the CTOA, under which human subjects in a clinical trial have or are to be administered a cell based therapy that incorporates the hTERT Antigen .



<b>“Confidential Information”</b>	means all information relating to the manufacturing methods, product specifications, customers, suppliers, business partners, clients, finances, operating budgets and forecasts, business plans and products, and the Development Plan, as revised or amended from time to time (in each case actual or prospective) of a Party which is not in the public domain and which is acquired by the other Party pursuant to this Agreement.
<b>“Contributors”</b>	has the same meaning as that ascribed to that phrase in the CTOA.
<b>“Control”</b>	means the possession (directly or indirectly) of fifty per cent or more of the voting stock or other equity interest of a subject entity with the power to vote, or the power in fact to control the management decisions of such entity through the ownership of securities or by contract or otherwise and <b>“Controls”</b> and <b>“Controlled by”</b> shall be construed accordingly.
<b>“Currency”</b>	means pounds sterling or such other currency as CRT may reasonably specify from time to time.
<b>“Data Exclusivity Period”</b>	means any period of clinical trial data or other regulatory exclusivity, together with any such periods under national implementations in the European Union of Article 10.1 of Directive 2001/EC/83 and all equivalents elsewhere in the Territory.
<b>“Data Listings”</b>	has the same meaning as that ascribed to that phrase in the CTOA.
<b>“Development Plan”</b>	means the development plan at Appendix 1 (as the same shall be updated in accordance with Clause 3.1) which describes: (i) the steps to be taken to develop Licensed Products (including at least one Primary Licensed Product) within the Field and the Territory; (ii) the relevant timescales within which such steps will be taken; and (iii) the estimated costs associated with each step.
<b>“Effective Date”</b>	means the date this Agreement is made.
<b>“Exclusive Results”</b>	has the same meaning as that ascribed to that phrase in the CTOA.
<b>“Expert Opinion”</b>	means the opinion of an independent expert appointed by agreement between the Parties or in default of such agreement within twenty one (21) days of either Party seeking in writing to the other to appoint such expert, by the President for the time being of the Association of the British Pharmaceutical Industry referred to in Clauses 12.3 and 24.1.

<b>“Field”</b>	means the use of the Product and/or any Related Product(s) in immunotherapy applications using ***, for the treatment, prophylaxis, prevention and/or cure of human disease and conditions.
<b>“Final Report”</b>	has the same meaning as that ascribed to that phrase in the CTOA.
<b>“First Commercial Sale”</b>	means, with respect to a Licensed Product, the first transfer or disposition for value of such Licensed Product by or on behalf of the Company or a Sub-Licensee or an Affiliate of either of them, after all relevant Regulatory Authorisations for the transfer or disposition of such Licensed Product have been obtained in respect of the relevant region or country.
<b>“FTO Royalties”</b>	means, on a Licensed Product by Licensed Product basis, any royalties on the sale of a Licensed Product payable by the Company under a license from a third party (after the application of any royalty stacking provisions contained therein) to the extent that: (i) but for such license the manufacture, sale, use or distribution of such Licensed Product would infringe the Intellectual Property Rights of such third party licensor, and (ii) such royalty payable is reasonably attributable to the grant of rights used in respect of a Licensed Product and not to unrelated rights also granted pursuant to the same agreement and/or by the same third party licensor.
<b>“hTERT Antigen”</b>	has the same meaning as that ascribed to that phrase in the CTOA
<b>“Indication”</b>	means a disease classification block as defined within the ‘International Statistical Classification of Diseases and Related Health Problems’ as published from time to time by the World Health Organization (e.g. “C50 Malignant neoplasm of Breast”, “C92 Myeloid leukaemia”, “B20 Human immunodeficiency virus [HIV] disease resulting in infectious and parasitic diseases”, “M34 Systemic sclerosis”).
<b>“Investigational Medicinal Product” or “IMP”</b>	has the same meaning as that ascribed to that phrase in the CTOA.
<b>“Intellectual Property Rights”</b>	has the same meaning as that ascribed to that phrase in the CTOA.

<b>“Know-How”</b>	has the same meaning as that ascribed to that phrase in the CTOA.
<b>“Licensed Intellectual Property”</b>	means the Clinical Trial Results and all Intellectual Property Rights therein.
<b>“Licensed Product”</b>	means any Primary Licensed Product and any Related Licensed Product
<b>“Major Markets”</b>	means ***.
<b>“Milestone Event”</b>	has the meaning specified in Clause 4.2.
<b>“Milestone Payments”</b>	has the meaning specified in Clause 4.2.
<b>“Net Sales Value”</b>	means, in relation to Licensed Product:  the gross amount invoiced by the Company or Sub-Licensee or Affiliate of the Company or a Sub-licensee less any value added tax or other sales tax, transport charges (including transport insurance) and costs of packaging to the extent that any of those items are included as separate items in the amount so invoiced, and after deducting any allowances for lost or damaged items or permitted returns, and discounts allowed and rebates given in the normal course of trade, and in the event of more than one such sale, the first such sale;
<b>“New Company IP”</b>	means any Intellectual Property Rights developed by or on behalf of the Company on or after the Effective Date that directly relate to a Licensed Product and its use.
<b>“Non-Exclusive Results”</b>	has the same meaning as that ascribed to that phrase in the CTOA.
<b>“Oncology Indication”</b>	means an Indication in the range C00 – D48 (e.g. “C50 Malignant neoplasm of Breast”, “C92 Myeloid leukaemia”).
<b>“Party”</b>	means either party to this Agreement and <b>“Parties”</b> means both of them.
<b>“Patent Rights”</b>	has the same meaning as ascribed to that phrase in the CTOA.
<b>“Phase II Clinical Trial”</b>	means a clinical trial of a Licensed Product (or in the adaptation of an existing clinical trial) in any country that would satisfy the requirements of 21 CFR §312.21(b) and is intended to establish dose response and/or preliminary data on the efficacy of Licensed Product and/or route of administration of the Licensed Product.

<b>“Phase III Clinical Trial”</b>	means a clinical trial of a Licensed Product (or the adaptation of an existing clinical trial) to be a larger scale (than Phase I or Phase II), usually multi-centered trial in any country that would satisfy the requirements of 21 CFR §312.21(c) and is intended to establish the efficacy and safety of the Licensed Product or any other human clinical trial of the Licensed Product intended as a pivotal trial for regulatory approval purposes whether or not such trial is a traditional Phase III trial.
<b>“Phase III Clinical Trial Completion”</b>	means the date of the last treatment visit of the last human subject under the relevant Phase III Clinical Trial.
<b>“pound” and “£”</b>	means British pound sterling or if England changes its currency during the Term, then a sum equivalent in the new currency based on the spot exchange rate at the date of adoption of the new currency.
<b>“Price Approval”</b>	means, in those countries in the Territory where Regulatory Authorities may approve or determine pricing and/or pricing reimbursement for pharmaceutical products, such approval or determination.
<b>“Primary Licensed Product”</b>	means any product that contains the Product whether or not as the sole active ingredient.
<b>“Product”</b>	has the same meaning as ascribed to that phrase in the CTOA.
<b>“Product Manufacturing Process”</b>	has the same meaning as ascribed to that phrase in the CTOA.
<b>“Quarter”</b>	means any of the three-monthly periods commencing on the first day of any of the months of January, April, July, and October in any year and <b>“Quarterly”</b> has a corresponding meaning.
<b>“Regulatory Authorisations”</b>	means all marketing authorisations, approvals, clearances and authorisations that may be required by a Regulatory Authority in any country or region within the Territory prior to Phase II Clinical Trial Commencement and/or Phase III Clinical Trial Commencement and/or commercial sale of the Licensed Product, including any necessary variations thereto, but excluding always any Price Approvals.
<b>“Regulatory Authority”</b>	means any local or national agency, court, authority, department, inspectorate, minister, ministry official or public or statutory person (whether autonomous or not) of, or of any government of, any country having jurisdiction over this Agreement or either of the Parties or over the development or marketing of medicinal products including, the European Medicines Agency and the European Court of Justice.

**“Related Licensed Product”**

means any product that is not a Primary Licensed Product and:

- (a) which contains a Related Product, whether or not as the sole active ingredient; and/or
- (b) whose application for a Regulatory Authorisation from a Regulatory Authority in any jurisdiction included the Clinical Trial Results and/or the Final Report and/or the Data Listings or any part of any of them

**Related Product**

has the same meaning as that ascribed to that phrase in the CTOA.

**“Signature Fee”**

means the sum of \*\*\*.

**“Sub-Licence Revenue”**

means any monies or non-monetary consideration (including securities) receivable from time to time by the Company or an Affiliate in respect of: (i) any sub-licence granted by the Company or an Affiliate under this Agreement; (ii) any licence granted by the Company or an Affiliate (whether under the Company Intellectual Property or otherwise) to sell Licensed Products anywhere in the Territory; and/or (iii) the grant of the right to acquire such a sub-licence or licence, including, in each case, option fees, licence issue fees or other up-front payments, annual licence fees, or other lump sum payments which are attributable to the grant of the rights in question, but excluding: (i) any milestone payments due on the achievement of specific development or sales milestones that are additional to those listed in Clause 4.2; (ii) royalties as referred to in Clause 4.5; (iii) sales to distributors or wholesalers for resale, and sales made by sales agents, where in any such case the sales have already been or will be accounted for to CRT in determining Net Sales Value; and (iv) any money or non-monetary consideration (including securities or licences of patents, know-how, or other intellectual property) received by the Company from an Affiliate, provided that such money or non-monetary consideration shall not reduce the Net Sales Value of any Licensed Product sold by the Company or any Affiliate. In the case of non-monetary Sub-Licence Revenue, the value shall be assessed at the date of receipt of the same by the Company or, at the option of CRT, at the date the non-monetary consideration is realised as monetary and in the absence of agreement by the Parties, the value shall be determined by Accountancy Opinion.

<b>“Sub-Licensee”</b>	means any person who is granted: (i) a sub-licence in accordance with Clause 2.3 in respect of the rights granted under this Agreement (and any further tiers of sub-licence there under); and/or (ii) a licence by the Company (whether under the Company Intellectual Property or otherwise) to sell Licensed Products anywhere in the Territory, but shall not mean distributors, wholesalers, and sales agents.
<b>“Term”</b>	means the term of this Agreement as determined under Clause 12.1.
<b>“Territory”</b>	means worldwide.
<b>“Tobacco Party”</b>	means: (i) any entity who develops, sells or manufactures tobacco products; and/ or (ii) any entity which makes the majority of its profits from the importation, marketing, sale or disposal of tobacco products. Furthermore, Tobacco Party shall include any entity that is an Affiliate of any entity referred to in (i) or (ii).
<b>“UK Pricing Authority”</b>	means any supra-national, national or regional government department, authority, agency or entity (including a non-departmental public body or similar entity) with responsibility for evaluating the cost effectiveness of medicinal products in the United Kingdom (or one or more constituent countries thereof) or otherwise determining whether the NHS (or constituent parts thereof) should purchase medicinal products.
<b>“Year”</b>	means a calendar year.

1.2 In this Agreement:

- 1.1.1 unless the context requires otherwise, all references to a particular Clause, paragraph or Appendix shall be references to that clause, paragraph or appendix, in or to this Agreement;
- 1.1.2 the headings are inserted for convenience only and shall be ignored in construing this Agreement;
- 1.1.3 unless the contrary intention appears, words importing the masculine gender shall include the feminine and vice versa and words in the singular include the plural and vice versa;
- 1.1.4 unless the contrary intention appears, words denoting persons shall include any individual, partnership, company, corporation, joint venture, trust, association, organisation or other entity, in each case whether or not having separate legal personality; and
- 1.1.5 references to the words 'include' or 'including' shall be construed without limitation to the generality of the preceding words.

**2. GRANT OF LICENCE**

2.1 Subject to the provisions of this Agreement and the surviving provisions of the CTOA, CRT hereby grants to the Company:

2.1.1 \*\*\*; and

2.1.2 \*\*\*,

in each case to research, develop, make, have made, import, use and sell Licensed Products in the Field in the Territory and to apply for Regulatory Authorisation for such Licensed Products in any jurisdiction.

2.2 CRT hereby reserves and excepts from the \*\*\* under Clause 2.1.1 the worldwide, perpetual and irrevocable right for the Contributors and the Charity (including use by scientists funded and/or employed by the Charity) to:

2.2.1 use the Licensed Intellectual Property for the purpose of non-commercial scientific research carried out by or for or under their respective direction in accordance with their respective charitable and/or academic status, whether alone or in collaboration with a third party or third parties and whether sponsored or funded, in whole or in part, by any third party including any commercial entity; and

2.2.2 make publications in relation to the Licensed Intellectual Property and any results of research using the same in accordance with generally accepted academic practice.

2.3 The Company shall be entitled to grant sub-licences in respect of the rights granted under this Agreement, provided that:-

2.3.1 any sub-licence granted by the Company shall be expressed to terminate automatically on the termination of this Agreement for any reason;

2.3.2 the Company shall ensure that there are included in the terms of any sub-licence like obligations and undertakings on the part of the Sub-Licensee for the benefit of the Charity as are contained in this Agreement (including Clause 9 (indemnity) and Clause 14 (confidentiality) and, if further tiers of sub-licensing is allowed, this Clause 2.3) and shall further ensure that all Sub-Licensees duly comply with the same;

- 2.3.3 no sub-licence shall be granted to a Tobacco Party;
- 2.3.4 the sub-licence (other than a sublicense with an Affiliate) shall be entered into on an arms-length basis reflecting the market value of the rights granted; and
- 2.3.5 the Company shall provide CRT with a copy of such sub-licence within thirty (30) days of entering into it.

2.4 Any breach of Clause 2.3 shall be deemed to be a material breach.

2.5 The grant of any sub-licence shall be without prejudice to the Company's obligations under this Agreement. Any act or omission of any such Sub-Licensee which, if it were the act or omission of the Company would be a breach of any of the provisions of this Agreement, will be deemed to be a breach of this Agreement by the Company who will be liable to CRT accordingly.

2.6 CRT will provide the Company with any Long Term Survival Data as and when the Charity has completed collection of the same.

2.7 Subject to the restrictions, pre-approvals and limitations as outlined in Section 6.1 and Schedule 7A of the CTOA, the Company hereby grants to the Charity a non-exclusive, royalty free licence under the Company Intellectual Property (including the right to use Company Materials) for the Charity and scientists funded by the Charity to adapt and use the Product Manufacturing Process and make and have made Products and Related Products for non-commercial research purposes, provided that such research will not include clinical research without the prior written consent of the Company which shall be in Company's sole control, on a case-by-case basis, and subject to establishment of a clinical trial agreement providing Company with appropriate safeguards and indemnities for such trial.

2.8

If, within one year of the Effective Date of this Agreement, Company wishes to publish or publicly disclose the Clinical Trial Results, it will first provide a copy of such intended disclosure to the Charity for its review at least thirty (30) days prior to the intended date of submission for publication or public disclosure. Charity will complete its review of such intended disclosure within thirty (30) days of receipt. If, during its thirty (30) day review period, Charity reasonably determines that information contained within such intended disclosure will materially impact the ability of Charity, CRT, or a Contributor to publish results of, or to protect any Intellectual Property Rights arising from, the Clinical Trial, Company will, at its discretion, either remove such information prior to disclosure or delay disclosure for up to ninety (90) days to allow for protection or publication. If Charity does not respond within thirty (30) days of receipt, it shall be deemed to have consented to the intended disclosure. The foregoing provisions of this Clause 2.8 shall not apply to disclosure of Clinical Trial Results, or any portion thereof, by the Company to the extent required for (a) satisfying mandatory reporting and disclosure obligations under United States and other securities laws; or (b) to existing licensors or sublicensees of the Company in order to comply with reporting obligations in existence as at the date of this agreement under Third Party Licences, provided that in the case of (b) the disclosure shall be limited to only information as may be reasonably required by the Third Party Licence and subject to the third party that is receiving the information being bound by confidentiality obligations that are no less restrictive than those that the Company is bound by under this Agreement in respect of confidential information disclosed to it by the Charity .



### 3. PERFORMANCE

- 3.1 The Company shall provide an updated Development Plan to CRT on at least a six-monthly basis throughout the Term.
- 3.2 The Company shall use its commercially reasonable endeavours to procure the achievement of Phase II Clinical Trial Commencement within \*\*\* of the Effective Date.
- 3.3 The Company shall use its commercially reasonable endeavours at all times during the Term to:
  - 3.3.1 comply with the most up-to-date version of the Development Plan;
  - 3.3.2 develop and pursue Regulatory Authorisation for a Licensed Product for use in \*\*\* in each of \*\*\*;
  - 3.3.3 introduce a Licensed Product for use in \*\*\* into each of \*\*\* as soon as reasonably and commercially practical following receipt of the corresponding Regulatory Authorisations and subsequently use commercially reasonable efforts to market the Licensed Product and pursue maximum market penetration in the Major Markets;
  - 3.3.4 launch each Licensed Product in the United Kingdom as soon as practicable and in any event no later than \*\*\* after the date the first Regulatory Authorisation is granted by the European Medicines Agency; and
  - 3.3.5 make Licensed Products that are launched in the United Kingdom available at an Affordable Price if required by a Regulatory Authority having jurisdiction over pricing in the United Kingdom.
- 3.4 Subject to Clause 3.5.2, at least once every six (6) months the Company shall provide CRT with a report as to the progress of the development of each Licensed Product, the progress of any applications for Regulatory Authorisation and Price Approval, and the progress of and plans for the marketing and sale of the Licensed Product and its compliance with the Development Plan, in such form and detail as CRT may reasonably require.
- 3.5 If, prior to the First Commercial Sale in the United Kingdom and two (2) other Major Markets, the Company undergoes a change of Control, or acquires or begins (whether independently or with a third party) a Competing Programme:
  - 3.5.1 it shall notify CRT in writing within thirty (30) days after the change of Control occurring, or its commencement or acquisition of the Competing Programme; and
  - 3.5.2 for the \*\*\* period following the change of Control, or commencement or acquisition of the Competing Programme, it shall provide CRT with a report described in Clause 3.4 at least once every three (3) months.
- 3.6 The Company shall give CRT prompt notice upon the occurrence of any Milestone Event.
- 3.7 The Company shall submit to CRT:
  - 3.7.1 a copy of its detailed operating budget (including a quarterly cash flow and expenditure forecast) for the Product in respect of each Financial Year as adopted by the Company's board (the "**Annual Budget**"), at least thirty (30) days prior to the commencement of the Financial Year to which the Annual Budget relates;

3.7.2 quarterly management accounts of the Company (to include, inter alia, a (consolidated) profit and loss account, balance sheet and cash flow statement and shall indicate where such management accounts differ to any material extent from the Annual Budget for such period), within five (5) business days after the date by which such financial statements are filed with the United States Securities and Exchange Commission for such period, but in no event later than fifty (50) days after quarter close for the first three financial quarters and ninety five (95) days after close of the financial year. Such quarterly management accounts shall be prepared in accordance with United States generally accepted accounting principles consistently applied.

3.8 Any breach of Clause 3 shall be deemed to be a material breach of this Agreement.

3.9 The Company may perform its obligations under Clause 3 in whole or in part through the efforts of its Affiliates, contractors, subcontractors, licensees and sublicensees.

#### 4. CONSIDERATION

4.1 The Company shall pay the Signature Fee to CRT within thirty (30) days after the Effective Date.

4.2 The Company shall pay the following payments (“Milestone Payments”) to CRT after the first occurrence of each of the following events (“Milestone Events”) in accordance with this Clause 4.2 and Clause 5.2:

4.2.1 Development Milestone Events in relation to \*\*\*:

(a) \*\*\*;

(b) \*\*\*;

4.2.2 Development Milestone Events in relation to \*\*\*:

(a) \*\*\*;

(b) \*\*\*;

4.2.3 Development Milestone Events in relation to \*\*\*:

(a) \*\*\*;

(b) \*\*\*;

4.2.4 Development Milestone Events in relation to \*\*\*:

(a) \*\*\*;

(b) \*\*\*;

4.2.5 Sales Milestone Events in relation to \*\*\*

(a) \*\*\*;

(b) \*\*\*; and

(c) \*\*\*.

4.2.6 Sales Milestone Events in relation to \*\*\*

(a) \*\*\*;

(b) \*\*\*; and

(c) \*\*\*.

Upon the occurrence of each \*\*\* in respect of a Licensed Product \*\*\*, if not already triggered, the corresponding \*\*\* \*\*\* for that same Licensed Product shall be deemed to have occurred. For the avoidance of doubt a Milestone Event may be triggered by the actions of the Company, a Sub-Licensee or any third party acting on behalf of the Company or any Sub-Licensee.

4.3 Subject to Clause 4.4, the Company shall pay to CRT:

4.3.1 \*\*\*;

4.3.2 \*\*\*;

4.3.3 \*\*\*; and

4.3.4 \*\*\*.

4.4 In the event that any Milestone Event is triggered by any Sub-Licensee, the Company shall pay to CRT the greater of: (i) \*\*\*; and (ii) \*\*\*.

4.5 Subject to Clauses 4.6 and 4.7, the Company will pay to CRT royalties on Licensed Products at the following royalty rates based on the Net Sales Value of Licensed Products in the applicable Year:

(a) \*\*\*; and

(b) \*\*\*; and

(c) \*\*\*; and

(d) \*\*\*.

4.6 The Company shall pay royalties to CRT in accordance with Clause 4.5 on a Licensed Product by Licensed Product, and country by country basis until the later of:

4.6.1 \*\*\*; and

4.6.2 \*\*\*.

4.6.3 \*\*\*.

4.7 In the event that the Company incurs FTO Royalties with respect to a Licensed Product in a country in a Quarter the following provisions shall take effect with respect to that Licensed Product in that country in that Quarter:

4.7.1 \*\*\*;

4.7.2 \*\*\*;

4.7.3 \*\*\*.

## 5. PAYMENT AND STATEMENT

5.1 All payments due to CRT under this Agreement shall be made in the Currency in cleared funds to the following bank account:

\*\*\*

or such other account as CRT may notify to the Company from time to time.

5.2 The Company shall pay to CRT:

5.2.1 the Signature Fee on the date specified in Clause 4.1;

5.2.2 each of the Milestone Payments within thirty (30) days after the relevant Milestone Event occurring;

- 5.2.3 CRT's share of Sub-Licence Revenue due under Clause 4.3 Quarterly within thirty (30) days after the end of the Quarter in which the consideration upon which Sub-Licence Revenue is based is received by the Company from Sub-Licensee ; and
  - 5.2.4 the royalties due pursuant to Clause 4.5 Quarterly within thirty (30) days after the end of each Quarter in which the relevant Net Sales Value is invoiced by the Company or a Sub-Licensee.
- 5.3 Where Licensed Products are sold or Sub-Licence Revenue is received by the Company (or a Sub-Licensee) in a currency other than the Currency, the rate of exchange to be used for converting such other currency into the Currency shall be the relevant mid-spot rate for the currency quoted by the Financial Times on the last day of the Quarter to which they relate.
- 5.4 All costs of transmission and currency conversion shall be borne by the Company.
- 5.5 All payments to CRT under this Agreement are expressed to be exclusive of value added tax howsoever arising, and the Company shall pay to CRT in addition to those payments or, if earlier, on receipt of a tax invoice or invoices from CRT, all value added tax for which CRT is liable to account in relation to any supply made or deemed to be made for value added tax purposes pursuant to this Agreement.
- 5.6 All sums payable under this Agreement shall be paid without deduction or deferment in respect of any claims whatsoever and of any taxes except any tax which the Company is required by law to deduct or withhold. If the Company is required by law to make any such tax deduction or withholding, the Company shall pay to CRT such amount as shall, after deduction, amount to the sum referred to in this Agreement give reasonable assistance to CRT to claim exemption from or (if that is not possible) a credit for the deduction or withholding under any applicable double taxation or similar agreement from time to time in force, and shall promptly give CRT proper evidence as to the deduction or withholding and payment over of the tax deducted or withheld.
- 5.7 Where CRT does not receive payment of any sums due to it by the due date, interest shall accrue both before and after any judgment on the sum due and owing to CRT at the rate equivalent to an annual rate of four percent (4%) over the then current base rate of the Bank of England, calculated on a daily basis, until the full amount is paid to CRT, without prejudice to CRT's right to receive payment on the due date.
- 5.8 Within thirty (30) days after the end of each Quarter, the Company shall send to CRT a written statement detailing in respect of that Quarter (including a nil report if appropriate):
- 5.8.1 any Milestone Payments which became due to CRT;
  - 5.8.2 for each sub-licence, details of each item of Sub-Licence Revenue received by the Company during that Quarter and the Sub-Licence Revenue payable to CRT thereon;
  - 5.8.3 the quantity of each type of Licensed Product sold or otherwise disposed of by the Company or any Sub-Licensees in each country in the Territory;
  - 5.8.4 the Net Sales Value in respect of each such type of Licensed Product in each country of the Territory;
  - 5.8.5 the aggregate Net Sales Value in respect of that Quarter for Licensed Product;
  - 5.8.6 the type and value of deductions made in the calculation of Net Sales Value by type of Licensed Product and country;

- 5.8.7 any currency conversions, showing the rates used;
- 5.8.8 any further information necessary for the calculation of Sub-Licence Revenue and Net Sales Value of Licensed Products and/or the royalties due to CRT; and
- 5.8.9 the amount of the royalties due to CRT in respect of that Quarter.

## **6. ACCOUNTS**

- 6.1 The Company shall:
  - 6.1.1 keep and notwithstanding termination of this Agreement, maintain and shall procure that each Sub-Licensee keeps and maintains, for at least six (6) years, true and accurate accounts and records (including any underlying documents supporting such accounts and records) in sufficient detail to enable the amount of all sums payable under this Agreement to be determined; and
  - 6.1.2 during the Term and thereafter until the said period of three (3) years relevant to the accounts and records has expired, at the reasonable request of CRT and (subject to Clause 6.2) at the expense of CRT from time to time, permit [or procure permission for] a qualified accountant nominated by CRT to inspect and audit those accounts and records and, to the extent that they relate to the calculation of those sums, to take copies of them. Subject to receiving not less than thirty (30) days written notice, the Company shall at the request of CRT assemble in one location each that is respectively convenient to the Company and Sub-Licensee(s) all such relevant accounts and records of the Company and Sub-Licensee(s).
- 6.2 If, following any inspection pursuant to Clause 6.1.2, CRT's nominated accountant certifies to CRT that the payments in respect of any Quarter or Year fall short of the sums which were properly payable in respect of that Quarter or Year under this Agreement, CRT shall send a copy of the certificate to the Company and the Company shall (subject to Clause 6.3) within seven (7) days of the date of receipt of the certificate pay the shortfall to CRT and, if the shortfall exceeds two per cent (2%) of the sum properly payable, the Company shall also reimburse to CRT the reasonable costs and expenses of CRT in making the inspection.
- 6.3 If within seven (7) days of the date of receipt by the Company any certificate produced pursuant to Clause 6.2 the Company notifies CRT in writing that it disputes the certificate, the dispute shall be referred for resolution by Accountancy Opinion in accordance with Clause 24.1.

## **7. INTELLECTUAL PROPERTY PROTECTION, PROCEEDINGS AND COSTS**

- 7.1 The Company shall throughout the Term continue to prosecute and maintain the Company Patent Rights at its own cost and shall use commercially reasonable endeavours to maximise the scope of such Company Patent Rights, or where prosecution and maintenance of such Patent Rights is controlled by a licensor of the Company, the Company will use commercially reasonable efforts to procure that the licensor continues to prosecute and maintain such Patent Rights where the licensor has such obligation under its Third Party Licence agreement; provided that the Company shall not be obligated to commence litigation for such purpose. Notwithstanding the foregoing, if the Company elects not to prosecute or maintain any part of the Company Patent Rights it controls in any part of the Territory, the Company shall notify CRT in writing at least ninety (90) days prior to the expiration of any applicable time bars. After receipt of such notice, CRT may elect, before the expiry of any such time bars, by written notice to the Company, to take an assignment of the relevant Company Patent Rights such that CRT may continue to prosecute and/or maintain the Company Patent Rights at CRT's sole discretion and expense.

- 7.2 If the Company becomes aware that a Company Patent Right being prosecuted or maintained by one of its licensors is due to expire or the licensor has elected not to prosecute or maintain any such Company Patent Rights the Company will promptly notify CRT in writing. In the case of a licensor electing not to prosecute or maintain any Company Patent Rights (as opposed to expiration), where reasonably possible, the Company will take assignment of such Patent Rights or request the right for CRT to take assignment of such Patent Rights.

## **8. WARRANTY**

- 8.1 Each Party warrants that it has the legal capacity to enter into this Agreement.
- 8.2 Each Party acknowledges that, in entering into this Agreement, it does not do so in reliance on any warranty or other provision except as expressly provided in this Agreement, and any conditions, warranties or other terms implied by statute or common law are excluded to the fullest extent permitted by law.
- 8.3 Without limiting the scope of Clause 8.2, CRT does not give any warranty, representation or undertaking:
- 8.3.1 as to the efficacy or usefulness or accuracy of the Clinical Trial Results; or
  - 8.3.2 that the exercise of rights granted under this Agreement will not infringe the intellectual property or other rights of any other person.

## **9. INDEMNITY**

- 9.1 The Company shall indemnify and hold harmless CRT, the Contributors and the Charity and their respective officers, employees and agents (the "Indemnified Parties") from and against \*\*\* arising from or in connection with the exercise of the rights granted in Clause 2 by the Company or any Affiliate of the Company or a Sub-Licensee or any affiliate of a Sub-Licensee in relation to the Licensed Product. This Clause 9 shall not limit the rights of the Company and the liabilities of CRT under Clause 9.1 of the CTOA.
- 9.2 Promptly after receipt by CRT of any claim or alleged claim or notice of the commencement of any action, administrative or legal proceeding, or investigation to which the indemnity provided for in this Clause 9 may apply, CRT shall give written notice to the Company of such fact and specifying that the Company shall have the option to assume the defence thereof by election in writing within seven (7) days of receipt of such notice. If the Company fails to make such election, the Indemnified Party may assume such defence and the Company will be liable for the legal and other expenses consequently incurred in connection with such defence. The Parties will co-operate in good faith in the conduct of any defence, provide such reasonable assistance as may be required to enable any claim properly to be defended and the Party with conduct of the action shall provide promptly to the other Party copies of all correspondence and documents and notice in writing of the substance of all oral communications relating to such action.
- 9.3 Should the Company assume conduct of the defence:
- 9.3.1 the Indemnified Party may retain separate legal advisers, at its sole cost and expense, save that if the Company denies the applicability of the indemnity or reserves its position in relation to the same, the indemnity in this Clause 9 shall extend to the Indemnified Party's costs and expenses so incurred if it is subsequently resolved between the Parties or determined by a court of competent jurisdiction (after exhaustion or expiration of all rights of appeal) that the indemnity under this Clause 9 was available to the Indemnified Party in the terms claimed by the Indemnified Party; and

- 9.3.2 the Company will not, except with the written consent of the Indemnified Party consent to the entry of any judgment or enter into any settlement provided always, that if the Indemnified Party unreasonably refuses to consent to such entry of judgment or settlement and the matter proceeds to trial at which a greater amount is ordered by the Court then the amount which the Indemnified Party shall be entitled to recover from the Company pursuant to this Clause 9 shall be limited to the amount for which the action would otherwise have been settled or compromised and the Indemnified Party shall assume all costs of defending the claim or proceeding from the date of the Indemnified Party's refusal; and
- 9.3.3 CRT shall not admit liability in respect of, or compromise or settle any such action without the prior written consent of the Company, such consent not to be unreasonably withheld, conditioned or delayed; and
- 9.3.4 the Company shall not be responsible for or bound by any settlement made by CRT in breach of Clause 9.3.3.

## **10. INSURANCE**

- 10.1 The Company shall maintain, at its own cost, comprehensive product liability insurance and general commercial liability insurance. Within thirty (30) days of the Effective Date and of the beginning of each policy period, the Company shall provide CRT with a certificate evidencing the coverage required hereby, and the amount thereof. Such insurance shall be with a reputable insurance company and shall be maintained for not less than six (6) years following the expiration/termination of this Agreement for any reason or if such coverage is of the 'claims made' type, for ten (10) years following the expiration or termination of this Agreement for any reason.

## **11. LIMITATION OF LIABILITY**

- 11.1 Neither Party nor the Charity, nor their respective officers, employees and agents shall have liability whether under statute or in tort (including negligence), contract or otherwise to the other Party in respect of any consequential, indirect or pure economic loss nor in any event for loss of goodwill, opportunity, profit or contract.
- 11.2 Nothing in this Agreement shall be construed as excluding or limiting the liability of either Party or the Charity or any of their respective officers, employees and agents to the other Party for death or personal injury of any person resulting from the negligence of such persons.

## **12. TERM AND TERMINATION**

- 12.1 This Agreement will become effective on the Effective Date and, subject to the provisions of this Clause 12, will remain effective in each country of the Territory until expiry of the obligation of the Company under Clauses 4.5 and 4.6 to pay royalties in relation to that country pursuant to this Agreement.
- 12.2 Without prejudice to any other rights of the Parties this Agreement may be terminated by notice in writing:
  - 12.2.1 by either Party forthwith if the other Party shall be in material breach of any of its obligations under this Agreement and in the case of a remediable breach fails to remedy the breach within sixty (60) days of written notice containing full particulars of the breach and requiring it to be remedied;

12.2.2 by CRT if a voluntary arrangement is proposed or approved or an administration order is made, or a receiver or administrative receiver is appointed of any of the Company's assets or undertakings or a winding-up resolution or petition is passed (otherwise than for the purpose of solvent reconstruction or amalgamation) or if any circumstances arise which entitle the Court or a creditor to appoint a receiver, administrative receiver or administrator or make a winding-up order or similar or equivalent action is taken against or by the Company by reason of its insolvency;

12.2.3 by CRT forthwith in the event that, by way of merger, acquisition or otherwise, the Company becomes a Tobacco Party; or

12.2.4 by CRT upon forty five (45) days written notice to the Company if the Company:

- (a) discontinues the development (including prosecuting application for Regulatory Authorisation) of all Licensed Products; or
- (b) after the filing of the IND, discontinues the development (including prosecuting application for Regulatory Authorisation) of one or more Licensed Product(s) in all disease indications (in which case termination shall not apply to the whole Agreement but shall be limited to such Licensed Product(s)); or
- (c) after the filing of the IND, discontinues the development (including prosecuting application for Regulatory Authorisation) of one or more Licensed Product(s) in oncology (in which case termination shall not apply to the whole Agreement but shall be limited to such Licensed Product(s) in oncology); or
- (d) fails to use its commercially reasonable efforts to obtain Regulatory Authorisation in a timely manner in all of the Major Markets, taking into account the unique aspects of the development and regulatory path for the Licensed Product, indication and market (in which case termination shall be effective only in respect of that Major Market); or
- (e) having obtained Regulatory Authorisation for a Licensed Product in a Major Market, ceases to actively market and sell such Licensed Product in such Major Market (in which case termination shall be effective only in respect of that Licensed Product in that Major Market); or
- (f) ceases to carry on business in the Field; or
- (g) without reasonable cause fails to commence sale of a Licensed Product in a Major Market within two (2) years of obtaining Regulatory Authorization to market the Licensed Product in such market; or
- (h) without CRT's prior written consent, abandons or fails to prosecute any of the Company Patent Rights in any Major Market.

12.3 In the event of disagreement between the Parties as to whether entitlement to terminate has arisen under Clause 12.2.1 or 12.2.4, the Parties at their joint cost and expense shall obtain an Expert Opinion which shall be final as to whether it has arisen.



- 12.4 For the purpose of Clause 12.2.4, the efforts and actions of the Company shall be deemed to include the efforts and actions of its Affiliates, contractors, subcontractors, licensees and sublicensees.

### 13. EFFECTS OF TERMINATION

- 13.1 Subject to Clause 13.2, upon the termination of this Agreement for any reason:

- 13.1.1 other than termination by CRT pursuant to Clause 12.2.1, 12.2.2 or 12.2.3 subject to all the terms of this Agreement (including without limitation payment of royalties), the Company shall be entitled for a period not exceeding \*\*\* following such termination to:
- (a) manufacture any of the Licensed Products to the extent necessary to satisfy orders accepted before termination; and
  - (b) sell, use or otherwise dispose of any unsold stocks of the Licensed Products.
- 13.1.2 subject to Clause 13.1.1, the Company shall, and shall procure that all Sub-Licensees shall, cease to exploit the Licensed Intellectual Property in any way, either directly or indirectly;
- 13.1.3 subject to Clause 13.1.1, the Company shall, at the request and option of CRT, return or destroy CRT's Confidential Information;
- 13.1.4 notwithstanding any provision of this Agreement allowing the Company credit, payment of royalties and all other sums to CRT shall become due and payable to CRT immediately upon notice of termination of this Agreement;
- 13.1.5 the Company shall, within fourteen (14) days of notice of termination of this Agreement provide CRT with a final written statement detailing, in respect of the time elapsed since the last statement under Clause 5.8, the matters set out in Clause 5.8;
- 13.1.6 other than termination by the Company pursuant to Clause 12.2.1, the Company:
- (a) subject to 13.1.6(b), shall execute with CRT an exclusive, perpetual, worldwide, sub-licensable licence under the Company Intellectual Property, Company Combination Patent Rights and New Company IP to research, develop, make, have made, market, use and sell Licensed Products, on revenue share terms to be agreed;

and in the case of Company Intellectual Property licensed to the Company under a Third Party Licence, such licence shall include a grant to CRT of a sub-licence reasonably similar to those provided for by Schedule 6 (CRT Licence) of the CTOA, and provide CRT with such assistance as CRT may reasonably request in liaising with the licensors under the Third Party Licences for the purpose of obtaining direct contractual rights with such licensors should they be so required;

- (b) at CRT's request, upon completion of such licence, shall promptly transfer to CRT (or any person nominated by CRT) any and all documents and information in the Company's control or possession relating to the Company Foreground Patent Rights and CRT may assume responsibility for the prosecution, maintenance and enforcement of the same; and
- (c) at CRT's request, upon completion of such licence, shall transfer to CRT (or its nominee) any Regulatory Authorisations, Price Approvals and other permits and applications relating to Licensed Products.

- 13.2 This Clause 13.2 shall not apply in the case of termination of this Agreement under Clause 12.1. In the event that this Agreement is terminated solely in respect of particular Licensed Product and/or Indication and/or Major Market, the provisions of Clause 13.1 shall apply, but solely in respect of the relevant Licensed Product, Indication and/or Major Market.
- 13.3 The termination of this Agreement howsoever arising will be without prejudice to the rights and duties of either Party accrued prior to termination. The following Clauses will continue to be enforceable notwithstanding termination: Clauses 1 (Definitions), 6 (Accounts), 9 (Indemnity), 10 (Insurance), 11 (Limitation of Liability), 12 (Termination), 13 (Effects of Termination), 14 (Confidentiality), 19 (Severability), 24 (Dispute Resolution) and 25 (Law and Jurisdiction).

#### **14. CONFIDENTIALITY**

- 14.1 Each Party undertakes with the other that it shall keep and it shall procure that its respective directors and employees keep secret and confidential all Confidential Information belonging to or controlled by the other Party and shall not disclose the same or any part of the same to any person whatsoever other than:
- 14.1.1 in the case of the Company: (i) to Sub-Licensees subject to compliance with Clause 2.3.4, (ii) to potential development partners, sublicensees, and investors bound by terms of confidentiality at least as strict as those herein, and (iii) as necessary in communications with Regulatory Authorities in the Territory relating to the Licensed Products.
  - 14.1.2 in the case of CRT to the Charity; and
  - 14.1.3 in the case of each Party, to its directors or employees directly or indirectly concerned in the exercise of the rights granted under this Agreement.
- 14.2 The provisions of Clause 14.1 shall not apply to Confidential Information which CRT or the Company (as the case may be):
- 14.2.1 can prove to have been in its possession (other than under an obligation of confidence to the other or to a third party) at the date of receipt or which enters the public domain otherwise than through a breach of any obligation of confidentiality owed to the Party communicating such information to the other;
  - 14.2.2 can prove it has independently developed; or
  - 14.2.3 is required to disclose by law or by the order of a competent court, solely to the extent of such disclosure.
- 14.3 The provisions of this Clause 14 shall remain in force for a period of five (5) years from the expiry or termination of this Agreement

#### **15. ASSIGNMENT**

- 15.1 The Company shall not without CRT's consent assign its rights under this Agreement except in conjunction with a merger or consolidation of the Company with another business entity or the sale of all or substantially all or a substantial part of its business and related assets that includes its business in relation to the Licensed Products other than a merger or consolidation with, or a sale of assets to, a Tobacco Party and provided that Company obtains a direct covenant from the acquiring party to CRT undertaking to be bound by the terms of this Agreement.

## 16. NOTICES

- 16.1 Any notice or other document to be given under this Agreement shall be in writing and shall be deemed to have been given:
- 16.1.1 upon delivery if given in person; or
  - 16.1.2 upon confirmation of receipt if sent by facsimile (or other similar means of electronic communication such as email); or
  - 16.1.3 (if posted to an inland destination) three (3) business days after deposit into First Class post; or
  - 16.1.4 (If posted to an overseas destination) five (5) days after deposit into airmail post,
  - 16.1.5 upon delivery by air delivery service;

to a Party at the address set out below for such Party or such other address as the Party may from time to time designate by written notice to the other Party.

Address of the Company

Asterias Biotherapeutics  
230 Constitution Dr  
Menlo Park, CA 94025  
Contact: Legal/contracts  
Fax: 001 650 433 2900

Address of CRT

Angel Building  
407 St. John Street  
London EC1V 4AD  
United Kingdom  
Contact: Chief Executive Officer  
Fax: +44 (0) 20 3014 8633

## 17. WAIVER

- 17.1 No failure or delay on the part of either Party hereto to exercise any right or remedy under this Agreement shall be construed as or operate as a waiver thereof nor shall any single or partial exercise of any right or remedy under this Agreement preclude the exercise of any other right or remedy or preclude the further exercise of such right or remedy as the case may be.

## 18. FORCE MAJEURE

- 18.1 Except in relation to obligations pursuant to Clauses 4 and/or 5, neither Party shall be liable to the other Party or shall be in default of its obligations hereunder if such default is the result of war, hostilities, revolution, civil commotion, strike, epidemic, accident, fire, wind, flood or because of any act of God or other cause beyond the reasonable control of the Party affected. The Party affected by such circumstances shall promptly notify the other Party in writing when such circumstances cause a delay or failure in performance (a "Delay") and where they cease to do so. In the event of a Delay lasting for twenty six (26) weeks or more the non-affected Party shall have the right to terminate this Agreement immediately by notice in writing to the affected Party.

**19. SEVERABILITY**

- 19.1 If and to the extent that any court or tribunal of competent jurisdiction holds any of the terms, provisions or conditions or parts thereof of this Agreement, or the application hereof to any circumstances, to be invalid or to be unenforceable in a final non-appealable order, the remainder of this Agreement and the application of such term, provision or condition or part thereof to circumstances other than those as to which it is held invalid or unenforceable shall not be affected thereby, and each of the other terms, provisions and conditions of this Agreement shall be valid and enforceable to the fullest extent permissible by law.

**20. ENTIRE AGREEMENT**

- 20.1 This Agreement and the surviving clauses of the CTOA, embodies and sets forth the entire agreement and understanding of the Parties and supersedes all prior oral or written agreements, understandings or arrangements relating to the subject matter of this Agreement. Without prejudice to any liability for fraudulent misrepresentation or fraudulent misstatement neither Party shall be entitled to rely on any agreement, understanding or arrangement which is not expressly set forth in this Agreement unless otherwise agreed between the Parties and recorded in writing.

**21. AMENDMENT**

- 21.1 This Agreement shall not be amended, modified, varied or supplemented except in writing signed by duly authorised representatives of the Parties.

**22. PUBLIC ANNOUNCEMENTS**

- 22.1 The text of any press release, shareholders' report or other communication to be published or disclosed to the public in any way by or in the media concerning CRT or the Charity, the subject matter of this Agreement or concerning this Agreement itself, other than as required by law or by any Regulatory Authority or the rules of any securities exchange, shall be submitted to CRT at least seven (7) days in advance of publication for approval, such approval not to be unreasonably withheld; provided, that disclosure that repeats or restates prior public disclosure permitted by this Agreement need not be submitted to the Charity or CRT for approval.

**23. FURTHER ASSURANCE**

- 23.1 The Parties hereby undertake to do all such other acts and things, and execute and provide all such documents at the requesting Party's cost as may be necessary or desirable to give effect to the purposes of this Agreement.

**24. DISPUTE RESOLUTION**

- 24.1 Insofar as this Agreement provides that a matter shall be resolved by Accountancy Opinion or Expert Opinion the opinion of such expert (who shall act as an expert and not as an arbitrator) shall be final and binding on the Parties. In the event of a Party seeking an Accountancy Opinion or Expert Opinion under this Agreement, each Party shall make written submissions to the expert so appointed and to the other Party within fourteen (14) days of the appointment. Each Party shall have seven (7) days to respond to the other's submissions. The expert shall be requested to deliver his Accountancy Opinion or Expert Opinion within a further thirty (30) days. The costs of any Accountancy Opinion or Expert Opinion shall be borne in such proportions as the expert may determine in his opinion to be fair and reasonable in all the circumstances or, if no such determination is made in the opinion, by the Parties in equal proportions.

24.2 It shall be a condition precedent to the commencement of any action in court or other tribunal (save an action for an interim injunction or an Expert Opinion sought under Clause 12.1) in respect of any dispute relating to this Agreement that the Parties have sought to resolve the dispute by either Party notifying the other Party in writing for resolution to the Chief Executive Officer (in the case of CRT) and the Chief Executive Officer (in the case of the Company) (or their express delegates) (the “Senior Executives”) who shall meet (whether in person or via teleconference) within twenty one (21) days of such notice to seek resolution in good faith. If the Senior Executives are unable to resolve the dispute at such meeting, either Party may pursue any remedy available to such Party at law or in equity, subject to the terms and conditions of this Agreement and the other agreements expressly contemplated hereunder.

**25. LAW AND JURISDICTION**

25.1 This Agreement shall be governed by and construed in accordance with English Law and, subject to the provisions of Clauses 24.1 and 24.2, each Party agrees to submit to the exclusive jurisdiction of the English Courts (except in respect of disputes under Clause 14 where jurisdiction is non-exclusive).

**26. EXECUTION**

26.1 This Agreement may be executed in any one or more number of counterpart agreements , and as scanned email attachments, and all signatures and counterparts so exchanged shall be considered as original and shall be deemed to form part of and together constitute this Agreement.

**27. CONTRACTS (RIGHTS OF THIRD PARTIES) ACT 1999**

27.1 Save that the Charity, the Contributors and their and CRT’s respective officers, employees and agents in respect of Clauses 9 and 11 may enforce those respective terms, no term of this Agreement is enforceable under the Contracts (Rights of Third Parties) Act 1999 by a person who is not a Party to this Agreement. Notwithstanding the provisions of this Clause, the Parties shall be entitled to amend, suspend, cancel or terminate this Agreement or any part of it in accordance with Clause 21, without the consent of any third party including those referred to in this Clause.

The Parties hereby execute this Agreement by their duly authorised representatives:

Signed by: \_\_\_\_\_

Name: \_\_\_\_\_

Title: \_\_\_\_\_

For and on behalf of  
**CANCER RESEARCH TECHNOLOGY LIMITED**

Signed by: \_\_\_\_\_

Name: \_\_\_\_\_

Title: \_\_\_\_\_

For and on behalf of  
**ASTERIAS BIOTHERAPEUTICS, INC**

**Appendix 1**  
**Development Plan**

**Appendix 2**  
**Executed CTOA**



## Schedule 5 No Fault Compensation Scheme

### Preamble

The Association of the British Pharmaceutical Industry favours a simple and expeditious procedure in relation to the provision of compensation for injury caused by participation in clinical trials. The Association therefore recommends that a member company sponsoring a clinical trial should provide without legal commitment a written assurance to the investigator — and through him to the relevant research ethics committee — that the following Guidelines will be adhered to in the event of injury caused to a patient attributable to participation in the trial in question.

### 1 Basic Principles

- 1.1 Notwithstanding the absence of legal commitment, the company should pay compensation to patient-volunteers suffering bodily injury (including death) in accordance with these Guidelines.
- 1.2 Compensation should be paid when, on the balance of probabilities, the injury was attributable to the administration of a medicinal product under trial or any clinical intervention or procedure provided for by the protocol that would not have occurred but for the inclusion of the patient in the trial.
- 1.3 Compensation should be paid to a child injured in utero through the participation of the subject's mother in a clinical trial as if the child were a patient-volunteer with the full benefit of these Guidelines.
- 1.4 Compensation should only be paid for the more serious injury of an enduring and disabling character (including exacerbation of an existing condition) and not for temporary pain or discomfort or less serious or curable complaints.
- 1.5 Where there is an adverse reaction to a medicinal product under trial and injury is caused by a procedure adopted to deal with that adverse reaction, compensation should be paid for such injury as if it were caused directly by the medicinal product under trial.
- 1.6 Neither the fact that the adverse reaction causing the injury was foreseeable or predictable, nor the fact that the patient has freely consented (whether in writing or otherwise) to participate in the trial should exclude a patient from consideration for compensation under these Guidelines, although compensation may be abated or excluded in the light of the factors described in paragraph 4.2 below.
- 1.7 For the avoidance of doubt, compensation should be paid regardless of whether the patient is able to prove that the company has been negligent in relation to research or development of the medicinal product under trial or that the product is defective and therefore, as the producer, the company is subject to strict liability in respect of injuries caused by it.

### 2 Type of Clinical Research Covered

- 2.1 These Guidelines apply to injury caused to patients involved in Phase II and Phase III trials, that is to say, patients under treatment and surveillance (usually in hospital) and suffering from the ailment which the medicinal product under trial is intended to treat but for which a product licence does not exist or does not authorise supply for administration under the conditions of the trial.
- 2.2 These Guidelines do not apply to injuries arising from studies in non-patient volunteers (Phase I), whether or not they are in hospital, for which separate Guidelines for compensation already exist.

- 2.3 These Guidelines do not apply to injury arising from clinical trials on marketed products (Phase IV) where a product licence exists authorising supply for administration under the conditions of the trial, except to the extent that the injury is caused to a patient as a direct result of procedures undertaken in accordance with the protocol (but not any product administered) to which the patient would not have been exposed had treatment been other than in the course of the trial.
- 2.4 These Guidelines do not apply to clinical trials which have not been initiated or directly sponsored by the company providing the product for research. Where trials of products are initiated independently by doctors under the appropriate Medicines Act 1968 exemptions, responsibility for the health and welfare of patients rests with the doctor alone (see also paragraph 5.2 below).

### **3 Limitations**

- 3.1 No compensation should be paid for the failure of a medicinal product to have its intended effect or to provide any other benefit to the patient.
- 3.2 No compensation should be paid for injury caused by other licensed medicinal products administered to the patient for the purpose of comparison with the product under trial.
- 3.3 No compensation should be paid to patients receiving placebo in consideration of its failure to provide therapeutic benefit.
- 3.4 No compensation should be paid (or it should be abated as the case may be) to the extent that the injury has arisen:
- 3.4.1 through a significant departure from the agreed protocol;
  - 3.4.2 through the wrongful act or default of a third party, including a doctor's failure to deal adequately with an adverse reaction;
  - 3.4.3 through contributory negligence by the patient.

### **4 Assessment of Compensation**

- 4.1 The amount of compensation paid should be appropriate to the nature, severity and persistence of the injury and should in general terms be consistent with the quantum of damages commonly awarded for similar injuries by an English Court in cases where legal liability is admitted.
- 4.2 Compensation may be abated, or in certain circumstances excluded, in the light of the following factors (on which will depend the level of risk the patient can reasonably be expected to accept):
- 4.2.1 the seriousness of the disease being treated, the degree of probability that adverse reactions will occur and any warnings given;
  - 4.2.2 the risks and benefits of established treatments relative to those known or suspected of the trial medicine.

This reflects the fact that flexibility is required given the particular patient's circumstances. As an extreme example, there may be a patient suffering from a serious or life-threatening disease who is warned of a certain defined risk of adverse reaction. Participation in the trial is then based on an expectation that the benefit/risk ratio associated with participation may be better than that associated with alternative treatment. It is, therefore, reasonable that the patient accepts the high risk and should not expect compensation for the occurrence of the adverse reaction of which he or she was told.

- 4.3 In any case where the company concedes that a payment should be made to a patient but there exists a difference of opinion between company and patient as to the appropriate level of compensation, it is recommended that the company agrees to seek at its own cost (and make available to the patient) the opinion of a mutually acceptable independent expert, and that his opinion should be given substantial weight by the company in reaching its decision on the appropriate payment to be made.

## 5 Miscellaneous

- 5.1 Claims pursuant to the Guidelines should be made by the patient to the company, preferably via the investigator, setting Out details of the nature and background of the claim and, subject to the patient providing on request an authority for the company to review any medical records relevant to the claim, the company should consider the claim expeditiously.
- 5.2 The undertaking given by a company extends to injury arising (at whatever time) from all administrations, clinical interventions or procedures occurring during the course of the trial but not to treatment extended beyond the end of the trial at the instigation of the investigator. The use of unlicensed products beyond the trial period is wholly the responsibility of the treating doctor and in this regard attention is drawn to the advice provided to doctors in MAL 3Q2 concerning the desirability of doctors notifying their protection society of their use of unlicensed products.
- 5.3 The fact that a company has agreed to abide by these Guidelines in respect of a trial does not affect the right of a patient to pursue a legal remedy in respect of injury alleged to have been suffered as a result of participation. Nevertheless, patients will normally be asked to accept that any payment made under the Guidelines will be in full settlement of their claims.
- 5.4 A company sponsoring a trial should encourage the investigator to make clear to participating patients that the trial is being conducted subject to the ABPI Guidelines relating to compensation for injury arising in the course of clinical trials and have available copies of the Guidelines should they be requested.

## References

- 1 Guidelines *for* Medical Experiments in Non-patient Human Volunteers, ABPI March 1988, as amended May 1990.
- 2 MAL 30— A Guide to the Provisions affecting Doctors and Dentists, DHSS, (Revised June 1985)



**The Association of the British Pharmaceutical Industry**  
12 Whitehall London SW1

**Schedule 6  
CRT Licence**

**THIS AGREEMENT is made the \_\_\_\_\_ day of \_\_\_\_\_ 20[●●]**

**BETWEEN:**

- (1) **CANCER RESEARCH TECHNOLOGY LIMITED**, a company registered in England and Wales with number 1626049 with registered office at [Angel Building, 407 St. John Street, London, EC1V 4AD, England] (“**CRT**”); and
- (2) **ASTERIAS BIOTHERAPEUTICS, INC**, a Delaware company with principal place of business at 230 Constitution Drive, Menlo Park, CA 94025, USA (the “**Company**”).

**WHEREAS**

- (A) CRT, the Company and the Charity (as defined below) are parties to a Clinical Trial and Option Agreement dated [●●●] (the “**CTOA**”) relating to the Investigational Medicinal Product (as defined in the CTOA).
- (B) Pursuant to clause 7.5 of the CTOA, the Company has agreed to licence the Company Intellectual Property (as defined below) and grant sub-licences under the Third Party Licences (as defined below) in return for a share of any revenue generated by CRT from the commercial exploitation of such intellectual property rights upon the terms and conditions set out below.

**NOW IT IS HEREBY AGREED** as follows:

**1. INTERPRETATION**

1.1 In this Agreement except where the context requires otherwise, the following words and expressions shall have the following meanings:

- |   |   |
|---|---|
| <b>“Charity”</b>                                  | means Cancer Research UK, a charity registered under number 1089464 of Angel Building, 407 St. John Street, London EC1V 4AD, England.   |
| <b>“Clinical Trial”</b>                           | has the meaning given in the CTOA.  |
| <b>“Company Background Intellectual Property”</b> | means those elements of the Company Intellectual Property with broad potential application within and outside the Field including the Company Combination Patent Rights and the Company Intellectual Property specified in Annexes 1A, 2A and 3A. |
| <b>“Company Combination Patent Rights”</b>        | means those Patent Rights of the Company which claim the use of the Product or Investigational Medicinal Product in combination with one or more other anti-cancer agents and all Patent Rights deriving priority there from.                     |

<b>“Company Foreground Intellectual Property”</b>	means those elements of the Company Intellectual Property with applications solely or primarily within the Field including the Company Intellectual Property specified in Annexes 1B, 2B and 3B.
<b>“Company Intellectual Property”</b>	means the Company Owned Patent Rights and all rights in the Company Materials, the Investigational Medicinal Product and the Company Know-How.
<b>“Company Know-How”</b>	means: (a) any Know How of the Company that was disclosed by the Company to the Charity pursuant to the Technology Transfer Plan and/or the CTOA; (b) any Know How described in Annex 2; and (c) such other Know How of the Company relating to the Investigational Medicinal Product (and any constituents thereof) or any Related Product including but not limited to: (i) any safety and toxicological data; (ii) information relating to manufacturing/production; (iii) information relating to quality; (iv) information relating to safe and proper handling, storage and use; and (v) any information which would in any way improve the prospects for its commercialisation.
<b>“Company Materials”</b>	means Materials owned by the Company which are necessary or useful to generate the Product, a Related or the Investigational Medicinal Product, more particularly described in Annex 3.
<b>“Company Owned Patent Rights”</b>	means (i) those Patent Rights listed in Annex 1; (ii) those Patent Rights of the Company which would be infringed by the unauthorised manufacture, use or sale in, or importation into, the relevant country of the Investigational Medicinal Product, Product or Related Products; (iii) the Company Combination Patent Rights and (iv) all Patent Rights deriving priority from (i), (ii) and (iii).
<b>“Control”</b>	has the meaning given in the CTOA.
<b>“Direct Costs”</b>	means any external costs and expenses incurred from time to time by or on behalf of CRT in filing, prosecuting, maintaining, enforcing, defending and exploiting the Company Intellectual Property, including without limitation: <ol style="list-style-type: none"><li>i. all charges paid by CRT pursuant to Clause 6.2;</li><li>ii. official patent filing, prosecution, maintenance and renewal fees;</li><li>iii. all patent agents, legal, accounting and other professional fees and expenses;</li><li>iv. travel and other out-of-pocket expenditure;</li><li>v. courier charges and third party printing costs;</li><li>vi. any non-recoverable taxes or charges including Value Added Tax which may be imposed; and</li><li>vii. all charges paid by CRT pursuant to Clause 2.3.</li></ol>

<b>“Effective Date”</b>	means the date of this Agreement.
<b>“Exclusive Third Party Licences”</b>	means those licences listed in Annex 4A.
<b>“Field”</b>	means the use of the Product and any Related Product(s) in immunotherapy applications using ***, for the treatment, prophylaxis, prevention and/or cure of human disease and conditions.
<b>“Gross Revenue”</b>	means any and all sums (or other consideration of monetary value) received by CRT from time to time in respect of the commercial exploitation of the Investigational Medicinal Product, Product or Related Products. For the avoidance of doubt, Gross Revenue shall exclude any sums received by CRT for the purpose of further research and/or development of the Investigational Medicinal Product.
<b>“Investigational Medicinal Product” or “IMP”</b>	has the meaning given in the CTOA.
<b>“Intellectual Property Rights”</b>	means all Patent Rights, Know-How, copyright, database rights, design rights, moral rights, rights in trade names, logos and trade and service marks, domain names, rights in Materials and all rights or forms of protection of a similar nature or having equivalent or similar effect to any of them which may subsist anywhere in the world, whether or not any of them are registered including any application for registration of any of them.
<b>“Know-How”</b>	has the meaning given in the CTOA.
<b>“Licence”</b>	has the meaning given in the CTOA.
<b>“Materials”</b>	has the meaning given in the CTOA.
<b>“Net Revenue”</b>	means Gross Revenue less Direct Costs.
<b>“Non-Exclusive Third Party Licences”</b>	means those licences and sublicences listed in Annex 4B.

<b>“Party”</b>	means either party to this Agreement and <b>“Parties”</b> means both of them.
<b>“Patent Rights”</b>	has the meaning given in the CTOA.
<b>“Product”</b>	has the meaning given in the CTOA.
<b>“Related Product”</b>	has the meaning given in the CTOA.
<b>“Technology Transfer Plan”</b>	has the meaning given in the CTOA.
<b>“Third Party Background Intellectual Property”</b>	means those elements of the Intellectual Property Rights licensed under the Third Party Licences with broad potential application within and outside the Field.
<b>“Third Party Foreground Intellectual Property”</b>	means those elements of the Intellectual Property Rights licensed under the Third Party Licences with applications solely or primarily within the Field.
<b>“Third Party Foreground Patent Rights”</b>	means those elements of the Patent Rights licensed under the Third Party Licences with applications solely or primarily within the Field.
<b>“Third Party Licences”</b>	means the Exclusive Third Party Licences and the Non-Exclusive Third Party Licences.
<b>“Third Party Licence Costs”</b>	means those milestone, royalty and other payments listed in Annex 5 (including any apportionment formulas or details) in respect of the Third Party Licences, in each case to the extent that the same becomes payable by the Company to the relevant third party licensor as a direct result of an act of CRT or its sub-licensee in the exercise of its rights pursuant to this Agreement.

1.2 The headings in this Agreement are for convenience only and shall not affect its interpretation. Unless the contrary intention appears, words denoting persons shall include any individual, partnership, company, corporation, joint venture, trust, association, organisation or other entity, in each case whether or not having separate legal personality. References to the words “include” or “including” shall be construed without limitation to the generality of the preceding words.

## 2. LICENCE

2.1 Pursuant to clause 7.5 of the CTOA, and in consideration of the provisions of Clauses 4 and 6, the Company hereby grants to CRT:

2.1.1 a\*\*\* under the Company Intellectual Property; and

2.1.2 an exclusive worldwide sub-licensable (through multiple tiers of sub-licences) sublicense under the hTERT Licensed Patents; and

2.1.3 a\*\*\* under the University of Western Ontario Licensed Patents; and

2.1.4 a\*\*\* under the Isis Licensed Patents; and

2.1.5 a \*\*\* under the Merix/Duke Licensed Patents; and

2.1.6 a \*\*\* under the Merix/Rockefeller Licensed Patents; and

2.1.7 a\*\*\* under the Immunomic/JHU Licensed Patents,

in each case subject to the terms and conditions described in Clause 6 below and further detailed in Annex 6, to research, develop, make, have made, import, use and sell Products and Related Products in the Field in the Territory.

- 2.2 The \*\*\* Licences prohibit further sublicensing without the consent of the licensor. The Company agrees to work with CRT and third party licensors under these Third Party Licences to attempt to obtain expanded sublicense rights as requested by CRT to facilitate the development and commercialization of Products and Related Products. If such expanded sublicensing rights cannot be negotiated with licensors, the Company will, to the maximum extent allowed under the applicable Third Party Licences, directly sublicense any third party CRT reasonably requests in order to facilitate the timely development and commercialization of Products and Related Products.
- 2.3 Subject to the restrictions and preapproval procedures described in Sections 2C and 4C of the WARF License and Annex 6, the Company agrees to directly sublicense any third party CRT reasonably believes to require a sublicense under the WARF License in order to facilitate the timely development and commercialization of Products and Related Products, provided however that CRT or such third party shall be responsible for payment of any sublicensing fees incurred as a result of such sublicense.
- 2.4 Those terms and provisions of any Third Party Licence that are required by the Third Party Licence to be referenced or included in a sublicense or sub-sublicense, as listed in Annex 6, are hereby incorporated into this Agreement by reference. CRT and the Company agree to amend this Agreement to add to this Agreement any provision of a Third Party Licence that the licensor or sublicensor may reasonably require to be so added under the terms of a Third Party Licence.
- 2.5 The Company agrees to disclose to CRT any Company Know-How and Know-How related to the IMP, the Product, or any Related Product licensed under a Third Party Licence that was not already disclosed to CRT pursuant to the CTOA within three (3) months of the Effective Date and agrees that the Company Know-How may be used by CRT and anyone to whom CRT discloses the Company Know-How and that, for so long as it is exclusively licensed to CRT under this Agreement, the Company shall not disclose the Company Know-How or Know-How licensed under a Third Party Licence to any third party for use within the Field, or use the same in any internal research programme within the Field.
- 2.6 The Company either has or agrees to transfer the Company Materials and those Materials licensed under a Third Party Licence (the "Third Party Materials") listed in Annex 3C to CRT (or any third party nominated by CRT) within three (3) months of the Effective Date and agrees that the Company Materials and Third Party Materials may be used by CRT and any third party authorised by CRT and that, for so long as it is exclusively licensed to CRT under this Agreement, the Company shall not transfer any Company Materials or Third Party Materials to any third party or use the same in any internal research programme within the Field.



- 2.7 At CRT's request, the Company shall negotiate with CRT in good faith on reasonable commercial terms a sub-licensable licence in respect of any Intellectual Property Rights which come under the Control of the Company after the Effective Date and which may be necessary and/or useful for the development and/or commercial exploitation of the Company Intellectual Property, and the Intellectual Property licensed under the Third Party Licences, in the Field.
- 2.8 CRT and its sublicensees shall not use any Company Materials, Third Party Materials or Products for any purpose outside that permitted by this Agreement, and will not use Company Materials or Third Party Materials to perform any of the following experiments: (a) intermixing of Company Materials or Third Party Materials with an intact embryo, either human or nonhuman; (b) implanting Company Materials or Third Party Materials in a uterus, or (c) attempting to make whole embryos by any method.
- 2.9 The Company hereby represents and warrants that as at the date of this Agreement:
  - 2.9.1 other than the Third Party Licences, it does not have an extant licence or right to acquire a licence for Intellectual Property Rights within the Field that has been or may be granted to it or an Affiliate of the Company by a third party; and
  - 2.9.2 CRT has been provided with complete (other than as visibly redacted) and accurate copies of the Third Party Licences, including all variations that have been made to them.
- 2.10 The Company undertakes not to make any variations to the Third Party Licences without the prior written consent of CRT.
- 2.11 If any Third Party Licence is liable to be, or is summarily terminated, the Company shall give as much notice as practicable to CRT and at CRT's request use its commercially reasonable endeavours to facilitate a continuance and an assignment of the Third Party Licence to CRT.

### **3. ASSISTANCE AND FURTHER ASSURANCE**

- 3.1 The Company hereby agrees to promptly provide to CRT or its nominated patent agent all documents relating to the filing, prosecution and maintenance of the Company Foreground Patent Rights and, to the extent that it has the right to such documents under the relevant Third Party Licence, the Third Party Foreground Patent Rights licensed under the Exclusive Third Party Licences.
- 3.2 The Company agrees to assist CRT and any third party that CRT may nominate in understanding and using the Company Know-How, the Company Materials and the Know-How and Materials licensed under Third Party Licences and to assist CRT and any such third party in relation to any further development of the Product, Investigational Medicinal Product or any Related Product and any regulatory application in relation thereto (including without limitation and to the extent that the Company may lawfully do so by the provision of information that may be requested from time to time in relation to the origin, development, and distribution by the Company to any third parties of the Product).
- 3.3 The Company will maintain and will not terminate any Third Party Licence without the prior written agreement of CRT.

### **4. REVENUE SHARE**

- 4.1 CRT and the Company shall share Net Revenue in the following proportions:

CRT           \*\*\*;  
Company       \*\*\*.

- 4.2 In the event that any Gross Revenue is received by CRT as part of the consideration for the grant of rights which include rights other than those in respect of Company Intellectual Property or licensed under the Third Party Licences, CRT shall apportion the consideration as between on the one hand, the rights granted in respect of the Company Intellectual Property and, on the other, any other rights granted, in such manner as is fair and reasonable.
- 4.3 If CRT receives any non-monetary consideration in respect of the commercial exploitation of the Company Intellectual Property (such as company stocks and shares), (i) prior to entering into any agreement providing for the payment of non-monetary consideration, CRT shall obtain the express written consents of Third Party Licensors for such non-cash payments as required under the relevant Third Party Licences and (ii) such non-monetary consideration shall not form Gross Revenue until CRT has received cash proceeds from the disposal or other realisation of such consideration. CRT shall at its sole discretion determine the timing of and price for any such realisation. For the avoidance of doubt, any dividend or similar monetary consideration received in respect of such non-monetary consideration shall form Gross Revenue.

**5. MANAGEMENT AND EXPLOITATION**

- 5.1 The filing, prosecution, maintenance, enforcement and defence of any Company Foreground Intellectual Property and further development and commercial exploitation thereof shall be at the sole cost and discretion of CRT.

**6. THIRD PARTY LICENCES**

- 6.1 To the extent that the Company has such rights under the relevant Third Party Licence, the Company agrees that the right to control the filing, prosecution, maintenance, enforcement and defence of any Third Party Foreground Intellectual Property, or to procure that the relevant licensor(s) under the Third Party Licence(s) does so, shall be transferred to CRT. To the extent that the control of any such Third Party Foreground Intellectual Property is transferred to CRT it will comply with the patent management provisions of the relevant Third Party Licence as identified in Annex 6.
- 6.2 CRT will be responsible for paying to the Company any signing fee, royalty fee, milestone payment, sub-licence fee, annual payment or other similar fee payable directly as a result of developing, out-licensing, marketing or selling Products and/or Related Products in the Field by CRT or its sub-licensees pursuant to this Agreement that the Company is obliged to pay under the Third Party Licences solely as a result of the said activities by CRT or its sub-licensees. Any such fees that relate to both activities under this Licence by CRT or its sub-licensees and to activities of or on behalf of the Company (whenever commenced) outside of the Field shall be subject to appropriate apportionment between CRT and the Company on a fair and equitable basis which the Parties shall agree at the time. The Company shall keep CRT informed in a timely manner of the Company's activities that have a bearing on the rights and obligations of CRT under this clause. For the avoidance of doubt (subject to CRT's right to require apportionment of fees between CRT and the Company as mentioned above in this clause 6.2) CRT shall have responsibility under and in accordance with this Clause 6.2 for the Third Party Licence Costs but shall not have liability for any penalties, costs or charges that are payable under the relevant Third Party Licence as a result of any negligence or breach of contract by the Company. CRT shall not be obliged to deal with the sub-licensors under the Third Party Licences directly, and provided that CRT has made the payments to the Company of the payments mentioned above in this Clause 6.2, CRT shall have no further liability and shall be indemnified by the Company in respect of any claim made by a sub-licensor regarding the same. CRT acknowledges that it has been provided with a redacted copy of the WARF License and unredacted copies of the other Third Party Licences, and is aware of the payment obligations thereunder.

CRT will notify the Company:

- 6.2.1 on becoming aware of the achievement of any milestone event that triggers Third Party Licence Costs; and
  - 6.2.2 on receipt of sales data and royalty payments from a sub-licensee in respect of which royalty based Third Party Licence Costs are payable, and will provide the Company with a copy of the relevant sales data received from CRT's sub-licensee to enable the Company to comply with its financial reporting obligations under the Third Party Licences.
- 6.3 CRT will pay to the Company the sums that CRT is obliged to pay to the Company pursuant to Clause 6.2 above in a timely manner so as to avoid the Company making late payment under the relevant Third Party Licence. Company will provide CRT with a copy of any invoice it receives for costs payable by CRT under any Third Party Licence, and CRT will make payment under any such properly due and payable invoices within thirty (30) days of receipt.
- 6.4 CRT will be responsible for fulfilling or obligating its sub-licensee(s) to fulfil any diligence and development reporting obligations under the Third Party Licences [as identified in Appendix 6]. CRT acknowledges that it has been provided with a redacted copy of the WARF License and unredacted copies of all other Third Party Licences, and is aware of the diligence and development reporting obligations thereunder.
- 6.5 Any payments or other contractual obligations of the Company owed to a third party that are not covered by Clauses 2.3, 6.1, 6.2, and 6.3 and 6.4 will remain the exclusive responsibility of the Company, whether or not connected to the rights granted to CRT under this Agreement.
- 6.6 The Company will as soon as reasonably possible (and in any event within seven (7) days) notify CRT if it becomes aware that it has breached the terms of any Third Party Licences or otherwise becomes aware of any acts or omissions which would give one or more of its licensors the right to terminate a Third Party Licence.
- 6.7 CRT will require as a term of any sub-licence of rights to commercialise Products or Related Products that the sub-licensee maintains levels of insurance coverage or a scheme of self insurance that is appropriate to cover the sub-licensees intended activities in respect of Products and/or Related Products.
- 6.8 CRT will endeavour to procure from any sub-licensee(s) to which it intends to grant rights to commercialise Products or Related Products indemnities in favour of the licensors under the Third Party Licences that are consistent with those provided by the Company. In the event that CRT is unable to procure such indemnities from a prospective sub-licensee and is not willing or able to provide them its self it will not enter into such sub-licence without the prior written agreement of the Company.

## 7. CONFIDENTIALITY

- 7.1 Subject to the other provisions of this Clause 7, each Party undertakes that both during and after termination of this Agreement, it will keep confidential and not disclose to any person other than to its officers, employees or professional advisors whose province it is to know, any confidential proprietary information of the other Party disclosed to or obtained by it in connection with this Agreement. For these purposes, Company Know-How shall be deemed to be the confidential information of CRT but only to the extent such Company Know-How pertains solely or directly to the Product or a Related Product and the Field. Additionally, subject to the provisions of Clause 7.2, any information of the Charity (and any charitable body succeeding to it) disclosed to or obtained by the Company in connection with this Agreement shall be deemed to be the confidential information of the Charity.
- 7.2 With the exception of Company Know-How which the Company shall keep confidential in accordance with Clause 7.1 and information that is required to be treated as confidential under the CTOA, Clause 7.1 shall not apply to:
- 7.2.1 information which is or was already known to the receiving Party at the time of disclosure under this Agreement, as shown by the receiving Party's written records, without any obligation to keep it confidential;
  - 7.2.2 information which at the time of being disclosed or obtained by the receiving Party under this Agreement or at any time thereafter, is published or otherwise generally available to the public other than due to default by the receiving Party of its obligations hereunder; or
  - 7.2.3 information which is required to be disclosed by a competent Court or regulatory authority or otherwise by applicable law or statute or any rule or regulation of any Regulatory Authority or other government or administrative agency or authority, to the extent of such disclosure, provided that the receiving Party shall give notice of such disclosure as soon as reasonably practicable.
- 7.3 Clause 7.1 above shall not apply to the use or disclosure of any information by any Party for the purpose of exercising or enforcing its rights under this Agreement.
- 7.4 Each Party will ensure that all personnel and third parties to whom confidential information of another Party is disclosed are informed of the provisions of this Clause 7.
- 7.5 So long as this Agreement remains in effect, as between CRT and the Company only, clause 5 of the CTOA shall cease to operate and this Clause 7 shall replace and supersede the obligations and rights of CRT and the Company only under such clause 5 of the CTOA. In the event that the Company exercises the Second Option under Clause 9 and this Agreement terminates, the terms of the Licence shall apply.

## 8. WARRANTIES

- 8.1 The Company represents and warrants to CRT that to the best of its knowledge and belief:
- 8.1.1 it is not aware of any inventors of the Company Owned Patent Rights other than the inventors named therein;
  - 8.1.2 it is the legal and beneficial owner of the Company Intellectual Property free of any third party rights or encumbrances other than those of the Geron Royalty Agreement effective October 1, 2013, a copy of which has been provided to CRT;

- 8.1.3 no claims of infringement of intellectual property rights owned or controlled by any third party have been made or threatened against the Company with respect to the Intellectual Property Rights licensed hereunder;
- 8.1.4 it has not and will not enter into any Agreement which prevents it fulfilling its obligations under this Agreement;
- 8.1.5 it has not done anything whereby the whole or any part of the rights licensed under the Agreement might be invalidated or registration of them refused;
- 8.1.6 the manufacture, use and possession of the Investigational Medicinal Product by CRT or any person authorised by CRT, in each case in accordance with the terms of this Agreement, shall not infringe the rights (including without limitation any Intellectual Property Rights) of any third party;
- 8.1.7 it is not aware of the existence of any fact or circumstance that may materially affect the successful development and commercialisation of the Product;
- 8.1.8 it has the full right, power and authority, and has obtained all approvals or consents necessary to grant the rights under the Third Party Licences as provided under this Agreement;
- 8.1.9 the Third Party Licences are the only third party licences held by the Company in respect of the manufacture, possession and use the IMP and the rights granted to CRT under this Agreement;
- 8.1.10 there are no outstanding breaches of the Third Party Licences by the Company;
- 8.1.11 there are no acts or omissions on the part of the Company which would give one or more of its licensors the right to terminate a Third Party Licence, either now or at a later date; and
- 8.1.12 it is entitled to make the Company Materials and the Materials licensed under the Third Party Licences available to CRT for the purposes of this Agreement.

8.2 Nothing in this Agreement shall be treated as imposing on CRT any liability to the Company in relation to the further development and commercial exploitation of the Investigational Medicinal Product or the Company Intellectual Property.

## **9. DURATION AND REVERSION OF RIGHTS**

- 9.1 Subject to the remainder of this Clause 9, this Agreement shall come into force on the Effective Date and shall extend for so long as CRT has the potential to receive Gross Revenue.
- 9.2 In the event that CRT has not, within \*\*\* of the Effective Date either (i) found a commercial partner that has commenced and is continuing diligent effort to develop and/or commercialize the Product or any Related Product; or (ii) initiated or is not continuing diligent further development of the Product or any Related Product using its own (or the Charity's) resources then:

- 9.2.1 the rights granted to CRT to the Company Background Intellectual Property and the Third Party Background Intellectual Property will terminate and revert to the Company;
- 9.2.2 CRT's obligations in respect of the Company Background Intellectual Property and the Third Party Background Intellectual Property, including those under Clauses 6.2 and 6.3, will terminate and revert to the Company;
- 9.2.3 the Company will have a renewed option (the "**Second Option**") exercisable within \*\*\* from the date of termination of CRT's licence rights to the Company Background Intellectual Property and Third Party Background Intellectual Property (the "**Second Option Period**") to enter into the Licence with a \*\*\* reduction to the financial consideration payable to CRT under clause 4 of the Licence. If the Company exercises its Second Option by written notice to CRT and enters into the Licence within the Second Option Period this Agreement will terminate;
- 9.2.4 if CRT has a bona fide offer from a third party to enter into a licence agreement in respect of the Clinical Trial Results, Company Foreground Intellectual Property and/or Third Party Foreground Intellectual Property during the Second Option Period CRT will provide the Company with written notice of its intention enter into such licence and the Company will have \*\*\* from the date of such notice to exercise its Second Option by written notice to CRT and, if it does so, a further \*\*\* to enter into the Licence. If the Company does not exercise its Second Option and enter into the Licence within such time periods the Second Option will lapse and Clause 9.2.5 will apply;
- 9.2.5 if the Company does not exercise the Second Option and enter into the Licence within the Second Option Period CRT will be free to continue to sub-licence or otherwise utilise the Clinical Trial Results, Company Foreground Intellectual Property and/or Third Party Foreground in accordance with the terms of this Agreement. In the event that CRT finds a commercial partner or development route for the Company Foreground Intellectual Property for which a licence under the Company Background Intellectual Property and/or Third Party Background Intellectual Property would be necessary or useful, in so far as the Company is still reasonably able to grant such rights, the Company will do and CRT's rights and obligations in respect of such Company Background Intellectual Property and/or Third Party Background Intellectual Property under this Agreement will be re-instated; and
- 9.2.6 if this Agreement terminates CRT shall, and shall require all of its sublicensees to, within thirty (30) days return to the Company or destroy (by a method specified by the Company) and at the Company's cost and expense any remaining quantities of the Company Materials and/or Confidential Information of the Company in the possession or control of CRT and its sublicensees.

## 10. GENERAL

- 10.1 The surviving terms and conditions of the CTOA shall, in accordance with its terms, continue in full force and effect.
- 10.2 This Agreement shall be governed by and construed in accordance with English law and each Party agrees to submit to the exclusive jurisdiction of the English courts (except in respect of disputes under Clause 7 where jurisdiction is non-exclusive).

**IN WITNESS** whereof this document is executed by the parties on the date stated at the beginning of this Agreement through their authorised signatories

Signed by: \_\_\_\_\_

Name: \_\_\_\_\_

Title: \_\_\_\_\_

For and on behalf of  
**CANCER RESEARCH TECHNOLOGY LIMITED**

Signed by: \_\_\_\_\_

Name: \_\_\_\_\_

Title: \_\_\_\_\_

For and on behalf of  
**ASTERIAS BIOTHERAPEUTICS, INC**

**ANNEX 1A  
COMPANY BACKGROUND PATENT RIGHTS**

<b>PATENT/ APPLICATION NUMBER</b>	<b>TITLE</b>	<b>TERRITORY</b>	<b>FILING DATE</b>

**ANNEX 1B  
COMPANY FOREGROUND PATENT RIGHTS**

<b>PATENT/ APPLICATION NUMBER</b>	<b>TITLE</b>	<b>TERRITORY</b>	<b>FILING DATE</b>

**ANNEX 2A  
COMPANY BACKGROUND KNOW-HOW**

**ANNEX 2B  
COMPANY FOREGROUND KNOW-HOW**

**ANNEX 3A  
COMPANY BACKGROUND MATERIALS**

**ANNEX 3B  
COMPANY FOREGROUND MATERIALS**

**ANNEX 3C  
THIRD PARTY MATERIALS**

**ANNEX 4A  
EXCLUSIVE THIRD PARTY LICENCES**



Exclusive License Agreement between Geron Corporation and Isis Innovation Limited effective March 23, 2006, which was subsequently assigned by Geron Corporation to Company effective October 1, 2013<sup>1</sup>

Exclusive License Agreement between Geron Corporation and The University of Western Ontario effective January 30, 2009, as amended January 30, 2011 and January 11, 2012, and subsequently assigned by Geron Corporation to Company effective October 1, 2013.<sup>2</sup>

Exclusive License Agreement between Geron Corporation and Immunomic Therapeutics Inc effective October 31, 2006, which was subsequently assigned by Geron Corporation to Company effective October 1, 2013.<sup>3</sup>

<sup>1</sup>Isis Innovation Limited retains rights to use the Licensed Technology and any Improvements (including those by the licensee), as defined in the Exclusive License Agreement, for academic and research purposes

<sup>2</sup>The University of Western Ontario retains rights to use the licensed patents for teaching and other non-commercial uses.

<sup>3</sup>Exclusive rights are for use with \*\*\*

#### **ANNEX 4B NON-EXCLUSIVE THIRD PARTY LICENCES**

Non-Exclusive License Agreement between Company and the Wisconsin Alumni Research Foundation, effective October 7, 2013

Exclusive License Agreement between Geron Corporation and Argos Therapeutics (formerly Merix Biosciences, Inc.) effective March 6, 2004, and subsequently assigned (along with sublicenses described below) by Geron Corporation to the Company effective October 1, 2013.<sup>4</sup>

Patent Assignment Agreement Dated as of August 1, 2002 Between Merix and Gerold Schuler (regarding cryoconservation and generation of dendritic cells in closed systems).<sup>4</sup>

Patent Assignment Agreement Dated as of August 1, 2002 Between Merix and Gerold Schuler (regarding Cd4+ Cd25+ Reg T Cells).<sup>4</sup>

Patent Assignment Agreement dated as of June 26, 2001 Between Merix and Gerold Schuler.<sup>4</sup>

Exclusive License Agreement Between Merix. and Duke University Effective as of January 10, 2000, as Amended as of July 28, 2003.<sup>5</sup>

Exclusive License Agreement Between Merix and the Rockefeller University Effective as of June 27, 2001, as Amended as of June 29, 2001.<sup>6</sup>

<sup>4</sup>The rights under this license are “co-exclusive” with Argos Therapeutics (formerly Merix Biosciences, Inc.)

<sup>5</sup>Sublicensed by Argos Therapeutics (formerly Merix Biosciences, Inc.) to Geron Corporation. The sublicense are “co-exclusive” with Argos Therapeutics

<sup>6</sup>Sublicensed by Argos Therapeutics (formerly Merix Biosciences, Inc.) to Geron Corporation. The rights to certain patents are non-exclusive in that they are shared with third parties named in the license agreement, and the rights to all patents are “co-exclusive” with Argos Therapeutics.

**ANNEX 5  
THIRD PARTY LICENCE COSTS**

**Annex 6**  
**Sublicensing Terms of Third Party Licences under CRT Licence**

**Schedule 7  
Third Party Licences and Payments**

The entire content of this Schedule 7 is subject to and to be interpreted in accordance with the consent letters tabulated immediately below which consent letters vary certain of the respective in- licences that are referred to in this Schedule 7:

Item No.	Name of Head Licensor	Date of Original Licence	Licensed Technology	Date of Consent Letter
1	Isis Innovation Ltd	March 23, 2006	Isis Licensed Patents	1st July 2014
2	Wisconsin Alumni Research Foundation	October 7, 2013	WARF Intellectual Property	28th August 2014
3	John Hopkins University	September 26, 2006 (Head License from JHU to Immunomic)  October 31, 2006 (sublicense from Immunomic to Asterias)	Immunomic Licensed Patents	5th September 2014

**Schedule 7A: Sublicensing Terms of Third Party Licences under CTOA**

Licensed Technology (CTOA Section Reference)	Underlying Third Party Agreement(s)	Language incorporated by reference	Other sublicensing terms & conditions (Section reference from underlying agreement)
hTERT Licensed Patents (6.1.2)	Exclusive Sublicense Agreement between Geron Corporation and Asterias Biotherapeutics, effective October 1, 2013  Intellectual Property License Agreement between Geron Corporation and University Technology Corporation, effective December 9, 1996	n/a	***

University of Western Ontario Licensed Patents (6.1.3)	License Agreement between Geron Corporation and University of Western Ontario, effective January 30, 2009 (assigned to Asterias by Geron effective October 1, 2013)	n/a	***
Isis Licensed Patents (6.1.4)	Exclusive License Agreement between Geron Corporation and Isis Innovation Ltd, effective March 23, 2006 (assigned to Asterias by Geron effective October 1, 2013)	***	***
Merix/Duke Licensed Patents (6.1.5)	Exclusive License Agreement between Geron Corporation and Merix Bioscience, effective March 6, 2004 (assigned to Asterias by Geron effective October 1, 2013)  License Agreement between Duke University and Merix Bioscience, effective January 10, 2000	n/a	***
Immunomic Licensed Patents (6.1.6)	Exclusive License Agreement between Geron Corporation and Immunomic Therapeutics Inc effective October 31, 2006 (assigned to Asterias by Geron effective October 1, 2013)  License Agreement between Johns Hopkins University and Immunomic Therapeutics, effective September 26, 2006	***	***

WARF Intellectual Property (6.1.7)	Non-exclusive License Agreement between Asterias Biotherapeutics and the Wisconsin Alumni Research Foundation, effective October 7, 2013		***
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**Schedule 7B Summary of Third Party Licence Payments payable by CRT<sup>1</sup>**

Agreement	Licensed IP	Milestone payments	Royalties/Revenue Share	Other financial obligations
WARF License	WARF Patents, Wisconsin Materials	***	***	***
hTERT License	hTERT Licensed Patents	***	***	***
Royalty Agreement between Asterias Biotherapeutics and Geron Corporation, effective October 1, 2013	Company Owned Patent Rights listed in Schedule 1A  University of Western Ontario Licensed Patents  Isis Licensed Patents  Merix/Duke Licensed Patents  Merix/Rockefeller Licensed Patents  Immunomic/JHU Licensed Patents	***	***	***
Merix License	Sublicense under Merix/Duke Licensed Patents  Sublicense under Merix/Rockefeller Licensed Patents	***	***	***

Duke License	Merix/Duke Licensed Patents	***	***	***
Rockefeller License	Merix/Rockefeller Licensed Patents	***	***	***
Immunomic License	Sublicense under Immunomic/JHU Licensed Patents	***	***	***
University of Western Ontario	University of Western Ontario Licensed Patents	***	***	***
Isis Innovation Ltd	Isis Licensed Patents	***	***	***

<sup>1</sup>The parties agree that the foregoing is a summary for convenience only. Although every attempt has been made to make the following summary as accurate and complete as possible, summarizing contractual terms can result in inaccuracies or incomplete information.  
\*\*\*



## **Schedule 8 Development Work Plan**

\*\*\*

Asterias will perform method development with minimal qualification with the expectation that that CR-UK or a designated analytical facility would perform the qualifications. Analytical in-process and non-qualified release assay protocols will be transferred to CR-UK or a designated analytics facility.

### **Technology Transfer**

As is referenced in the agreement Asterias will collaborate with CR-UK to develop an appropriate Technology Transfer Plan to assure a successful transfer of the AST-VAC2 process.

Based upon the achievement of the Phase I development criteria, Asterias will provide documentation and select materials for the AST-VAC2 project. Documentation includes any specified development reports, a process description and flow diagrams; \*\*\*; equipment, materials and reagent lists, and supplier information.

Training on the AST-VAC2 process and analytical protocols at Asterias will be initiated at a time and schedule that is documented in the Technology Transfer Plan and compatible to CR-UK's schedule for a successful transfer of information and selected materials.

### **Proposed Time Lines**

The following represents a projected schedule and sequence of events for the development and tech transfer of the AST-VAC2 process to CR-UK (Figure 1).

**Figure 1: Proposed Time Line**

\*\*\*

**Milestones & Deliverables:**

**Table 1: Milestones**

\*\*\*

Asterias will supply monthly updates discussing data and progress toward agreed upon development objectives as well as any foreseen critical issues.

Based on the Technology Transfer Plan referenced in the agreement, Asterias deliverables will include the following as part of the transfer of the AST-VAC2 process:

- Working Cell Bank vials (\*\*\*)
- Regulatory history files on lines and bank
- Available RNA plasmid vials
- Process Description
- Process Flow Diagram(s)
- Equipment lists
- Bill of Materials
- Reagent Preparation-Protocols and Forms
- Analytical Method Protocols
- Stage I, II & III protocols

A final technology transfer summary may also be considered to realize the completion of the technology transfer milestone(s). The Technology Transfer Plan will contain the summation of the on-site training plan as well as the results of the receiving site's independent process run.

Additional requirements can be detailed in the Technology Transfer Plan.

**Schedule 9  
Additional Studies**

- In tumour biopsies collected during surgical resection:
  - o \*\*\*
- In blood samples collected after the commencement of therapy and up until surgical resection:
  - o \*\*\*
  - o \*\*\*
- Scale-up runs performed by the Charity for technology transfer of AST-VAC2 process
- Engineering run for AST-VAC2 manufacture performed by the Charity prior to manufacture of cGMP batch of AST-VAC2 IMP
- cGMP manufacturing of AST-VAC2 IMP by the Charity
- Studies performed by the Charity to assess and qualify the \*\*\* used for the final production of AST-VAC2
- Studies performed by the charity to qualify the use of AST-VAC2 release assays at the Charity
- In process, release, and stability testing of AST-VAC2 IMP performed by the Charity

For the avoidance of doubt, all references in this Schedule 9 to anything done “by the Charity” shall be construed as including anything done on behalf of or at the instruction of the Charity.

**Schedule 10  
Form of Progress Report**



**Project XXXXXXXX: <Month Year> DDO Monthly Project Report**

**Confidential**

<Enter Phase> Phase – Current Status:		Project Phase Transition	Project Phase End Point	Forecast / Actual Date & Traffic Light
			NAC approval	XXXXXXX
		Exploratory	Exploratory Criteria met & approved	XXXXXXX
		Pre-Clinical & Trial Preparation	CTA submission	XXXXXXX
		Study Set Up	1st Site Open Notification	XXXXXXX
		Study Open	LPFV	XXXXXXX
		Study Closedown	Final CSR	XXXXXXX
		Study Archive	Archive	XXXXXXX
Key Project Activities This Month	Key Project Activities for Next Month	Significant issues / risks and potential impact		Mitigation of Significant issues / risks and potential impact
1. 2. 3. 4. 5.	1. 2. 3. 4. 5.	1. 2. 3. 4. 5.		1. 2. 3. 4. 5.
<b>Alert message:</b>				

If you have any questions concerning the clinical trial, please contact "name" (Clinical Study Manager). For other project-related questions, please contact "name" (Project Manager).

**Schedule 11**  
Clinical Protocol Summary

Indication	***
Number of patients	***
Number of administrations per patient	***
Dose per administration	***
Primary endpoints	***
[Secondary endpoints]	***
Major inclusion criteria	***

## CERTIFICATIONS

I, Michael D. West, certify that:

1. I have reviewed this quarterly report on Form 10-Q of BioTime, 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 officers 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 the periodic reports are 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.
5. The registrant's other certifying officers 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 7, 2014

/s/ Michael D. West

Michael D. West  
Chief Executive Officer

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## CERTIFICATIONS

I, Robert W. Peabody, certify that:

1. I have reviewed this quarterly report on Form 10-Q of BioTime, 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 officers 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 the periodic reports are 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.
5. The registrant's other certifying officers 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 7, 2014

/s/ Robert W. Peabody

Robert W. Peabody  
Chief 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 BioTime, Inc. (the "Company") for the quarter ended September 30, 2014 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), we, Michael D. West, Chief Executive Officer, and Robert W. Peabody, Chief Financial Officer of the Company, 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 7, 2014

*/s/ Michael D. West*

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Michael D. West  
Chief Executive Officer

*/s/ Robert W. Peabody*

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Robert W. Peabody  
Chief Financial Officer

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