# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

# **FORM 10-Q**

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[ ] QUARTERLY REPORT	Γ PURSUANT TO SECTI	ON 13 OR 15(d) OF THE SECUR	RITIES EXCHANGE ACT OF 1934
	For the quarterly p	period ended <u>September 30, 2015</u>	
		OR	
[ ] TRANSITION REPORT	Γ PURSUANT TO SECTI	ON 13 OR 15(d) OF THE SECUF	RITIES EXCHANGE ACT OF 1934
	For the Transit	ion Period from to	
	Commissio	n File Number: <u><b>001-34949</b></u>	
<u>A</u>		HARMA CORPORA' gistrant as Specified in Its Charter	
(State or Othe	nmbia, Canada er Jurisdiction of or Organization)		980597776 (I.R.S. Employer dentification No.)
		<b>kway, <u>Burnaby, BC, Canada V5</u></b> Principal Executive Offices)	<u>J 5J8</u>
	(Registrant's Teleph	604-419-3200 one Number, Including Area Code	e)
	the preceding 12 months	(or for such shorter period that t	by Section 13 or 15(d) of the Securities he registrant was required to file such
	be submitted and posted	pursuant to Rule 405 of Regulation	n its corporate Web site, if any, every on S-T during the preceding 12 months
	finitions of "large accelera		er, a non-accelerated filer, or a smaller ler, smaller reporting company" in Rule
Large accelerated filer [ ]	Accelerated filer [X]	Non-accelerated filer [ ] (Do not check if a smaller reporting company)	Smaller reporting company [ ]
Indicate by check mark whether Yes [ ] No [X]	the registrant is a shell co	mpany (as defined in Rule 12b-2 c	of the Exchange Act).
As of October 31, 2015, the reg	istrant had 54,569,791 con	nmon shares, no par value, outstan	ding.
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# ARBUTUS BIOPHARMA CORP.

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# PART I. FINANCIAL INFORMATION

# ITEM 1. FINANCIAL STATEMENTS (UNAUDITED)

# ARBUTUS BIOPHARMA CORPORATION

(formerly Tekmira Pharmaceuticals Corporation)

# **Condensed Consolidated Balance Sheets**

(Unaudited)

(Expressed in US Dollars and in thousands, except share and per share amounts)

(Prepared in accordance with US GAAP)

		mber 30 2015	December 31 2014
Assets			
Current assets:			
Cash and cash equivalents	\$	181,089 \$	72,187
Short-term investments (note 2)		15,006	39,974
Accounts receivable		2,192	1,903
Accrued revenue		454	538
Investment tax credits receivable		52	86
Prepaid expenses and other assets		1,234	1,730
Total current assets		200,027	116,418
I and the side of the 22		10.041	
Long-term investments (note 2)		10,041	12.050
Property and equipment		12,243	12,959
Less accumulated depreciation		(9,918)	(11,199)
Property and equipment, net of accumulated			
depreciation		2,325	1,760
Intangible assets (note 3)		353,601	-
Goodwill (note 3)		156,637	-
Total assets	\$	722,631	118,178
Liabilities and stockholders' equity Current liabilities:			
Accounts payable and accrued liabilities (note 5)	\$	7,501 \$	9,328
Deferred revenue (note 4)	Ψ	4,835	5,779
Warrants (note 2)		1,495	5,099
Total current liabilities		13,831	20,206
Deferred revenue, net of current portion (note 4)		6,888	9,937
Contingent consideration (note 8)		6,665	3,337
Deferred tax liability (note 3)		141,440	
Total liabilities		168,824	30,143
Stockholders' equity:		100,024	50,145
Common shares (note 3 and note 6)			
Authorized - unlimited number with no par value			
Issued and outstanding: 54,569,791			
(December 31, 2014 - 22,438,169)		828,578	290.004
Additional paid-in capital		28,538	26,208
Deficit		(261,721)	(205,864)
Accumulated other comprehensive loss		(41,588)	(22,313)
Total stockholders' equity		553,807	88.035
Total liabilities and stockholders' equity	\$	722,631	118,178
Total naturates and Stockholders equity	3	722,031	110,1/8

Nature of business and future operations (note 1) Contingencies and commitments (note 8)

(formerly Tekmira Pharmaceuticals Corporation)

# **Condensed Consolidated Statements of Operations and Comprehensive Loss**

(Unaudited)

(Expressed in US Dollars and in thousands, except share and per share amounts) (Prepared in accordance with US GAAP)

	Three months September		Nine mont Septem	
	2015	2014	2015	2014
Revenue (note 4)				
Collaborations and contracts	\$ 3,035 \$	3,578	8,865	\$ 8,411
Licensing fees, milestone and royalty payments	1,030	784	3,322	2,192
Total revenue	4,065	4,362	12,187	10,603
Expenses				
Research, development, collaborations and contracts	16,354	9,309	36,601	26,811
General and administrative	7,706	1,764	18,084	5,601
Depreciation of property and equipment	153	133	420	416
Acquisition costs (note 3)	-	-	9,656	-
Impairment of intangible assets (note 3)	37,990		37,990	-
Total expenses	62,203	11,206	102,751	32,828
Loss from operations	(58,138)	(6,844)	(90,564)	(22,225)
Other income (losses)				
Interest income	183	304	466	708
Foreign exchange gains	11,801	3,076	16,268	1,791
Decrease (increase) in fair value of warrant liability (note 2)	1,976	(5,140)	2,777	(12,943)
Total other income (losses)	13,960	(1,760)	19,511	(10,444)
Loss before income taxes	(44,178)	(8,604)	(71,053)	(32,669)
Income tax benefit (note 3)	15,196	-	15,196	-
Net loss	\$ (28,982) \$	(8,604)	(55,857)	\$ (32,669)
Loss per common share				
Basic and diluted	\$ (0.57) \$	(0.39) \$	(1.28)	\$ (1.53)
Weighted average number of common shares				
Basic and diluted	50,756,484	22,159,269	43,580,555	21,349,315
Comprehensive loss				
Cumulative translation adjustment	(10,101)	(4,827)	(19,275)	(3,211)
Comprehensive loss	\$ (39,083) \$	(13,431) \$	(75,132)	\$ (35,880)

(formerly Tekmira Pharmaceuticals Corporation)

# **Condensed Consolidated Statement of Stockholders' Equity**

(Unaudited)

(Expressed in US Dollars and in thousands, except share and per share amounts)

(Prepared in accordance with US GAAP)

	Number of shares	Share capital	Additional paid-in capital	Deficit	Accumulated other comprehensive loss	Total stockholders' equity
Balance, December 31, 2014	22,438,169	\$ 290,004	\$ 26,208 \$	(205,864)	\$ (22,313)	\$ 88,035
Stock-based compensation	-	10,962	3,771	-	` -	14,733
Issuance of common shares						
pursuant to exercise of options	639,557	4,243	(2,568)	-	-	1,675
Issuance of common shares						
pursuant to exercise of warrants	18,750	377	-	-	-	377
Issuance of common shares in conjunction with the						
public offering, net of issuance costs of \$9,700,000	7,500,000	142,177	-	-	-	142,177
Issuance of equity instruments in conjunction with the						
acquisition of Arbutus Inc. (note 3)	23,973,315	380,815	1,127	-	-	381,942
Currency translation adjustment	-	-	-	-	(19,275)	(19,275)
Net loss	-	-	-	(55,857)	-	(55,857)
Balance, September 30, 2015	54,569,791	\$ 828,578	\$ 28,538 \$	(261,721)	\$ (41,588)	\$ 553,807

(formerly Tekmira Pharmaceuticals Corporation)

# **Condensed Consolidated Statements of Cash Flow**

(Unaudited)

(Expressed in US Dollars and in thousands)

(Prepared in accordance with US GAAP)

		Three months September		Nine months e	
		2015	2014	2015	2014
OPERATING ACTIVITIES					
Net loss for the period	\$	(28,982) \$	(8,604) \$	(55,857) \$	(32,669)
Items not involving cash:					
Deferred Income taxes (note 3)		(15,196)	-	(15,196)	-
Depreciation of property and equipment		153	133	420	416
Stock-based compensation - research, development,					
collaborations and contract expenses		2,671	326	5,376	1,966
Stock-based compensation - general and administrative					
expenses		4,832	119	9,357	748
Unrealized foreign exchange (gains) losses		(11,790)	(3,245)	(16,208)	(1,913)
Change in fair value of warrant liability		(1,976)	5,140	(2,777)	12,943
Impairment of intangible assets (note 3)		37,990	-	37,990	-
Net change in non-cash operating items:					
Accounts receivable		4,047	(1,852)	(577)	(2,030)
Accrued revenue		(164)	39	14	51
Deferred expenses		· -	56	-	168
Prepaid expenses and other assets		469	(383)	171	342
Accounts payable and accrued liabilities		2,408	2,357	(2,935)	2,465
Deferred revenue		3,011	(806)	2,054	11,938
		·	, ,	·	
Net cash provided by (used in) operating activities		(2,527)	(6,720)	(38,168)	(5,575)
INVESTING ACTIVITIES					
Disposition (acquisition) of short and long-term investments		(17,144)	(291)	10,275	(43,283)
Cash acquired through acquisition (note 3)		(17,144)	(231)	324	(43,203)
Acquisition of property and equipment		(589)	(152)	(1,113)	(733)
Acquisition of property and equipment		(303)	(132)	(1,113)	(733)
Net cash provided by (used) in investing activities		(17,733)	(443)	9,486	(44,016)
TANANG ACTIVITIES					
FINANCING ACTIVITIES				440.488	E0 488
Proceeds from issuance of common shares, net of issuance costs		-	-	142,177	56,477
Issuance of common shares pursuant to exercise of options		116	268	1,675	2,340
Issuance of common shares pursuant to exercise of warrants		-	416	43	1,390
Martine de la constitució de l		110	C0.4	442.005	CO 207
Net cash provided by financing activities		116	684	143,895	60,207
Effect of foreign exchange rate changes on cash and					
cash equivalents		(E 072)	(611)	<i>(G</i> 211)	(1,156)
Cash equivalents		(5,972)	(611)	(6,311)	(1,150)
Increase in cash and cash equivalents		(26,116)	(7,090)	108,902	9,460
Cash and cash equivalents, beginning of period					
	¢	207,205	85,267	72,187	68,717
Cash and cash equivalents, end of period	\$	181,089 \$	78,177 \$	181,089 \$	78,177
Supplemental cash flow information					
Non-cash transactions:					
Fair value of warrants exercised on a cashless basis		<u>-</u>	_	- \$	(116)
Investment tax credits received		_	- \$	2 <b>4</b>	(110)
Acquisition of Arbutus Inc. excluding cash acquired		_	- \$	381,618	-
requisition of ributus inc. excluding cash acquired		-	- D	301,010	-

(formerly Tekmira Pharmaceuticals Corporation)

Notes to condensed consolidated financial statements

(Unaudited)

(Expressed in US dollars – tabular amounts in thousands)

#### 1. Nature of business and future operations

Arbutus Biopharma Corporation (the "Company" or "Arbutus") is a Canadian biopharmaceutical business dedicated to discovering, developing, and commercializing a cure for patients suffering from chronic hepatitis B infection ("HBV"), a disease of the liver caused by hepatitis B virus ("HBV"). The Company is also developing a pipeline focused on advancing novel RNA interference therapeutics (RNAi) leveraging the Company's expertise in Lipid Nanoparticle ("LNP") technology.

Effective July 31, 2015, the corporate name changed from Tekmira Pharmaceuticals Corporation ("Tekmira") to Arbutus Biopharma Corporation. Also effective July 31, 2015, the corporate name of the wholly-owned subsidiary, OnCore Biopharma, Inc. ("OnCore") changed to Arbutus Biopharma Inc. ("Arbutus Inc."). Including Arbutus Inc., the Company has five wholly-owned subsidiaries: Protiva Biotherapeutics Inc. ("Protiva"), Protiva Biotherapeutics (USA) Inc. ("Protiva USA"), Protiva Agricultural Development Company Inc. ("PADCo"), and Enantigen Therapeutics, Inc. ("Enantigen").

The success of the Company is dependent on obtaining the necessary regulatory approvals to bring its products to market and achieve profitable operations. The continuation of the research and development activities and the commercialization of its products are dependent on the Company's ability to successfully complete these activities and to obtain adequate financing through a combination of financing activities and operations. It is not possible to predict either the outcome of future research and development programs or the Company's ability to continue to fund these programs in the future.

# 2. Significant accounting policies

#### Basis of presentation

These unaudited condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles of the United States of America ("U.S. GAAP") for interim financial statements and accordingly, do not include all disclosures required for annual financial statements. These statements should be read in conjunction with the Company's audited consolidated financial statements and notes thereto for the year ended December 31, 2014 and included in the Company's 2014 annual report on Form 10-K. The unaudited condensed consolidated financial statements reflect, in the opinion of management, all adjustments and reclassifications necessary to present fairly the financial position, results of operations and cash flows at September 30, 2015 and for all periods presented. The results of operations for the three and nine months ended September 30, 2015 and September 30, 2014 are not necessarily indicative of the results for the full year. These condensed consolidated financial statements follow the same significant accounting policies as those described in the notes to the audited consolidated financial statements of the Company for the year ended December 31, 2014, except as described below.

#### **Principles of Consolidation**

These condensed consolidated financial statements include the accounts of the Company and four of its wholly-owned subsidiaries, Arbutus Inc., Protiva, Protiva USA, and Enantigen. All intercompany transactions and balances have been eliminated on consolidation.

The Company records its investment in PADCo using the equity method. The Company has determined that PADCo is a variable interest entity ("VIE") of which it is not the primary beneficiary. The Company is not the primary beneficiary as it does not have the power to make the decisions that most significantly affect the economic performance of the VIE nor does not have the right to receive the benefits or the obligation to absorb losses that in either case could potentially be significant to the VIE. PADCo is described further in note 4(b).

# Replacement awards

Replacement awards are share-based payment awards exchanged for awards held by employees of Arbutus Inc. As part of the Company's acquisition of Arbutus Inc. (formerly OnCore), Arbutus (formerly Tekmira) shares were exchanged for Arbutus Inc.'s shares subject to repurchase rights held by Arbutus Inc.'s employees – see note 3.

As at the date of acquisition of Arbutus Inc., the Company determined the total fair value of replacement awards and attributed a portion of the replacement awards to pre-combination service as part of the total acquisition consideration, and a portion to post-combination service, which is recognized as compensation expense over the expiry period of repurchase provision rights subsequent to the acquisition date.

(formerly Tekmira Pharmaceuticals Corporation)

#### Notes to condensed consolidated financial statements

(Unaudited)

(Expressed in US dollars – tabular amounts in thousands)

The replacement awards consist of common shares that were issued at acquisition. Accordingly, as stock compensation expense related to these awards is recognized, share capital is increased by a corresponding amount.

# Goodwill and intangible assets

The costs incurred in establishing and maintaining patents for intellectual property developed internally are expensed in the period incurred.

Intangible assets consist of in-process research and development arising from the Company's acquisition of Arbutus Inc. – see note 3. In-process research and development (IPR&D) intangible assets are classified as indefinite-lived and are not amortized. IPR&D becomes definite-lived upon the completion or abandonment of the associated research and development efforts. Intangible assets with finite useful lives are amortized on a straight-line basis over their estimated useful lives, which are the respective patent terms. Amortization begins when intangible assets with finite lives are put into use. If there is a major event indicating that the carrying value of intangible assets may be impaired, then management will perform an impairment test and if the carrying value exceeds the recoverable value, based on discounted future cash flows, then such assets are written down to their fair values. Goodwill represents the excess of purchase price over the value assigned to the net tangible and identifiable intangible assets of Arbutus Inc. – see note 3. Goodwill has an indefinite accounting life and is therefore not amortized. Instead, goodwill is subject to a two-step impairment test on an annual basis, unless the Company identifies impairment indicators that would require earlier testing. The first step compares the fair value of the reporting unit to its carrying amount, which includes the goodwill. When the fair value of a reporting unit exceeds its carrying amount, goodwill of the reporting unit is considered not to be impaired, and the second step of the impairment test is unnecessary. If the carrying amount exceeds the implied fair value of the goodwill, the second step measures the amount of the impairment loss. If the carrying amount exceeds the fair value of the goodwill, an impairment loss is recognized equal to that excess.

The Company reviews the recoverable amount of intangible assets on an annual basis, and the annual evaluation for goodwill is performed as of November 30 each year. In addition, the Company evaluates for events or changes in the business that could indicate impairment and earlier testing. Such indicators include, but are not limited to on an ongoing basis: (a) industry and market considerations such as increased competitive environment or adverse change in legal factors including an adverse assessment by regulators; (b) an accumulation of costs significantly in excess of the amount originally expected for the development of the asset; (c) current period operating or cash flow loss combined with a history of operating or cash flow losses or a projection or forecast that demonstrates continuing losses associated with the use of the asset; and (d) if applicable, a sustained decrease in share price.

#### Income or loss per share

Income or loss per share is calculated based on the weighted average number of common shares outstanding. Diluted loss per share does not differ from basic loss per share since the effect of the Company's stock options and warrants is anti-dilutive. Diluted income per share is calculated using the treasury stock method which uses the weighted average number of common shares outstanding during the period and also includes the dilutive effect of potentially issuable common shares from outstanding, in-themoney stock options and warrants. During the nine months ended September 30, 2015, potential common shares of 6,481,295 (September 30, 2014 – 2,356,025) were excluded from the calculation of income per common share because their inclusion would be anti-dilutive, of which 3,625,411 relates to shares issued subject to repurchase provisions as part of consideration paid for the acquisition of Arbutus Inc. – see note 3.

#### Fair value of financial instruments

The Company measures certain financial instruments and other items at fair value.

To determine the fair value, the Company uses the fair value hierarchy for inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the most observable inputs be used when available. Observable inputs are inputs market participants would use to value an asset or liability and are developed based on market data obtained from independent sources. Unobservable inputs are inputs based on assumptions about the factors market participants would use to value an asset or liability. The three levels of inputs that may be used to measure fair value are as follows:

- Level 1 inputs are quoted market prices for identical instruments available in active markets.
- Level 2 inputs are inputs other than quoted prices included within Level 1 that are observable for the asset or liability either directly or indirectly. If the asset or liability has a contractual term, the input must be observable for substantially the full term. An example includes quoted market prices for similar assets or liabilities in active markets.

(formerly Tekmira Pharmaceuticals Corporation)

#### Notes to condensed consolidated financial statements

(Unaudited)

(Expressed in US dollars – tabular amounts in thousands)

• Level 3 inputs are unobservable inputs for the asset or liability and will reflect management's assumptions about market assumptions that would be used to price the asset or liability.

The following tables present information about the Company's assets and liabilities that are measured at fair value on a recurring basis, in thousands, and indicates the fair value hierarchy of the valuation techniques used to determine such fair value:

		Level 1	Level 2		Level 3		September 30, 2015
Assets		20,611	26,612		20,610		5 cptcm5cr 50, <b>2</b> 015
Cash and cash equivalents	\$	181,089	-		_	\$	181,089
Guaranteed investment certificate	•	15,006	-		_	•	15,006
Term deposit		10,041	-		-		10,041
Total	\$	206,136				\$	206,136
Liabilities							
Warrants		_	_	\$	1,495	\$	1,495
Contingent consideration		_	-	\$	6,665	\$	6,665
Financial instrument		_	_	Ψ	-	Ψ	-
Total		_	_	\$	8,160	\$	8,160
10441				Ψ	0,100	Ψ	0,100
		Level 1	Level 2		Level 3		December 31, 2014
Assets							
Cash and cash equivalents	\$	72,187	-		-	\$	72,187
Guaranteed investment certificates		39,974	-		-		39,974
Total	\$	112,161	-		-	\$	112,161
Liabilities							
Warrants		-	-	\$	5,099	\$	5,099
Financial instrument		-	-		-		-
Total		-	-	\$	5,099	\$	5,099

The Company acquired a term deposit in May 2015 with an original maturity of 24 months and it has been classified as a long-term investment on the balance sheet. The Company also acquired a Guaranteed Investment Certificate in August 2015 with an original maturity of 12 months and it has been classified as a short-term investment on the balance sheet. For the period ended September 30, 2015, the fair value of the long-term investment is \$10,041,000, and the fair value of the short-term investment is \$15,006,000 (C\$20,027,000), which include the principal and accrued interest earned as at the balance sheet date.

The Company used a discounted cash flow model to determine the fair value of the financial instrument, related to Monsanto's call option to acquire the equity or all of the assets of PADCo, as described in note 4(b). The fair value was determined at the date of recognition, and at each reporting date. The initial fair value of the financial liability was nil, and there has been no change to its fair value as at September 30, 2015.

Contingent consideration is a liability assumed by the Company from its acquisition of Arbutus Inc. – see notes 3 and 8. The Company used a discounted cash flow model to determine the fair value of the contingent consideration as at the acquisition date, and at each subsequent reporting date. The Company's preliminary estimate of the fair value of the contingent consideration was \$6,665,000 as at September 30, 2015.

(formerly Tekmira Pharmaceuticals Corporation)

#### Notes to condensed consolidated financial statements

(Unaudited)

(Expressed in US dollars – tabular amounts in thousands)

The following table presents the changes in fair value of the Company's warrants, in thousands:

		Opening liability of	Fair value of	Increase		
	Liability at beginning	warrants issued in	warrants exercise	d (decrease) in fair	Foreign exchange	Liability at end
	of the period	the period	in the period	value of warrants	(gain) loss	of the period
Nine months ended September 30, 2014	\$ 5,379	-	\$ (9,260	\$ 12,943	\$ (355)	\$ 8,707
Nine months ended September 30, 2015	\$ 5,099	-	\$ (334	\$ (2,777)	\$ (493)	\$ 1,495

The change in fair value of warrant liability for the nine months ended September 30, 2015 is recorded in the statement of operations and comprehensive loss.

The weighted average Black-Scholes option-pricing assumptions and the resultant fair values, in thousands, for warrants outstanding at September 30, 2015 and at December 31, 2014 are as follows:

	September 30, 2015	December 31, 2014
Dividend yield	0.00%	0.00%
Expected volatility	65.43%	85.22%
Risk-free interest rate	0.52%	1.00%
Expected average term	0.9 years	0.5 years
Fair value of warrants outstanding	\$ 3.94	\$ 12.80
Aggregate fair value of warrants outstanding	\$ 1,495	\$ 5,099
Number of warrants outstanding	379,500	398,250

#### Foreign currency translation and reporting currency

#### **Functional currency**

The functional currency of the Company and its integrated subsidiaries (Protiva and Protiva USA) is the Canadian dollar. Foreign currency monetary assets and liabilities are translated into Canadian dollars at the rate of exchange prevailing at the balance sheet date. Non-monetary assets and liabilities are translated at historical exchange rates. The previous month's average rate of exchange is used to translate revenue and expense transactions. Exchange gains and losses are included in income or loss for the period.

The local currency of Arbutus Inc. (including its subsidiary, Enantigen) is the United States dollars which has been determined to be its functional currency, as it is the currency of the primary economic environment in which Arbutus Inc. operates and expends cash. Foreign currency monetary assets and liabilities are translated into United States dollars at the exchange rate prevailing at the balance sheet date. Non-monetary assets and liabilities are translated at historical exchange rates. The previous month's average rate of exchange is used to translate revenue and expense transactions. Exchange gains and losses are included in income or loss for the period.

#### Reporting currency

The Company is using United States dollars as its reporting currency. All assets and liabilities are translated using the exchange rate at the balance sheet date. Revenues, expenses and other income (losses) are translated using the average rate for the period, except for large transactions, for which the exchange rate on the date of the transaction is used. Equity accounts are translated using the historical rate. The translation differences from the Company's functional currency to the Company's reporting currency of U.S. dollars are unrealized gains and losses; therefore, the differences are recorded in other comprehensive income (loss), and do not impact the calculation of Income or Loss per Share.

(formerly Tekmira Pharmaceuticals Corporation)

#### Notes to condensed consolidated financial statements

(Unaudited)

(Expressed in US dollars – tabular amounts in thousands)

# Recent accounting pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board (FASB) or other standard setting bodies that are adopted by the Company as of the specified effective date. Unless otherwise discussed, the Company believes that the impact of recently issued standards that are not yet effective will not have a material impact on its financial position or results of operations upon adoption.

In September 2015, the FASB issued ASU 2015-16, Business Combinations (Topic 805): Simplifying the Accounting for Measurement-Period Adjustments. The update eliminates the requirement to retrospectively adjust the provisional amounts recognized at the acquisition date with a corresponding adjustment to goodwill during the measurement period when new information is obtained about the facts and circumstances that existed as of the acquisition date, that if known, would have affected the measurement of the amounts initially recognized or would have resulted in the recognition of additional assets or liabilities. The amendments in this update are effective for fiscal years beginning after December 15, 2015, which for the Company means January 1, 2016, and should be applied prospectively to adjustments to provisional amounts that occur after the effective date of this update. Early application permitted for financial statements that have not been issued. The Company does not plan to early adopt this update and is currently assessing the impact of the adoption.

In May 2014, the FASB issued ASU 2014-09, Revenue from Contracts with Customers (ASC 606). The standard is intended to clarify the principles for recognizing revenue and to develop a common revenue standard for U.S. GAAP and IFRS by creating a new Topic 606, Revenue from Contracts with Customers. This guidance supersedes the revenue recognition requirements in ASC 605, Revenue Recognition, and supersedes some cost guidance included in Subtopic 605-35, Revenue Recognition – Construction-Type and Production-Type Contracts. The core principle of the accounting standard is that an entity recognizes revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those good or services. The amendments should be applied by either (1) retrospectively to each prior reporting period presented; or (2) retrospectively with the cumulative effect of initially applying this ASU recognized at the date of initial application. In August 2015, the FASB issued ASU 2015-14, Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date to defer the effective date of Update 2014-09 for all entities by one year. The new guidance would be effective for fiscal years beginning after December 15, 2017, which for the Company means January 1, 2018. Entities are permitted to adopt in accordance with the original effective date if they choose. The Company has not yet determined the extent of the impact of adoption.

In August 2014, the FASB issued ASU 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. The update is intended to provide guidance in GAAP about management's responsibility to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern and to provide related footnote disclosures. Under amendments to GAAP, the assessment period is within one year after the date that the financial statements are issued (or available to be issued). The amendments are effective for the annual period ending after December 15, 2016, which for the Company means January 1, 2017, and for annual periods and interim periods thereafter. Early application is permitted. The Company does not plan to early adopt this update. The extent on the impact of this adoption has not yet been determined.

# 3. Merger with Arbutus Biopharma Inc. (formerly OnCore BioPharma, Inc.)

# (a) Purchase Price Allocation

On January 11, 2015, the Company entered into a Merger Agreement to acquire 100% of the outstanding shares of Arbutus Inc. and its wholly-owned subsidiary, Enantigen (see note 8). Arbutus Inc. was a privately owned U.S. company focused on discovery, development and commercialization of an all-oral cure regimen for patients with HBV. The merger was approved by the Company's shareholders on March 3, 2015 and consummated on March 4, 2015. Arbutus Inc.'s results of operations and fair value of assets acquired and liabilities assumed are included in the Company's consolidated financial statements from the date of acquisition.

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(Unaudited)

(Expressed in US dollars – tabular amounts in thousands)

The transaction has been accounted for using the acquisition method based on ASC 805, Business Combinations, with Arbutus (formerly Tekmira) identified as the acquirer, based on managements' analysis and evaluation of the form of the acquisition, the relative contribution and rights of the predecessor groups post-closing, and the relative number of shares issued by the Company on acquisition of Arbutus Inc. Under the acquisition method, the consideration transferred is measured at fair value; common shares as consideration are issued at the market price as at the acquisition date. The excess of the purchase price over the preliminary fair value assigned to the net assets acquired has been recorded as goodwill. Acquisition costs were expensed as incurred. The Company recorded \$9,656,000 of acquisition costs for the nine-months ended September 30, 2015.

The Company issued consideration with a total fair value of \$381,942,000 on acquisition. Of this consideration, 23,973,315 common shares were issued, which is comprised of 20,347,906 common shares issued without subjects and 3,625,412 common shares issued to Arbutus Inc.'s founding executives and subject to repurchase provisions. The fair value of the common shares issued without subjects has been determined to be the Company's NASDAQ closing price of \$18.26 on the date prior to the acquisition's consummation, March 4, 2015. The total fair value of the common shares issued subject to repurchase provision has been determined to be \$66,196,000, using the Black-Scholes pricing model with assumed risk-free interest rate of 0.74%, volatility of 81%, a zero dividend yield and an expected life of 4 years. Of the total fair value, \$9,262,000 has been attributed as precombination service and included as part of the total acquisition consideration. The post-combination attribution of \$56,934,000 will be recognized as compensation expense over the period of expiry of repurchase provision rights. The Company recorded \$10,962,000 in stock-based compensation expense related to services performed during the period of expiration of repurchase provision rights from the acquisition date through to September 30, 2015. In July 2015, in conjunction with amendments to the employment contracts of Arbutus Inc.'s founding executives, the Company amended the repurchase provision rights period of expiry from August 2018 to August 2017. This amendment results in an acceleration of compensation expense recognized in each subsequent period by approximately \$1,900,000 per quarter, effective in Q3 2015.

As at the acquisition date, 3,625,412 shares were issued and outstanding which were and continue to remain subject to a repurchase provision. Subsequent to the acquisition date and the July 2015 amendment to the repurchase provision rights, the rights expire at a rate of 302,120 on November 30, 2015 and February 29, 2016 and at a rate of 503,552 shares every three months commencing May 31, 2016.

The Company has further reserved 184,332 shares for the future exercise of Arbutus Inc. stock options. The total fair value of Arbutus Inc. stock options at the date of acquisition has been determined to be \$3,287,000, using the Black-Scholes pricing model with an assumed risk-free interest rate of 0.97%, volatility of 78%, a zero dividend yield and an expected life of 8 years, which are consistent with the assumption inputs used by the Company to determine the fair value of its options. Of the total fair value, \$1,127,000 has been attributed as pre-combination service and included as part of the total acquisition consideration. The post-combination attribution of \$2,160,000 will be recognized as compensation expense over the vesting period of the stock options through to December 2018. The Company has included \$330,000 compensation expense related to the vesting of Arbutus Inc. stock options from the acquisition date through to September 30, 2015.

The aggregate fair value of consideration transferred to acquire Arbutus Inc.'s outstanding shares has been determined to be \$381,942,000, and has been attributed to preliminary fair values of assets acquired and liabilities assumed. The Company has refined the preliminary allocation of the purchase price for intangible assets, goodwill, contingent consideration and deferred tax liability from what was disclosed in prior periods. The following table summarizes the Company's purchase price allocation as at September 30, 2015, which remains preliminary as the assessments of the fair value of assets acquired and liabilities assumed are ongoing:

Consideration paid:	
Common shares issued without subjects	\$ 371,553
Common shares issued subject to repurchase provision	9,262
Common shares issuable for Arbutus Inc. stock options	1,127
	\$ 381,942
	 ,
Identifiable assets acquired and liabilities assumed:	
Cash	\$ 324
Prepaid expenses and other assets	116
Accounts receivable	8
Property and equipment	147
Acquired intangible assets	391,591
Goodwill	156,637
Accounts payable and accrued liabilities	(3,580)

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Other noncurrent liabilities (note 8)	(6,665)
Deferred income tax liability	(156,636)
Total purchase price allocation	\$ 381,942

The preliminary fair value of intangible assets is estimated to be \$391,591,000. The fair value of each IPR&D is estimated using the income approach. The income approach uses valuation techniques to discount future economic benefits attributed to the subject intangible asset to a present value. Present value is based on current market expectations about those future amounts and includes management's estimates of risk-adjusted future incremental earnings that may be achieved upon regulatory approval, promotion, and distribution associated with the rights and includes estimated cash flows of approximately 20 years and a discount rate of approximately 13.9%. The identifiable intangible assets acquired consist of in-process research and development (IPR&D) HBV assets, as summarized in the table below:

	\$
IPR&D – Cyclophilins	37,990
IPR&D – Immune Modulators	188,498
IPR&D – Antigen Inhibitors	35,374
IPR&D – cccDNA Sterilizers	129,729
Total IPR&D	\$ 391,591

All IPR&D acquired is currently classified as indefinite-lived and is not currently being amortized. IPR&D becomes definite-lived upon the completion or abandonment of the associated research and development efforts, and will be amortized from that time over an estimated useful life based on respective patent terms. The fair value of each IPR&D asset will continue to be evaluated on a quarterly basis for indicators of impairment.

Based on the preliminary fair values above, an amount of \$156,637,000 has been allocated to goodwill, which represents the excess of the purchase price over the fair values assigned to the net assets acquired. Goodwill is attributable to synergies expected to arise after the Company's acquisition of Arbutus Inc. The full amount of the preliminary value of goodwill has been assigned to the entire Company, since management has determined that the Company has only one reporting unit. The goodwill is not deductible for tax purposes, and is not amortized, but will be evaluated for impairment on an annual basis or more often if the Company identifies impairment indicators that would require earlier testing.

The amount of net loss of Arbutus Inc. included in the consolidated statements of operations from the acquisition date, through the period ended September 30, 2015 was \$9,067,000. Arbutus Inc. did not earn any revenues from the acquisition date through the period ended September 30, 2015.

The following table presents the unaudited pro forma results for the three and nine months ended September 30, 2015 and 2014. The pro forma financial information combines the results of operations of Arbutus, Arbutus Inc., Protiva, Protiva USA, and Enantigen as though the businesses had been combined as of the beginning of fiscal 2014. The pro forma financial information is presented for informational purposes only, and is not indicative of the results of operations that would have been achieved if the merger had taken place at the beginning of fiscal 2014. The pro forma financial information presented includes acquisition costs, amortization charges for acquired tangible assets, estimated impairment charge on acquired intangible assets (as described in note 3b below), but does not include amortization charges for acquired intangible assets as these assets have not yet been put in use.

	Three Months Ended September 30,			Nine Months Ended September 30,			
	2015		2014	2015		2014	
Pro forma information							
Gross Revenue	\$ 4,065	\$	4,362	\$ 12,187	\$	10,603	
Loss from operations	(58,138)		(11,222)	(97,629)		(35,501)	
Net loss	(28,928)		(12,976)	(62,922)		(45,939)	
Basic and diluted loss per share	(0.57)		(0.28)	(1.31)		(1.02)	

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(Unaudited)

(Expressed in US dollars – tabular amounts in thousands)

#### (b) Impairment evaluations for intangible assets and goodwill

As indicated in note 2 above, the Company will evaluate the recoverable amount of intangible assets on an annual basis and perform an annual evaluation of goodwill as of November 30 each year, unless there is an event or change in the business that could indicate impairment and earlier testing.

On October 28, 2015, the Company announced that the development of the cyclophilin drug candidate, OCB-030 has been discontinued. The decision was based on extensive preclinical evaluations performed by the Company of OCB-030 and other competitive cyclophilin inhibitors following the acquisition of Arbutus Inc., which concluded that cyclophilins do not play a meaningful role in HBV biology. Although the final conclusion was made subsequent to the period end, it reflected management's best estimate as at September 30, 2015, and as such, the Company recorded an estimated impairment charge of \$37,990,000 and a corresponding income tax benefit of \$15,196,000 related to the decrease in deferred tax liability for the discontinuance of OCB-030 in the consolidated statement of operations and comprehensive loss. For all other IPR&D, no impairment triggers were identified. The following table summarizes the preliminary carrying values, net of estimated impairment of the intangible assets as at September 30, 2015:

	\$
IPR&D – Cyclophilins	-
IPR&D – Immune Modulators	188,498
IPR&D – Antigen Inhibitors	35,374
IPR&D – cccDNA Sterilizers	129,729
Total IPR&D	\$ 353,601

The Company further determined that in conjunction with the sustained decline in the share price, the estimated impairment on cyclophilins reflect significant changes in the business that would trigger an earlier evaluation of the carrying value of goodwill prior to the annual impairment testing date of November 30. Goodwill was recorded as a result of the acquisition of Arbutus Inc. as described in note 3(a), and has a preliminary carrying value of \$156,637,000. As part of the evaluation of the recoverability of goodwill, the Company has identified only one reporting unit to which the total preliminary carrying amount of goodwill has been assigned. The income approach is used to estimate the fair value of the reporting unit, which requires estimating future cash flows and risk-adjusted discount rates. Changes in these estimates and assumptions could materially affect the determination of fair value of the reporting unit and may result in impairment charges in future periods. As at September 30, 2015, the fair value of the reporting unit exceeded the preliminary carrying value of the reporting unit, and as such the second step of the impairment test, which measures the amount of impairment charge, was not required. In addition to the income approach, the Company considered the market capitalization of approximately \$332,330,000 as at September 30, 2015. Although the Company's carrying value of \$553,807,000 exceeded the market capitalization, the Company reconciled the income approach determination of fair value with the market capitalization by considering macroeconomic factors, and as such, the Company does not believe that market capitalization appropriately reflected the value of the Company for the purpose of testing goodwill impairment in the interim. No impairment charge on goodwill was recorded for the period ended September 30, 2015.

# 4. Collaborations, contracts and licensing agreements

The following tables set forth revenue recognized under collaborations, contracts and licensing agreements, in thousands:

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(Unaudited)

(Expressed in US dollars – tabular amounts in thousands)

	Three months ended September 30		Nine months ended September 30			
	2015		2014	2015		2014
Collaborations and contracts						
DoD (a)	\$ 2,002	\$	1,493	\$ 6,909	\$	5,594
Monsanto (b)	309		283	826		809
BMS (d)	-		1,552	-		1,758
Dicerna (e)	724		250	1,130		250
Total research and development collaborations and contracts	3,035		3,578	8,865		8,411
Licensing fees, milestone and royalty payments						
Monsanto licensing fees and milestone payments (b)	727		730	2,374		1,901
Acuitas milestone payments (c)	-		-	-		150
Dicerna licensing fee (e)	263		-	789		-
Spectrum royalty payments (f)	40		54	159		141
Total licensing fees, milestone and royalty payments	1,030		784	3,322		2,192
Total revenue	\$ 4,065	\$	4,362	\$ 12,187	\$	10,603

The following table sets forth deferred collaborations and contracts revenue:

	September 30, 2015	December 31, 2014
DoD (a)	\$ 57	\$ 313
Monsanto current portion (b)	3,773	4,245
Dicerna current portion (e)	1,005	1,221
Deferred revenue, current portion	4,835	5,779
Monsanto long-term portion (b)	6,446	8,666
Dicerna long-term portion (e)	442	1,271
Total deferred revenue	\$ 11,723	\$ 15,716

#### (a) Contract with United States Government's Department of Defense ("DoD") to develop TKM-Ebola

On July 14, 2010, the Company signed a contract with the DoD to advance TKM-Ebola, an RNAi therapeutic utilizing the Company's lipid nanoparticle technology to treat Ebola virus infection.

In the initial phase of the contract, funded as part of the Transformational Medical Technologies program, the Company was eligible to receive up to \$34,700,000. This initial funding is for the development of TKM-Ebola including completion of preclinical development, filing an Investigational New Drug application with the United States Food and Drug Administration ("FDA") and completing a Phase 1 human safety clinical trial. On May 8, 2013, the Company announced that the contract had been modified to support development plans that integrate recent advancements in lipid nanoparticle ("LNP") formulation and manufacturing technologies. The contract modification increased the stage one targeted funding by an additional \$6,970,000. On April 22, 2014, the Company and the DoD signed a contract modification to further increase the stage one targeted funding by \$2,100,000 to \$43,819,000. The additional funding is to compensate the Company for unrecovered overheads related to the temporary stop-work period that occurred in 2012 and to provide additional overhead funding should it be required. In May 2015, the Company and the DoD signed a contract modification to further increase stage one funding by up to \$1,000,000.

The DoD has the option of extending the contract beyond the initial funding period to support the advancement of TKM-Ebola through to the completion of clinical development and FDA approval. Based on the contract's budget this would provide the Company with up to \$140,000,000 in funding for the entire program. In October 2014, the Company and the DoD exercised an option to add \$7,000,000 for the manufacture of TKM-Ebola-Guinea (the "Ebola-Guinea Amendment"), developed by the Company, targeting the Ebola-Guinea strain responsible for the current outbreak in West Africa.

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(Unaudited)

(Expressed in US dollars – tabular amounts in thousands)

In March 2015, the Company and the DoD signed a contract modification to provide up to \$2,250,000 to fund the Company for TKM- Ebola-Guinea IND submission expenses.

Under the contract, the Company is reimbursed for costs incurred, including an allocation of overhead costs, and is paid an incentive fee. At the beginning of the fiscal year the Company estimates its labor and overhead rates for the year ahead. At the end of the year the actual labor and overhead rates are calculated and revenue is adjusted accordingly. The Company's actual labor and overhead rates will differ from its estimated rates based on actual costs incurred and the proportion of the Company's efforts on contracts and internal products versus indirect activities. Within minimum and maximum collars, the amount of incentive fee the Company can earn under the contract varies based on costs incurred versus budgeted costs. During the contractual period, incentive fee revenue and total costs are impacted by management's estimate and judgments which are continuously reviewed and adjusted as necessary using the cumulative catch-up method. At September 30, 2015, the Company believes it can reliably estimate the final contract costs so has recognized the portion of expected incentive fee which has been earned to date.

On October 1, 2015, the Company received formal notification from the DoD that, due to the unclear development path for TKM-Ebola and TKM-Ebola-Guinea, the Ebola-Guinea Manufacturing and the Ebola-Guinea IND submission statements of work had been terminated, subject to the completion of certain post-termination obligations. The TKM-Ebola portion of the contract is expected to complete before the end of 2015 at which point contract close out procedures will commence.

#### (b) Option and Services Agreements with Monsanto Company ("Monsanto")

On January 13, 2014, the Company and Monsanto signed an Option Agreement and a Services Agreement (together, the "Agreements"). Under the Agreements, Monsanto has an option to obtain a license to use the Company's proprietary delivery technology and related intellectual property for use in agriculture. Over the option period, which is expected to be approximately four years, the Company will provide lipid formulations for Monsanto's research and development activities, and Monsanto will make certain payments to the Company to maintain its option rights. The maximum potential value of the transaction, following the successful completion of milestones, is \$86,200,000.

In May 2015, the arrangement was amended to extend the option period by approximately five months, with payments up to \$2,000,000 for the extension period. From inception of the contract to September 30, 2015, the Company had received \$19,300,000 from Monsanto. The amounts received relate to research services and use of the Company's technology over the option period, and are recognized as revenue on a straight-line basis over the extended option period.

Under the Agreements, the Company has established a wholly-owned subsidiary, PADCo. The Company has determined that PADCo is a variable interest entity ("VIE"); however, Monsanto is the primary beneficiary of the arrangement. PADCo was established to perform research and development activities, which have been funded by Monsanto in return for a call option to acquire the equity or all of the assets of PADCo. At any time during the option period, Monsanto may choose to exercise its option, in which case Monsanto would pay the Company an option exercise fee and would receive a worldwide, exclusive right to use the Company's proprietary delivery technology in the field of agriculture. Monsanto may elect to terminate this option at their discretion. The Company retains all rights to therapeutics uses of all current intellectual property and intellectual property developed under the Agreements. The Company's initial investment is not significant, and has no implied or unfunded commitments and the maximum exposure to loss is limited to the amount of investment in the entity. The Company has included its investment in PADCo in Other Assets. There were no significant assets or liabilities for PADCo as at September 30, 2015. There was no equity income or loss with respect to PADCo recorded for the nine months ended September 30, 2015.

(c) License and collaboration with Alnylam Pharmaceuticals, Inc. ("Alnylam") and Acuitas Therapeutics Inc. ("Acuitas", formerly AlCana Technologies Inc.)

Milestone receipts and payments

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(Unaudited)

(Expressed in US dollars – tabular amounts in thousands)

In the nine months ended September 30, 2014, the Company earned a \$150,000 milestone from Acuitas, subsequent to Acuitas receiving a milestone payment from Alnylam with respect to Alnylam initiating a Phase III trial for ALN-TTR02.

# Arbitration with Alnylam and Ascletis Pharmaceuticals (Hangzhou) Co. Ltd. ("Ascletis")

On June 21, 2013, the Company transferred manufacturing process technology to Ascletis to enable them to produce ALN-VSP, a product candidate licensed to them by Alnylam. The Company believes that under the new licensing agreement with Alnylam, the technology transfer to Ascletis triggers a \$5,000,000 milestone obligation from Alnylam to the Company. However, Alnylam has demanded a declaration that the Company has not yet met its milestone obligations. The Company disputes Alnylam's position. To remedy this dispute, the Company and Alnylam have commenced arbitration proceedings as provided for under the agreement. The hearing date for this arbitration took place in May 2015, and the decision of the arbitrator is pending. The Company has not recorded any revenue in respect of this milestone.

#### (d) Bristol-Myers Squibb ("BMS") collaboration

On May 10, 2010 the Company announced the expansion of its research collaboration with BMS. Under the new agreement, BMS uses small interfering RNA ("siRNA") molecules formulated by the Company in LNP technology to silence target genes of interest. BMS is conducting the preclinical work to validate the function of certain genes and share the data with the Company. The Company could use the preclinical data to develop RNAi therapeutic drugs against the therapeutic targets of interest. The Company received \$3,000,000 from BMS concurrent with the signing of the agreement and recorded the amount as deferred revenue. The Company was required to provide a pre-determined number of LNP batches over the four-year agreement. BMS had a first right to negotiate a licensing agreement on certain RNAi products developed by the Company that evolve from BMS validated gene targets.

Revenue from the May 10, 2010 agreement with BMS was being recognized as the Company produces the related LNP batches.

The revenue earned for the nine months ended September 30, 2014 was related to BMS batches shipped during the period. In August 2014, the agreement expired and both companies' obligations under the agreement ended.

# (e) License and Development and Supply Agreement with Dicerna Pharmaceuticals, Inc. ("Dicerna")

On November 16, 2014, the Company signed a License Agreement and a Development and Supply Agreement (together, the "Agreements") with Dicerna to develop, manufacture, and commercialize products directed to the treatment of Primary Hyperoxaluria 1 ("PH1"). In consideration for the rights granted under the Agreements, Dicerna paid the Company an upfront cash payment of \$2,500,000. The Company is also entitled to receive payments from Dicerna on manufacturing and services provided, as well as further payments with the achievement of development and regulatory milestones of up to \$22,000,000, in aggregate, and potential commercial royalties. Further, under the Agreements, a joint development committee has been established to provide guidance and direction on the progression of the collaboration.

The Company determined the deliverables under the Agreements included the rights granted, participation in the joint development committee, materials manufactured and other services provided, as directed under the joint development committee. The Company has determined that manufacturing services and other services provided have standalone value, as a separate statement of work is executed and invoiced for each manufacturing or service work order. The relative fair values are determined as a batch price or fee is estimated upon the execution of each work order, with actual expenditures charged at comparable market rates with embedded margins on each work order. Manufacturing work orders are invoiced at the time of execution of the work order, at the initiation of manufacture, and at the release of materials. Revenue from service work orders is recognized as the services are performed. The license and participation in the joint development committee have been determined by the Company to not have standalone value due to the uniqueness of the subject matter under the Agreements. Therefore, these deliverables are treated as one unit of accounting and recognized as revenue over the performance period, which the Company has estimated to be approximately 28 months.

The Company believes the development and regulatory milestones are substantive, due to the existence of substantive uncertainty upon the execution of the arrangement, and that the achievement of the development and regulatory events are based, in part, on the Company's performance and the occurrence of a specific outcome resulting from performance. The Company has not received any milestone payments to date.

#### (f) Agreements with Spectrum Pharmaceuticals, Inc. ("Spectrum")

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(Unaudited)

(Expressed in US dollars – tabular amounts in thousands)

On May 6, 2006, the Company signed a number of agreements with Talon Therapeutics, Inc. ("Talon", formerly Hana Biosciences, Inc.) including the grant of worldwide licenses (the "Talon License Agreement") for three of the Company's chemotherapy products, Marqibo®, Alocrest <sup>TM</sup> (Optisomal Vinorelbine) and Brakiva <sup>TM</sup> (Optisomal Topotecan).

On August 9, 2012, the Company announced that Talon had received accelerated approval for Marqibo from the FDA for the treatment of adult patients with Philadelphia chromosome negative acute lymphoblastic leukemia in second or greater relapse or whose disease has progressed following two or more anti-leukemia therapies. Marqibo is a liposomal formulation of the chemotherapy drug vincristine. There are no further milestones related to Marqibo but the Company is eligible to receive total milestone payments of up to \$18,000,000 on Alocrest and Brakiva.

Talon was acquired by Spectrum in July 2013. The acquisition does not affect the terms of the license between Talon and the Company. On September 3, 2013, Spectrum announced that they had shipped the first commercial orders of Marqibo. For the three and nine months ended September 30, 2015, the Company recorded \$40,000 and \$159,000 in Marqibo royalty revenue (three and nine months ended September 30, 2014 - \$54,000 and \$141,000 respectively). For the nine months ended September 30, 2015, the Company accrued 2.5% in royalties due to TPC in respect of the Marqibo royalty earned by the Company – see note 8, contingencies and commitments.

#### 5. Accounts payable and accrued liabilities

Accounts payable and accrued liabilities is comprised of the following, in thousands:

	September 30	ptember 30, 2015		nber 31, 2014
Trade accounts payable	\$	2,898	\$	2,044
Research and development accruals		2,964		2,391
License fee accruals		-		250
Professional fee accruals		336		1,294
Deferred lease inducements		325		250
Payroll accruals		26		2,873
Other accrued liabilities		952		226
	\$	7,501	\$	9.328

#### 6. Financing

On March 25, 2015, the Company announced that it had completed an underwritten public offering of 7,500,000 common shares, at a price of \$20.25 per share, representing gross proceeds of \$151,875,000. The Company also granted the underwriters a 30-day option to purchase an additional 1,125,000 shares for an additional \$22,781,000 to cover any over-allotments. The underwriters did not exercise the option. The cost of financing, including commissions and professional fees, was \$9,700,000, resulting in net proceeds of \$142,177,000.

#### 7. Concentrations of credit risk

Credit risk is defined by the Company as an unexpected loss in cash and earnings if a collaborative partner is unable to pay its obligations in due time. The Company's main source of credit risk is related to its accounts receivable balance which principally represents temporary financing provided to collaborative partners in the normal course of operations.

The Company does not currently maintain a provision for bad debts as the majority of accounts receivable are from collaborative partners or government agencies and are considered low risk.

The carrying amount of financial assets represents the maximum credit exposure. The maximum exposure to credit risk at September 30, 2015 was the accounts receivable balance of \$2,192,000 (December 31, 2014 - \$1,903,000).

All accounts receivable balances were current as at September 30, 2015 and at December 31, 2014.

#### 8. Contingencies and commitments

Product development partnership with the Canadian Government

(formerly Tekmira Pharmaceuticals Corporation)

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(Unaudited)

(Expressed in US dollars – tabular amounts in thousands)

The Company entered into a Technology Partnerships Canada ("TPC") agreement with the Canadian Federal Government on November 12, 1999. Under this agreement, TPC agreed to fund 27% of the costs incurred by the Company, prior to March 31, 2004, in the development of certain oligonucleotide product candidates up to a maximum contribution from TPC of \$7,179,000 (C\$9,323,000). As at September 30, 2015, a cumulative contribution of \$2,774,000 (C\$3,702,000) has been received and the Company does not expect any further funding under this agreement. In return for the funding provided by TPC, the Company agreed to pay royalties on the share of future licensing and product revenue, if any, that is received by the Company on certain non-siRNA oligonucleotide product candidates covered by the funding under the agreement. These royalties are payable until a certain cumulative payment amount is achieved or until a pre-specified date. In addition, until a cumulative amount equal to the funding actually received under the agreement has been paid to TPC, the Company agreed to pay 2.5% royalties on any royalties the Company receives for Marqibo. For the three and nine months ended September 30, 2015, the Company earned royalties on Marqibo sales in the amount of \$40,000 and \$159,000 respectively (three and nine months ended September 30, 2014 – \$54,000 and \$141,000 respectively) (see note 4(f)), resulting in \$4,000 being recorded by the Company as royalty payable to TPC (September 30, 2014 - \$4,000). The cumulative amount paid or accrued up to September 30, 2015 was \$10,000, resulting in the contingent amount due to TPC being \$2,765,000 (C\$3,690,000).

#### License agreement with Marina Biotech, Inc. ("Marina")

On November 29, 2012 the Company announced a worldwide, non-exclusive license to a novel RNAi payload technology called Unlocked Nucleobase Analog ("UNA") from Marina for the development of RNAi therapeutics.

UNA technology can be used in the development of RNAi therapeutics, which treats disease by silencing specific disease causing genes. UNAs can be incorporated into RNAi drugs and have the potential to improve them by increasing their stability and reducing off-target effects.

Under the license agreement the Company paid Marina an upfront fee of \$300,000 during the year ended December 31, 2012. A further license payment of \$200,000 was paid in 2013 and the Company will make milestone payments of up to \$3,250,000 and royalties on each product developed by the Company that uses Marina's UNA technology. The payments to Marina are expensed to research, development, collaborations and contracts expense.

Effective August 9, 2013, Marina's UNA technology was acquired by Arcturus Therapeutics, Inc. ("Arcturus") and the UNA license agreement between the Company and Marina was assigned to Arcturus. The terms of the license are otherwise unchanged. On December 22, 2014, the Company received clearance from Health Canada to conduct a Phase I Clinical Study with TKM-HBV, which utilizes Arcturus' UNA technology. This triggered the accrual of \$250,000 as at December 31, 2014 related to the milestone payable to Arcturus upon the dosing of first subject in a Phase I clinical trial of TKM-HBV, which occurred and was paid by the Company in January 2015.

# Arbitration with the University of British Columbia ("UBC")

Certain early work on lipid nanoparticle delivery systems and related inventions was undertaken at UBC. These inventions are licensed to the Company by UBC under a license agreement, initially entered in 1998 as amended in 2001, 2006 and 2007. The Company has granted sublicenses under the UBC license to Alnylam as well as to Spectrum. Alnylam has in turn sublicensed back to the Company under the licensed UBC patents for discovery, development and commercialization of RNAi products. In 2009, the Company entered into a supplemental agreement with UBC, Alnylam and Acuitas, in relation to a separate research collaboration to be conducted among UBC, Alnylam and Acuitas to which the Company has license rights. The settlement agreement signed in late 2012 to resolve the litigation among the Company, Alnylam, and Acuitas, provided for the effective termination of all obligations under such supplemental agreement as between and among all litigants.

On November 10, 2014, UBC filed a notice of arbitration against the Company and on January 16, 2015, filed a Statement of Claim, which alleges entitlement to \$3,500,000 in allegedly unpaid royalties based on publicly available information, and an unspecified amount based on non-public information. UBC also seeks interest and costs, including legal fees. The Company is currently disputing UBC's allegations, and no dates have been scheduled for this arbitration. The Company has not recorded an estimate of the possible loss associated with this arbitration, due to the uncertainties related to both the likelihood and amount of any possible loss or range of loss. Costs related to the arbitration have been recorded by the Company as incurred.

(formerly Tekmira Pharmaceuticals Corporation)

#### Notes to condensed consolidated financial statements

(Unaudited)

(Expressed in US dollars – tabular amounts in thousands)

# Contingent consideration from Arbutus Inc. acquisition of Enantigen and License Agreements between Enantigen and the Baruch S. Blumberg Institute ("Blumberg") and Drexel University ("Drexel")

In October 2014, Arbutus Inc. acquired all of the outstanding shares of Enantigen pursuant to a stock purchase agreement. Through this transaction, Arbutus Inc. acquired a HBV surface antigen secretion inhibitor program and a capsid assembly inhibitor program, each of which are now assets of Arbutus, following the Company's merger with Arbutus Inc. – see note 3.

Under the stock purchase agreement, Arbutus Inc. agreed to pay up to a total of \$21,000,000 to Enantigen's selling stockholders upon the achievement of certain triggering events related to Enantigen's two programs in pre-clinical development related to HBV therapies, as well as \$102.5 million to Enantigen's selling stockholders upon the achievement of certain development milestones and sales performance milestones, respectively. The first triggering event is the enrollment of first patient in Phase 1b clinical trial in HBV patients, which the Company does not expect to occur in the next twelve-month period.

The regulatory, development and sales milestone payments have an estimated fair value of approximately \$6,665,000 as at the date of acquisition of Arbutus Inc., and have been treated as contingent consideration payable in the purchase price allocation (note 3), based on information available at the date of acquisition, using a probability weighted assessment of the likelihood the milestones would be met and the estimated timing of such payments, and then the potential contingent payments were discounted to their present value using a probability adjusted discount rate that reflects the early stage nature of the development program, time to complete the program development, and overall biotech indices.

As part of its acquisition of Arbutus Inc. on March 4, 2015 as described in note 3, the other non-current liabilities assumed by the Company included the contingent consideration of \$6,665,000 related to Arbutus Inc.'s acquisition of Enantigen. Contingent consideration is considered as a financial liability, and the Company determines its fair value at each reporting period with any changes in fair value from the previous reporting period recorded in the statement of operations and comprehensive loss. The Company is currently undertaking valuation assessments of assets acquired and liabilities assumed from Arbutus Inc., which includes a valuation assessment of the contingent consideration. No change to the fair value of the contingent consideration has been recorded for the three and nine-months ended September 30, 2015.

#### **Drexel and Blumberg**

In February 2014, Arbutus Inc. entered into a license agreement with Blumberg and Drexel that granted an exclusive, worldwide, sub-licensable license to three different compound series: cccDNA inhibitors, capsid assembly inhibitors and HCC inhibitors.

In partial consideration for this license, Arbutus Inc. paid a license initiation fee of \$150,000 and issued warrants to Blumberg and Drexel. The warrants were exercised prior to the Company's acquisition of Arbutus Inc. Under this license agreement, Arbutus Inc. also agreed to pay up to \$3,500,000 in development and regulatory milestones per licensed compound series, up to \$92,500,000 in sales performance milestones per licensed product, and royalties in the mid-single digits based upon the proportionate net sales of licensed products in any commercialized combination. The Company is obligated to pay Blumberg and Drexel a double digit percentage of all amounts received from the sub-licensees, subject to customary exclusions.

In November 2014, Arbutus Inc. entered into an additional license agreement with Blumberg and Drexel pursuant to which it received an exclusive, worldwide, sub-licensable license under specified patents and know-how controlled by Blumberg and Drexel covering epigenetic modifiers of cccDNA and STING agonists. In consideration for these exclusive licenses, Arbutus Inc. made an upfront payment of \$50,000. Under this agreement, the Company will be required to pay up to \$1,000,000 for each licensed product upon the achievement of a specified regulatory milestone and a low single digit royalty, based upon the proportionate net sales of compounds covered by this intellectual property in any commercialized combination. The Company is also obligated to pay Blumberg and Drexel a double digit percentage of all amounts received from its sub-licensees, subject to exclusions.

# Research Collaboration and Funding Agreement with Blumberg

In October 2014, Arbutus Inc. entered into a research collaboration and funding agreement with Blumberg under which the Company will provide \$1,000,000 per year of research funding for three years, renewable at the Company's option for an additional three years, for Blumberg to conduct research projects in HBV and liver cancer pursuant to a research plan to be agreed upon by the parties. Blumberg has exclusivity obligations to Arbutus with respect to HBV research funded under the agreement. In addition, the Company has the right to match any third party offer to fund HBV research that falls outside the scope of the research being funded under the agreement. Blumberg has granted the Company the right to obtain an exclusive, royalty bearing, worldwide license to any intellectual property generated by any funded research project. If the Company elects to exercise its right to obtain such a license, the Company will have a specified period of time to negotiate and enter into a mutually agreeable license agreement with Blumberg. This license agreement will include the following pre negotiated upfront, milestone and royalty payments: an upfront payment in the amount of \$100,000; up to \$8,100,000 upon the achievement of specified development and regulatory milestones; up to \$92,500,000 upon the achievement of specified commercialization milestones; and royalties at a low single to mid-single digit rates based upon the proportionate net sales of licensed products from any commercialized combination.

(formerly Tekmira Pharmaceuticals Corporation)

#### Notes to condensed consolidated financial statements

(Unaudited)

(Expressed in US dollars – tabular amounts in thousands)

#### NeuroVive Pharmaceutical AB ("NeuroVive")

In September 2014, Arbutus Inc. entered into a license agreement with NeuroVive that granted them an exclusive, worldwide, sublicensable license to develop, manufacture and commercialize, for the treatment of HBV, oral dosage form sanglifehrin based cyclophilin inhibitors (including OCB-030). Under this license agreement, the Company has been granted a non-exclusive, royalty free right and license and right of reference to NeuroVive's relevant regulatory approvals and filings for the sole purpose of developing, manufacturing and commercializing licensed products for the treatment of HBV. Under this license agreement, the Company has (1) an option to expand its exclusive license to include treatment of viral diseases other than HBV and (2) an option, exercisable upon specified conditions, to expand its exclusive license to include development, manufacture and commercialization of non-oral variations of licensed products for treatment of viral diseases other than HBV. NeuroVive retains all rights with respect to development, manufacture and commercialization of licensed products and non-oral variations of licensed products for all indications (other than HBV) for which the Company has not exercised its option.

In partial consideration for this license, Arbutus Inc. paid NeuroVive a license fee of \$1 million. As described in note 3 above, Arbutus Inc. became our wholly owned subsidiary by way of a Merger Agreement, which does not trigger any milestone payments. We have conducted significant research and analysis on the NeuroVive Product, OCB-030. Based on this research and analysis, we have decided to discontinue the OCB-030 development program. Otherwise, the license agreement and ongoing relationship with NeuroVive remains in full effect at this time.

# Cytos Biotechnology Ltd ("Cytos")

On December 30, 2014, Arbutus Inc. entered into an exclusive, worldwide, sub-licensable (subject to certain restrictions with respect to licensed viral infections other than hepatitis) license to six different series of compounds. The licensed compounds are Qbeta-derived virus-like particles that encapsulate TLR9, TLR7 or RIG-I agonists and may or may not be conjugated with antigens from the hepatitis virus or other licensed viruses. The Company has an option to expand this license to include additional viral infections other than influenza and Cytos will retain all rights for influenza, all non-viral infections, and all viral infections (other than hepatitis) for which it has not exercised its option.

In partial consideration for this license, the Company is obligated to pay Cytos up to a total of \$67,000,000 for each of the six licensed compound series upon the achievement of specified development and regulatory milestones; for hepatitis and each additional licensed viral infection, up to a total of \$110,000,000 upon the achievement of specified sales performance milestones; and tiered royalty payments in the high-single to low-double digits, based upon the proportionate net sales of licensed products in any commercialized combination.

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

You should read the following discussion and analysis by our management of our financial position and results of operations in conjunction with our audited consolidated financial statements and related notes thereto included as part of our Annual Report on Form 10-K for the year ended December 31, 2014 and our unaudited condensed consolidated financial statements for the three and nine month periods ended September 30, 2015. Our consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles and are presented in U.S. dollars.

#### FORWARD-LOOKING STATEMENTS

The information in this report contains forward-looking information and forward-looking statements (collectively, forward-looking statements) within the meaning of applicable securities laws. Forward-looking statements in this report include statements about our strategy, future operations, clinical trials, prospects and the plans of management; the discovery, development and commercialization of a cure for HBV; our beliefs and development path and strategy to achieve a cure for HBV; the formation of a discrete business unit to manage, develop and maximize the value of our non-HBV assets (including new product development and partnering opportunities) and the independent financing of the discrete business unit; our intention to conduct a rolling Phase II clinical program for HBV (using an iterative process of combination drug candidates), the use of results from this program to design additional treatment regimens for next cohorts and to conduct a Phase III clinical trial intended to ultimately support regulatory filings for marketing approval; our intention to continue expanding our HBV pipeline through internal development, acquisitions and in-licenses; plans to progress lead pipeline candidate TKM-HBV into a multi-dose Phase II study in HBV infected patients by year-end, pending confirmation from the relevant regulatory authorities, with HBsAg reduction results expected to be reported in 2016; expectations to file an IND (or equivalent filing) for a cccDNA formation inhibitor in 2016, with a plan to include the molecule in combination studies in 2017; expectations for filing an IND with the FDA, or equivalent filing with foreign regulatory authorities, for two core protein inhibitors as oral therapeutics for the treatment of chronic HBV infection and initiating clinical development of one of these compounds in 2016; plans to start clinical development of CYT003 in 2016, in time to enable inclusion of the molecule in combination studies in early 2017; discontinuing development of OCB-030 and suspending interest in the cyclophilin inhibitor class; the research benefits of the collaboration with The Baruch S. Blumberg Institute, including expansion of our HBV pipeline through internal development, acquisitions and in-licenses; our belief in the significant value of our non-HBV assets and the maximization of these asset values; our expanded Phase I/II clinical trial with TKM-PLK1; partnering or external funding opportunities to maximize Ebola assets, TKM-Marburg, TKM-HTG, TKM-ALDH; the effects of our products on the treatment of chronic Hepatitis B infection, cancer, infectious disease, alcohol use disorder, and other diseases; the potential of RNAi to generate a new class of therapies; our RNAi pipeline and the advancement thereof with a focus on realizing the value of these assets; new product development and partnering opportunities in LNP technology; the expected efficacy of our various HBV therapies; our continued commitment to its non-HBV assets, both clinical and preclinical, and realization of value for these non-HBV assets; the quantum and triggering of payments to our partners, including payments to Dicerna, Cytos, Blumberg, Drexel, Enantigen's selling stockholders and NeuroVive; future changes in the fair value of our warrant liability; the expected return from strategic alliances, licensing agreements, and research collaborations, such as the potential value of a transaction with Monsanto Company; our intent to retain earnings, if any, to finance the growth and development of their business and not to pay dividends or to make any other distributions in the near future; arbitration proceedings with Alnylam Pharmaceuticals, Inc. in connection with ALN-VSP; arbitration proceedings with the University of British Columbia in connection with alleged unpaid royalties; anticipated royalty receipts; statements with respect to revenue and expense fluctuation and quidance; and the quantum and timing of potential funding.

With respect to the forward-looking statements contained in this report, we have made numerous assumptions regarding, among other things: LNP's status as a leading RNAi delivery technology; our research and development capabilities and resources; the effectiveness of our products as a treatment for chronic Hepatitis B infection, cancer, infectious disease, alcohol use disorder, or other diseases; the timing and quantum of payments to be received under contracts with our partners including Alnylam, Spectrum and Monsanto; assumptions related to our share price volatility, expected lives of warrants and warrant issuances and/or exercises; and our financial position and its ability to execute its business strategy. While we consider these assumptions to be reasonable, these assumptions are inherently subject to significant business, economic, competitive, market and social uncertainties and contingencies.

Our actual results could differ materially from those discussed in the forward-looking statements as a result of a number of important factors, including the risk factors discussed in this report and the risk factors discussed in our Annual Report on Form 10-K under the heading "Risk Factors," and the risks discussed in our other filings with the Securities and Exchange Commission and Canadian Securities Regulators. Readers are cautioned not to place undue reliance on these forward-looking statements, which reflect management's analysis, judgment, belief or expectation only as of the date hereof. We explicitly disclaim any obligation to update these forward-looking statements to reflect events or circumstances that arise after the date hereof, except as required by law.

#### **OVERVIEW**

Arbutus Biopharma Corporation ("Arbutus", "we", "us", and "our") is a publicly traded industry-leading therapeutic solutions company focused on discovering, developing and commercializing a cure for patients suffering from chronic hepatitis B (HBV) infection, a disease of the liver caused by hepatitis B. Effective July 31, 2015, our corporate name changed from Tekmira Pharmaceuticals Corporation to Arbutus Biopharma Corporation. Also effective July 31, 2015, the corporate name of our wholly owned subsidiary, OnCore Biopharma, Inc. changed to Arbutus Biopharma Inc. ("Arbutus Inc."). Including Arbutus Inc., we have four wholly owned subsidiaries: Protiva Biotherapeutics Inc. ("Protiva"), Protiva Agricultural Development Company Inc. ("PADCo"), and Protiva Biotherapeutics (USA) Inc. ("Protiva USA"). Unless stated otherwise or the context otherwise requires, references herein to "Arbutus", "we", "us" and "our" refer to Arbutus Biopharma Corporation, and, unless the context requires otherwise, one or more subsidiaries through which we conduct business.

In March of 2015, we completed a merger whereby Arbutus Inc. became our wholly owned subsidiary. The transaction was approved by 99.5% of votes cast by our shareholders voting at a Special Meeting held on Tuesday, March 3, 2015, and representing 51.2% of our common shareholders. In connection with the transaction, we issued 23,973,315 common shares to the shareholders of Arbutus Inc. in exchange for their Arbutus Inc. securities, and Arbutus Inc. became our wholly-owned subsidiary.

Together with our subsidiaries, we have an industry leading pipeline focused on finding a cure for chronic HBV infection. This HBV pipeline consists of multiple drug candidates, with complementary mechanisms of action. We believe that direct-acting antiviral drugs such as TKM-HBV, cccDNA formation inhibitors and core protein/capsid assembly inhibitors represent the most important approaches with the highest probability of contributing to a cure. As a result, we have prioritized and accelerated development of our direct acting antiviral product candidates including our cccDNA formation inhibitors and core protein/capsid assembly inhibitors.

We believe combination therapies are the key to HBV treatment and a potential cure, and development can be accelerated when multiple components of a combination therapy regimen are controlled by the same company. This is why, together with our subsidiaries, [we have retained exclusive worldwide development and commercialization rights to all of our drug candidates and programs in HBV].

Arbutus is also recognized as a world leader in RNA interference (RNAi) delivery technology. We have focused on advancing novel RNAi-based therapeutics. RNA interference is considered one of the most important discoveries in the field of biomedical science in the last decade. RNAi has the potential to generate a new class of therapies that take advantage of the body's own natural processes to silence genes and, by extension, treat serious human diseases that often rely on the production of certain proteins at the genetic level. With this ability to eliminate disease-causing proteins from cells, RNAi therapies represent opportunities for therapeutic intervention that have not been achievable with conventional therapeutics.

In addition to our HBV pipeline, we also have an RNAi product pipeline which is focused on antivirals, oncology and metabolic product platforms, in areas where there is a significant medical need and commercial opportunity. Our proprietary lipid nanoparticle (LNP) Delivery Platform allows for the delivery of RNAi drugs. Encapsulation of the RNAi trigger molecules using our LNP technology enables efficient delivery and uptake into target cells. Our LNP technology represents the most widely adopted delivery method in RNAi and has been administered to hundreds of patients.

We have formed a business unit to manage, develop and maximize the value of our non-HBV assets. This business unit will support current and potential collaborations and partnerships, and includes preclinical RNAi product candidates, intellectual property and related know how of the LNP delivery technology platform and strategic partnerships exploiting the LNP technology. Ongoing technology development efforts conducted will benefit the LNP delivery platform and can support future product development efforts including potential future generations of TKM-HBV. Because LNP can enable a wide variety of nucleic acid triggers, including mRNA, we continue to seek new product development and partnering opportunities based on what we believe is our industry-leading delivery expertise.

We remain committed to continuing to support the work of our product development partners and intellectual property licensees with the goal of realizing the short-term and long-term financial potential of these partnerships.

#### Voluntary Delisting from the Toronto Stock Exchange (TSX) and NASDAQ Ticker Change.

Our common shares were voluntarily delisted from the Toronto Stock Exchange ("TSX") as of the close of business on Tuesday, March 3, 2015. Prior to the voluntary delisting, our common shares traded on the TSX under the symbol "TKM". We continue to be listed on the NASDAQ. In conjunction with our name change to Arbutus Biopharma Corporation our ticker symbol was changed to "ABUS" on August 3, 2015.

# **Public Offering of Common Shares**

On March 25, 2015, we completed an underwritten public offering of 7.5 million common shares at a price of US\$20.25 per share for aggregate gross proceeds of US\$151.9 million before deducting underwriting discounts and commissions and other offering expenses.

#### **Our Product Candidates**

We have what we believe is an industry-leading pipeline focused on curing HBV. Our belief is that to achieve an HBV cure, a combination of products that affect the main drivers of HBV need to be utilized. Specifically, this means that to be successful, we believe we need to have products that address HBV persistence and include antiviral, host cell and immune targets.

Once multiple compounds within the portfolio with sufficient anti-HBV activity and safety have been identified, we intend, subject to discussions with regulatory authorities, to conduct a rolling Phase II clinical program. These studies will likely evaluate combinations of two or more drug candidates in small cohorts of patients with chronic HBV infection to identify active combinations and those that do not have sufficient antiviral activity. We also plan to evaluate different treatment durations to determine the optimal duration for a finite duration therapy. We expect to use these results to design additional treatment regimens for the next cohorts. We plan to continue this iterative process until we select combination therapy regimens and treatment durations to conduct Phase III clinical trials intended to ultimately support regulatory filings for marketing approval.

We intend to continue to expand our HBV pipeline through internal development, acquisitions and in-licenses. We believe that a major engine for internal innovation is our collaboration with The Baruch S. Blumberg Institute ("Blumberg"), one of the leading non-profit research institutes in the world focused on HBV. The Baruch S. Blumberg Institute was established in 2003 by the Hepatitis B Foundation. We believe that this collaboration will provide us with access to cutting-edge research in new target identification, assay development, mechanism of action studies and lead generation efforts focused on hepatitis B virus. This relationship also provides us with access to research that we believe is equal to, or surpasses that of other biotechnology or pharmaceutical companies, and can add value to our current and future R&D efforts in HBV.

#### **HBV Product Pipeline**

#### **TKM-HBV**

HBV causes the most common serious liver infection in the world. The Hepatitis B Foundation estimates that 400 million people worldwide are chronically infected with the virus, and other estimates suggest this could include up to 1.4 million people in the United States. Individuals chronically infected with HBV are at an increased risk of developing significant liver disease, including cirrhosis, or permanent scarring of the liver, as well as liver failure and hepatocellular carcinoma (HCC) or liver cancer. According to the Hepatitis B Foundation, HBV is the cause of up to 80% of liver cancers. Individuals with liver cancer typically have a five-year survival rate of about 15%. The WHO estimates that an estimated 1 million people die every year due to the consequences of hepatitis B infection.

Our extensive experience in antiviral drug development has been applied to our TKM-HBV program to develop an RNAi therapeutic for chronic hepatitis B infection. Small molecule nucleotide therapy has been the standard of care for chronic HBV infected patients. However, many of these patients continue to express a viral protein called HBV surface antigen (HBsAg). This protein causes inflammation in the liver leading to cirrhosis and, in some cases, hepatocellular carcinoma (HCC) and death.

TKM-HBV is designed to address an unmet medical need and reduce HBsAg expression in patients chronically infected with HBV. Reducing HBsAg is thought to be a key prerequisite to enable a patient's immune system to raise an adequate immune response against the virus. The ability of TKM-HBV to inhibit numerous viral elements in addition to HBsAg increases the likelihood of successfully controlling the viral infection.

TKM-HBV is being developed as a RNAi therapeutic that simultaneously targets three sites on the HBV genome. Targeting three distinct and highly conserved sites on the HBV genome is intended to facilitate potent knockdown of all viral messenger RNA (mRNA) transcripts and viral antigens across a broad range of HBV genotypes (pan-genotypic activity). All three triggers used in TKM-HBV target the HBsAg mRNAs.

TKM-HBV results in potent and rapid reduction in HBsAg in several preclinical models. In these models, TKM-HBV treatment resulted in reductions in both intrahepatic and serum HBsAg, as well as reductions in HBV DNA, cccDNA, Hepatitis B e antigen (HBeAg) and HBcAg (Hepatitis B c antigen). A rapid 1 log reduction in serum HBsAg was achieved with a single 1 mg/kg dose of TKM-HBV in the humanized mouse model. 1-2 log viral reductions from similar single-dose LNP treatments in two other true-infection animal models were also demonstrated. This data was presented at the DIA/FDA Oligonucleotide-Based Therapeutics Conference in Washington, DC, on September 9, 2015. We presented additional data at the 2015 International Meeting on Molecular Biology of Hepatitis B Viruses in Dolce Bad Nauheim, Germany, on October 6-7, 2015, and plan to present at the upcoming 2015 AASLD Liver Meeting in San Francisco, on November 13-17, 2015.

Preclinical studies conducted on infected primary human hepatocytes showed that TKM-HBV had robust and consistent activity against different viral strains representing the major clinical genotypes A, B, C and D. Our data shows that inclusion of three RNAi triggers results in a more broadly effective knockdown of hepatitis B viral elements than a single trigger alone. The mode of action of TKM-HBV complements standard of care nucleoside/nucleotide (NUC) therapy, and lack of drug antagonism has been demonstrated with entecavir, lamivudine and tenofovir on infected primary human hepatocytes, making combination therapy a viable option.

Our data supports the utility of TKM-HBV as a potential new therapeutic option for treating patients with chronic HBV infection. In early 2015, we advanced two TKM-HBV product candidates into a Phase I trial. Both product candidates employ the same unique combination of three RNAi trigger molecules. However, they differ in their LNP composition. One formulation employs a third generation LNP, and the other employs a new, fourth generation LNP, which incorporates novel lipid chemistry and demonstrates improved potency in preclinical studies.

The TKM-HBV Phase I clinical trial is a randomized, single-blind, placebo-controlled study, involving single ascending doses of TKM-HBV. The study is assessing the safety, tolerability and pharmacokinetics of intravenous administration of two LNP formulations (third and fourth generation) of TKM-HBV in healthy adult subjects. In order to enable maximum TKM-HBV dose escalation, steroid premedication was added to the Phase I protocol. No dose limiting toxicities were seen with either formulation through 0.4mg/kg, the highest dose tested in Phase I. At this time, a maximum tolerated dose has not been reached and evaluation of higher doses is under consideration.

Our ongoing TKM-PLK1 HCC study has enrolled patients with chronic HBV infection. These patients are maintained on nucleoside therapy throughout the HCC study treatment to control their HBV DNA levels. Based on preliminary data we have seen no evidence that these patients have experienced an exacerbation of their HBV when receiving steroid premedication with each of their weekly doses of TKM-PLK1.

TKM-HBV is progressing to a Phase II multi-dosing study in HBV infected patients based on results to date from a Phase I single ascending dose study. Pending confirmation from the relevant regulatory authorities, the Phase II study will evaluate two dose levels of TKM-HBV administered as three monthly doses in chronic HBV infected patients who are on stable background nucleot(s)ide analog therapy. In the proposed protocol, eight subjects will be enrolled in each of the two dose cohorts with six subjects receiving TKM-HBV, and two receiving placebo. Dosing in this study is expected to begin by year-end. We anticipate results from this Phase II trial in 2016.

#### cccDNA Formation Inhibitors

We are developing small molecule cccDNA formation inhibitors. The inhibition of cccDNA formation is expected to reduce the amount of cccDNA in the infected liver cell. We acquired the exclusive, worldwide rights to this program through an in-license from Blumberg. We have made significant progress with the discovery of potent and small molecule cccDNA formation inhibitors. As presented at the 2015 International Meeting on Molecular Biology of Hepatitis B Viruses in October 2015, our cccDNA formation inhibitors demonstrate synergy with approved nucleot(s)ide analogs in preclinical models, which could lead to faster declines in cccDNA levels in patients than is seen with nucleot(s)ide analogs alone. We plan to file an IND (or equivalent filing) for a cccDNA formation inhibitor in 2016, and plan to include the molecule in combination studies in 2017.

#### Core Protein/ Capsid Assembly Inhibitors

HBV core protein, or capsid, is required for viral replication and core protein may have additional roles in cccDNA function. Current nucleot(s)side analog therapy significantly reduces serum HBV DNA levels in the serum but significant HBV replication continues in the liver, thereby enabling HBV infection to persist. Effective therapy for patients requires new agents which will effectively block viral replication. We are developing two core protein inhibitors (also known as capsid assembly inhibitors) as oral therapeutics for the treatment of chronic HBV infection. By inhibiting assembly of the viral capsid, the ability of hepatitis B virus to replicate is impaired, resulting in reduced cccDNA. We acquired exclusive, worldwide rights to these drug candidates through an in-license from Blumberg and Drexel University, or ("Drexel"), and through Arbutus Inc.'s recent acquisition of Enantigen Therapeutics, Inc. ("Enantigen"). We expect to file an IND with the FDA, or an equivalent filing with foreign regulatory authorities, and initiate clinical development of one of these compounds in 2016.

#### TLR9 Agonist (CYT003)

Pharmaceutical activation of toll-like receptors (TLRs) is a novel and attractive approach for the treatment of chronic HBV because agonism of these receptors triggers innate immune responses and also stimulates adaptive immunity. It is hoped that immune stimulation by TLR agonists can overcome the immunologic blocks that allow chronic HBV persistence, including direct activation of the host's innate antiviral response, to overcome the functional weakness in HBV-specific immune cell responses.

Licensed from Cytos Biotechnology Ltd., ("Cytos"), CYT003 is a biological carrier which is filled with the immunostimulatory oligonucleotide called G10. G10 a toll-like receptor-9 (TLR-9) agonist. CYT003 has been shown to directly activate B cells and stimulates human (plasmacytoid dendritic cells) pDC to secrete Interferon alpha. CYT003 also activates other antigen presenting cells indirectly and promotes the development of TH1 type cytokine response. This is thought to be potentially beneficial in promoting anti-HBV T cell immunity. CYT003 has previously been utilized in human trials in other indications and therefore could move quickly into the clinic in HBV infected patients. We plan to start clinical development of CYT003 in 2016 to enable inclusion of this molecule in combination studies in early 2017.

#### **Surface Antigen Secretion Inhibitors**

We are developing multiple small molecule orally bioavailable HBV surface antigen secretion inhibitors. By inhibiting the secretion of HBV surface antigen from infected cells, we expect that the immune response of patients treated with this therapy can re-engage and thereby mount a more robust response to a hepatitis B virus infection. We acquired these drug candidates from Enantigen.

#### cccDNA Epigenetic Modifiers

In addition to cccDNA formation inhibitors, we are developing cccDNA epigenetic modifiers. By controlling cccDNA transcription, we anticipate that we may be able to inhibit the formation of new virus and sub viral particles from cccDNA. This development program, which is currently in the discovery research stage, is based on proof of concept data generated by Blumberg using known inhibitors of enzymes involved in DNA information processing.

#### Cyclophilin Inhibitor — OCB-030

Cyclophilins are proteins that have been shown to play a role in several biological processes, including viral infection. There is a hypothesis that inhibition of cyclophilin can impair the ability of HBV to replicate and enhance the host immune response toward HBV. Based on that hypothesis we licensed from NeuroVive Pharmaceutical AB, or ("NeuroVive"), the exclusive rights to develop and commercialize cyclophilin inhibitor drug candidates, including OCB-030, for the treatment of hepatitis B. After extensive preclinical evaluation of OCB-030 and other competitive cyclophilin inhibitors against HBV, we have concluded that the data do not support further development of OCB-030 as a single agent or in combination with our other drug candidates. As a result, we have discontinued the development OCB-030 and have suspended our interest in the cyclophilin inhibitor class so we can focus our resources on higher priority agents that directly target HBV. This decision was based on a significant amount of research and analysis by our scientific team, which will be presented at the HepDart conference in December 2015.

#### STING Agonists

We are developing STING (stimulator of interferon genes) agonists. By activating interferon genes, we anticipate that the body can produce additional interferon alpha and beta, which have antiviral properties. Our development program, which is currently in the discovery research stage, is based on proof of concept data in mice generated by Blumberg which showed that STING agonists can elicit an antiviral response and inhibit HBV replication in mouse liver cells. In collaboration with Blumberg, our plan is to identify potent, orally active small molecule human STING agonists that possess the desired characteristics to progress into human clinical studies.

#### Non-HBV Assets (LNP Enabled)

We have suspended further development of our non-HBV assets but LNP technology advancements are ongoing. We remain committed to maximizing this value. We are exploring partnering or external funding opportunities to maximize the value of our non-HBV assets. These assets include our LNP platform TKM-PLK for oncology, TKM-Ebola and TKM-Marburg for hemorrhagic fever viruses, TKM-HTG for metabolic disorders, and TKM-ADLH for severe alcohol use disorder.

#### **LNP Platform Technology**

We plan to continue to develop our proprietary LNP delivery technology and receive clinical validation from LNP-based products currently in clinical trials. The most advanced LNP-enabled therapeutic, which is being developed by Alnylam Pharmaceuticals, Inc., has entered a Phase III clinical trial. Our LNP technology remains an important element of our business development activities moving forward. We recently announced the latest (fourth) generation of the platform which comprises a rational re-design of the lipid architecture, as well as formulation and process advances. These attributes can be utilized in programs entering the clinic and are expected to yield significant increases in potency and therapeutic index.

Because LNP can enable a wide variety of nucleic acid triggers, including messenger RNA (mRNA), we continue to see new product development and partnering opportunities based on what we believe is our industry-leading delivery expertise. In February 2014, we presented new preclinical data at the AsiaTIDES scientific symposium in Tokyo, Japan demonstrating that mRNA can be effectively delivered to target proteins expressed. In October 2015, we presented data on formulation advances with LNP technology at the Annual Meeting of the Oligonucleotide Therapeutics Society.

We are exploring opportunities to maximize the value of our LNP platform technology and related intellectual property.

#### TKM-PLK1

Our oncology product platform, TKM-PLK1, targets PLK1, a protein involved in tumor cell proliferation and a validated oncology target. Inhibition of PLK1 expression prevents the tumor cell from completing cell division, resulting in cell cycle arrest and death of the cancer cell. Evidence that patients with elevated levels of PLK1 in their tumors exhibit poorer prognosis and survival rates has been documented in the medical literature. TKM-PLK1 is being evaluated in the following oncology indications where there are limited or ineffective therapies available: Gastrointestinal Neuroendocrine Tumors (GI-NET), Adrenocortical Carcinoma (ACC) and Hepatocellular Carcinoma (HCC).

#### **GI-NET** and ACC

GI-NET is the gastrointestinal subset of neuroendocrine tumors. According to a paper by Yao et al., (2008), a historical analysis of the U.S. National Cancer Institute, SEER database reveals the incidence of neuroendocrine tumors has increased faster in the last few decades than any other neoplasm, with a growth rate of greater than 3% expected to continue in the near term. The prevalence of GI-NET in the U.S. is estimated to be approximately 55,000 individuals. Prognosis for advanced or metastatic GI-NET, the target population for TKM-PLK1, is poor with 25-54% of patients surviving less than one year.

ACC is an ultra-rare form of cancer that develops in the adrenal gland. Data from the U.S. National Cancer Institute indicates there are approximately 500 patients in the U.S. with ACC. Survival prognosis for patients with ACC is poor. A large percentage of patients are not good surgical candidates and there is a lack of effective systemic therapies.

We presented updated Phase I TKM-PLK1 data at the 6th Annual NET Conference hosted by the North American Neuroendocrine Tumor Society (NANETS) in Charleston, South Carolina on October 4, 2013. This data set included a total of 36 patients in a population of advanced cancer patients with solid tumors. Doses ranged from 0.15 mg/kg to 0.90 mg/kg during the dose escalation portion of the trial, with the maximum tolerated dose (MTD) of 0.75 mg/kg. Serious adverse events (SAEs) were experienced by four subjects in this heavily pre-treated, advanced cancer patient population, with three of four subjects continuing on study. Forty percent (6 out of 15) of patients evaluable for response, treated at a dose equal to or greater than 0.6 mg/kg, showed clinical benefit. Three out of the four ACC patients (75%) treated with TKM-PLK1 achieved stable disease, including one patient who saw a 19.3% reduction in target tumor size after two cycles of treatment. This subject is still in the study receiving TKM-PLK1. Of the two GI-NET patients enrolled, both experienced clinical benefit: one patient had a partial response based on Response Evaluation Criteria in Solid Tumors (RECIST) criteria, and the other GI-NET patient achieved stable disease and showed a greater than 50% reduction in Chromogranin-A (CgA) levels, a key biomarker used to predict clinical outcome and tumor response.

Based on encouraging results from the dose escalation portion and expansion cohort from our Phase I TKM-PLK1 clinical trial, we expanded into a Phase I/II clinical trial with TKM-PLK1, which is specifically enrolling patients within the two therapeutic indications: advanced GI-NET or ACC. This multi-center, single arm, open label study is designed to measure efficacy using RECIST criteria for GI-NET patients and ACC patients as well as evaluate the safety, tolerability and pharmacokinetics of TKM-PLK1. TKM-PLK1 is administered weekly with each four-week cycle consisting of three once-weekly doses followed by a rest week. In the fall of 2014, we achieved our enrollment target of patients with advanced GI-NET or ACC tumors. These patients will continue treatment and be followed to determine if TKM-PLK1 produces a meaningful clinical benefit.

The TKM-PLK1 Phase I/II study evaluated the safely, tolerability, and anti-tumor activity of TKM-PLK1 in a population of 63 subjects with advanced solid tumors, including 15 subjects with GI-NET. We provided an update on the Phase I/II GI-NET clinical study in October 2015 at the NANETS in Austin, Texas. The results from this study provide evidence of anti-tumor activity based on a decrease in tumor size from baseline for 50% of subjects, including a partial response reduction in tumor size of 61% in of the subjects, as well as stable disease with duration of 2-14 cycles for 77% of subjects. Therapy with TKM-PLK1 was received for up to 14 months and was generally well tolerated by the majority of subjects. The TKM-PLK1 GI-NET/ACC trial has concluded.

We are exploring partnering or external funding opportunities to maximize the value of our oncology related assets.

#### **HCC**

HCC is one of the most common cancers, one of the most deadly and a common outcome of chronic HBV infection, with over 650,000 deaths each year worldwide according to the Globocan 2012 database. US incidence is estimated at 27,000 individuals with annual growth rates greater than 2%. HCC is an aggressive, hard-to-treat disease with one-year survival rates of less than 50% and five-year rates as low as 4% (National Cancer Institute). To date, Nexavar (sorafenib) is the only agent approved to treat HCC with an improvement in overall survival of just two to three months.

In May 2014, we initiated another Phase I/II clinical trial with TKM-PLK1, enrolling patients with advanced HCC. Patient dosing has commenced and we have completed the dose escalation portion of this trial. This Phase I/II clinical trial is a multi-center, single arm, open label dose escalation study designed to evaluate the safety, tolerability and pharmacokinetics of TKM-PLK1 as well as determine the maximum tolerated dose in patients with advanced HCC. It will also include a preliminary assessment of the antitumor activity of TKM-PLK1 in this patient population. In August 2015 we announced initiation of patient dosing in the expansion cohort in a Phase IIa clinical trial in multiple sites in Canada, the United States and Asia, and have since completed enrollment. Based on a hypothesis that inhibition of PLK-1 could have utility in treating HBV, we have modified the clinical program for TKM-PLK1 to study the effect of PLK1 on viral parameters in chronic HBV patients enrolled in the HCC trial, if possible. This trial is designed to assess efficacy in terms of tumor response rate in approximately 20 subjects.

We are exploring partnering or external funding opportunities to maximize the value of our oncology related assets.

#### TKM-Ebola

TKM-Ebola-Kikwit, an anti-Ebola RNAi therapeutic, has been developed under a \$140 million contract with the U.S. Department of Defense (DoD) awarded in July 2010. We were granted Fast Track designation from the FDA for the development of TKM-Ebola-Kikwit in March 2014, and in May 2014, we successfully completed the single ascending dose portion of the TKM-Ebola-Kikwit Phase I clinical trial in healthy human volunteers. Results demonstrated that administration of the TKM-Ebola-Kikwit therapeutic, in the absence of any steroid containing pre-medication, was well-tolerated at a dose level of 0.3 mg/kg, determined to be the maximum tolerated dose. In July 2014, we received notice from the FDA placing the IND for TKM-Ebola on clinical hold, which was subsequently modified to a partial clinical hold to permit the administration of TKM-Ebola-Kikwit to patients with a suspected or confirmed Ebola virus infection. Under the FDA's expanded access program, several patients with a confirmed or suspected Ebola virus infection were treated with TKM-Ebola-Kikwit. In December 2014, the U.S. Congress amended the Rare and Tropical Disease list to include Ebola as a candidate for a potential Accelerated Review Voucher. In April 2015, the FDA notified us that the partial clinical hold had been modified to permit repeat dosing of healthy volunteers at a dose of 0.24 mg/kg/day. Given the unclear development path for TKM-Ebola, development activities have been suspended and the contract with the DoD has been terminated, as expected subject to the completion of our post-termination obligations.

In September 2014, we joined an international consortium led by the International Severe Acute Respiratory and Emerging Infection Consortium (ISARIC) at the University of Oxford, UK, to provide TKM-Ebola-Guinea for expedited clinical studies in West Africa. In March 2015, a TKM-Ebola-Guinea Phase II single arm trial called RAPIDE (Rapid Assessment of Potential Interventions & Drugs for Ebola), was initiated in Sierra Leone. The study was led by ISARIC with funding from the Wellcome Trust. In April 2015, we, along with our collaborators at the University of Texas Medical Branch (UTMB) at Galveston, USA, published positive Ebola treatment data in the journal Nature (Thi EP., et al. Lipid Nanoparticle siRNA Treatment of Ebola-Virus-Makona-Infected Nonhuman Primates; *Nature*, April 22, 2015). Data demonstrated 100% survival of nonhuman primates previously infected with the West African Makona strain of Ebola virus even when treatment did not begin until three days after viral exposure a time point at which animals were five to six days away from death. These efficacy results are comparable to those obtained with TKM-Ebola-Kikwit, which also demonstrated up to 100% protection from an otherwise lethal dose of the virus. In June 2015 we announced closing of the enrollment for the trial as it reached a futility boundary, which was a predefined statistical endpoint. Data analysis is ongoing and the full results are pending.

We are exploring partnering or external funding opportunities to maximize the value of our Ebola related assets.

#### **Technology, Product Development and Licensing Agreements**

In the field of RNAi therapeutics, we have licensed our LNP delivery technology to Alnylam, and to Merck & Co., Inc. (which has since been acquired by Alnylam). Alnylam has provided royalty bearing access of our LNP delivery technology to some of its partners. We have a licensing and collaboration agreement with Dicerna Pharmaceuticals, Inc. In addition, we have ongoing research relationships with Monsanto, U.S. government grants and contracts and other undisclosed pharmaceutical and biotechnology companies. Outside the field of RNAi, we have a legacy licensing agreement with Spectrum Pharmaceuticals, Inc.

We have rights under the RNAi intellectual property of Alnylam to develop 13 RNAi therapeutic products. In addition, we have a broad non-exclusive license to use Unlocked Nucleobase Analogs (UNAs) from Arcturus Therapeutics, Inc., for the development of RNAi therapeutic products directed to any target in any therapeutic indication.

#### **Strategic Alliances**

#### Alnylam Pharmaceuticals, Inc. ("Alnylam")

Alnylam has a license to use our Intellectual Property (IP) to develop and commercialize products and may only grant access to our LNP technology to its partners if it is part of a product sublicense. Alnylam's license rights are limited to patents that we have filed, or that claim priority to a patent that was filed, before April 15, 2010. Alnylam does not have rights to our patents filed after April 15, 2010 unless they claim priority to a patent filed before that date. Alnylam will pay low single digit royalties as Alnylam's LNP-enabled products are commercialized. Alnylam currently has three LNP-based products in clinical development: ALN-TTR02 (patisiran), ALN-VSP, and ALN-PCS02.

In November 2013, Alnylam presented positive results from its Phase II clinical trial with patisiran (ALN-TTR02), an RNAi therapeutic targeting transthyretin (TTR) for the treatment of TTR-mediated amyloidosis (ATTR), which is enabled by our LNP technology. Alnylam also announced the initiation of the APOLLO Phase III trial of patisiran, with the study now open for enrollment to evaluate efficacy and safety of patisiran in ATTR patients with Familial Amyloidotic Polyneuropathy (FAP).

In December 2013, we received a \$5 million milestone from Alnylam, triggered by the initiation of the APOLLO Phase III trial of patisiran. We have entered an arbitration proceeding with Alnylam, as provided for under our licensing agreement, to resolve a matter related to a disputed \$5 million milestone payment to us by Alnylam for its ALN-VSP product. We have not recorded any revenue in respect of this milestone.

In April 2014, Alnylam presented positive new data from its Phase II clinical trial with patisiran. These results provide support for Alnylam's Phase III APOLLO trial in which patisiran is being evaluated for its potential efficacy and safety in ATTR patients with FAP. Alnylam has disclosed that it continues to enroll patients in its APOLLO Phase III trial, with over 20 sites in nine countries, which are now open and active. The Phase III trial is intended to demonstrate the efficacy and safety of patisiran in support of marketing authorization in countries around the world.

In October 2014, Alnylam reported positive clinical data for the ongoing patisiran Phase II Open Label Extension (OLE) study in patients with FAP, which is also enabled by our LNP technology. The results demonstrated sustained knockdown of serum TTR of up to 90% and a favorable tolerability profile out to one year of treatment.

In April 2015, Alnylam announced positive data from the ongoing open-label study with patisiran which demonstrated continued evidence for possible halting of neuropathy progression after the first 12 months of treatment. In addition, patisiran treatment showed robust mean knockdown of serum TTR of up to 88%. Alnylam's ongoing OLE study is an open-label, multi-center trial designed to evaluate the long-term safety and tolerability of patisiran administration in FAP patients that were previously enrolled in a Phase II study.

In July 2015, Alnylam announced initiation of a Phase III open label OLE study with patisiran ("APOLLO-OLE") to evaluate the long-term safety and tolerability of patisiran in ATTR amyloidosis patients with FAP who were previously enrolled in the APOLLO Phase III study. In September 2015, Alnylam reported evidence of reduced pathogenic, misfolded TTR monomers and oligomers in TTR-mediated amyloidosis patients with FAP.

The patisiran program represents the most clinically advanced application of our LNP delivery technology. Furthermore, Alnylam's results demonstrate that multi-dosing with our LNP has been well-tolerated with treatments out to 21 months.

Our licensing agreement with Alnylam grants us IP rights for the development and commercialization of RNAi therapeutics for specified targets. In consideration for these three exclusive and 10 non-exclusive licenses, we have agreed to pay single-digit royalties to Alnylam on product sales, with milestone obligations of up to \$8.5 million on the non-exclusive licenses and no milestone obligations on the three exclusive licenses.

# Acuitas Therapeutics Inc. ("Acuitas")

Consistent with the terms of the settlement agreement signed in November 2012, we finalized and entered a cross-license agreement with Acuitas (formerly AlCana Technologies, Inc.) in December 2013. The terms of the cross-license agreement provide Acuitas with access to certain of our earlier IP generated prior to April 2010. At the same time, the terms provide us with certain access to Acuitas' technology and licenses in the RNAi field, along with a percentage of each milestone and royalty payment with respect to certain products. Acuitas has agreed that it will not compete in the RNAi field for a period of five years, ending in November 2017.

#### Spectrum Pharmaceuticals, Inc. ("Spectrum")

In September 2013, we announced that our licensee, Spectrum, had launched Marqibo® through its existing hematology sales force in the United States. Since then commercial sales have occurred. Arbutus is entitled to mid-single digit royalty payments based on Marqibo®'s commercial sales. Marqibo®, which is a novel sphingomyelin/cholesterol liposome-encapsulated formulation of the FDA-approved anticancer drug vincristine, was originally developed by Arbutus. We out-licensed the product to Talon Therapeutics in 2006, and in July 2013, Talon was acquired by Spectrum. Marqibo®'s approved indication is for the treatment of adult patients with Philadelphia chromosome-negative acute lymphoblastic leukemia (Ph-ALL) in second or greater relapse or whose disease has progressed following two or more lines of anti-leukemia therapy. Spectrum has ongoing trials evaluating Marqibo® in three additional indications, which are: first line use in patients with Ph-ALL, Pediatric ALL and Non-Hodgkin's lymphoma.

# Monsanto Company ("Monsanto")

In January 2014, we signed an Option Agreement and a Service Agreement with Monsanto, and granted Monsanto an option to obtain a license to use our proprietary LNP delivery technology. The transaction supports the application of LNP technology and related IP for use in agriculture. The potential value of the transaction could reach \$86.2 million following the successful completion of milestones. In January 2014, we received \$14.5 million of the \$17.5 million in near term payments. We received additional payments of \$1.5 million each in June 2014 and October 2014 following the achievement of specific program objectives. In May 2015, the arrangement was amended to extend the option period by approximately five months, with payments up to \$2.0 million for the extension period. As of September 30, 2015, we have received \$19.3 million.

#### Marina Biotech, Inc. ("Marina") / Arcturus Therapeutics, Inc. ("Arcturus")

In November 2012, we disclosed that we had obtained a worldwide, non-exclusive license to a novel RNAi trigger technology called Unlocked Nucleobase Analog (UNA) from Marina for the development of RNAi therapeutics. UNAs can be incorporated into RNAi drugs and have the potential to improve them by increasing their stability and reducing off-target effects. In August 2013, Marina assigned its UNA technology to Arcturus and the UNA license agreement was then assigned to Arcturus. The terms of the license are otherwise unchanged.



To date, we have paid Marina \$0.5 million in license fees and there are milestones of up to \$3.2 million plus royalties for each product that we develop using UNA technology licensed from Marina. We announced on January 21, 2015, that we had initiated a Phase I clinical trial with TKM-HBV. As TKM-HBV utilizes UNA technology in-licensed from Arcturus, the initiation of the trial triggered a single milestone payment of \$250,000 paid by us to Arcturus.

#### Merck & Co., Inc. ("Merck") and Alnylam license agreement

As a result of the settlement between Protiva and Merck in 2008, we acquired a non-exclusive royalty-bearing world-wide license agreement with Merck. Under the license, Merck will pay up to \$17 million in milestones for each product they develop covered by our IP, except for the first product for which Merck will pay up to \$15 million in milestones, and will pay royalties on product sales. Merck's license rights are limited to patents that Protiva filed, or that claim priority to one of Protiva's patents that was filed, before October 9, 2008. Merck does not have rights to Protiva patents filed after October 9, 2008 unless they claim priority to a patent filed before that date. On March 6, 2014, Alnylam announced that they acquired all assets and licenses from Merck, which included our license agreement.

# **Bristol-Myers Squibb Company ("BMS")**

In May 2010, we announced a research collaboration with BMS. Under this agreement, BMS conducted preclinical work to validate the function of certain genes and shared the data with us to potentially develop RNAi therapeutic drugs against therapeutic targets of interest. We formulated the required RNAi trigger molecules enabled by our LNP technology to silence target genes of interest. BMS paid us \$3.0 million concurrent with the signing of the agreement. We provided a predetermined number of LNP batches over the four-year agreement. In May 2011, we announced a further expansion of the collaboration to include broader applications of our LNP technology and additional target validation work. In May 2014, the collaboration expired and all parties' obligations ended.

#### U.S. National Institutes of Health ("NIH")

On October 13, 2010 we announced that together with collaborators at UTMB, we were awarded a new NIH grant, worth \$2.4 million, to support research to develop RNAi therapeutics to treat Ebola and Marburg hemorrhagic fever viral infections using our LNP delivery technology. In February 2014, we along with UTMB and other collaborators were awarded additional funding of \$3.4 million over five years from the NIH in support of this research.

#### Dicerna Pharmaceuticals, Inc. ("Dicerna")

In November 2014, we signed a licensing agreement and a development and supply agreement with Dicerna to license our LNP delivery technology for exclusive use in Dicerna's primary hyperoxaluria type 1 (PH1) development program. Dicerna will use our third generation LNP technology for delivery of DCR-PH1, Dicerna's product incorporating its Dicer substrate RNA (DsiRNA) molecule, for the treatment of PH1, a rare, inherited liver disorder that often results in kidney failure and for which there are no approved therapies. On September 2, 2015, Dicerna announced the filing of an IND for DCR-PH1, with plans to initiate the Phase I clinical trial in second half of 2015. Under the agreements, Dicerna paid a \$2.5 million upfront and will potentially make payments of \$22 million in aggregate development milestones, plus tiered mid-single-digit royalty payments on future PH1 sales. This partnership also includes a supply agreement under which we will provide clinical drug supply and regulatory support for the rapid advancement of this product candidate.

#### Cytos Biotechnology Ltd ("Cytos")

On December 30, 2014, Arbutus Inc., our wholly owned subsidiary, entered into an exclusive, worldwide, sub-licensable (subject to certain restrictions with respect to licensed viral infections other than hepatitis) license to six different series of compounds. The licensed compounds are Qbeta-derived virus-like particles that encapsulate TLR9, TLR7 or RIG-I agonists and may or may not be conjugated with antigens from the hepatitis virus or other licensed viruses. We have an option to expand this license to include additional viral infections other than influenza and Cytos will retain all rights for influenza, all non-viral infections, and all viral infections (other than hepatitis) for which we have not exercised an option.

In partial consideration for this license, we will be obligated to pay Cytos up to a total of \$67 million for each of the six licensed compound series upon the achievement of specified development and regulatory milestones; for hepatitis and each additional licensed viral infection, up to a total of \$110 million upon the achievement of specified sales performance milestones; and tiered royalty payments in the high-single to low-double digits, based upon the proportionate net sales of licensed products in any commercialized combination.

#### The Baruch S. Blumberg Institute ("Blumberg") and Drexel University ("Drexel")

In February 2014, Arbutus Inc., our wholly owned subsidiary, entered into a license agreement with Blumberg and Drexel that granted an exclusive (except as to certain know-how and subject to retained non-commercial research rights), worldwide, sublicensable license to three different compound series: cccDNA inhibitors, capsid assembly inhibitors and HCC inhibitors.

In partial consideration for this license, Arbutus Inc. paid a license initiation fee of \$150,000 and issued warrants to Blumberg and Drexel. No warrants were outstanding as at the date Arbutus merged with Arbutus Inc. Under this license agreement, Arbutus Inc. also agreed to pay up to \$3.5 million in development and regulatory milestones per licensed compound series, up to \$92.5 million in sales performance milestones per licensed product, and royalties in the mid-single digits based upon the proportionate net sales of licensed products in any commercialized combination. We are obligated to pay Blumberg and Drexel a double digit percentage of all amounts received from the sub-licensees, subject to customary exclusions.

In November 2014, Arbutus Inc. entered into an additional license agreement with Blumberg and Drexel pursuant to which it received an exclusive (subject to retained non-commercial research rights), worldwide, sub-licensable license under specified patents and know-how controlled by Blumberg and Drexel covering epigenetic modifiers of cccDNA and STING agonists. In consideration for these exclusive licenses, Arbutus Inc. made an upfront payment of \$50,000. Under this agreement, we will be required to pay up to \$1.0 million for each licensed product upon the achievement of a specified regulatory milestone and a low single digit royalty, based upon the proportionate net sales of compounds covered by this intellectual property in any commercialized combination. We are also obligated to pay Blumberg and Drexel a double digit percentage of all amounts received from its sub-licensees, subject to exclusions.

#### License Agreements between Enantigen and Blumberg and Drexel

In October 2014, Arbutus Inc., our wholly owned subsidiary, acquired all of the outstanding shares of Enantigen pursuant to a stock purchase agreement. Through this transaction, Arbutus Inc. acquired a HBV surface antigen secretion inhibitor program and a capsid assembly inhibitor program, each of which are now assets of Arbutus, following our merger with Arbutus Inc.

Under the stock purchase agreement, we agreed to pay up to a total of \$21.0 million to Enantigen's selling stockholders upon the achievement of specified development and regulatory milestones, for the first two products that contain either a capsid compound, or a HBV surface antigen compound that is covered by a patent acquired under this agreement; or a capsid compound from an agreed upon list of compounds. The amount paid could be up to a total of \$102.5 million in sales performance milestones in connection with the sale of the first commercialized product by us for the treatment of HBV, regardless of whether such product is based upon assets acquired under this agreement; and low single digit royalty on net sales of such first commercialized HBV product, up to a maximum royalty payment of \$1.0 million that, if paid, would be offset against our milestone payment obligations.

Under the stock purchase agreement, we also agreed that Enantigen would fulfill its obligations as they relate to the three patent license agreements with Blumberg and Drexel. Pursuant to each patent license agreement, Enantigen is obligated to pay Blumberg and Drexel up to approximately \$500,000 in development and regulatory milestones per licensed product, royalties in the low single digits, and a percentage of revenue it receives from its sub-licensees.

#### Research Collaboration and Funding Agreement with Blumberg

In October 2014, Arbutus Inc., our wholly owned subsidiary, entered into a research collaboration and funding agreement with Blumberg under which we will provide \$1.0 million per year of research funding for three years, renewable at our option for an additional three years, for Blumberg to conduct research projects in HBV and liver cancer pursuant to a research plan to be agreed upon by the parties. Blumberg has exclusivity obligations to Arbutus with respect to HBV research funded under the agreement. In addition, we have the right to match any third party offer to fund HBV research that falls outside the scope of the research being funded under the agreement. Blumberg has granted us the right to obtain an exclusive, royalty bearing, worldwide license to any intellectual property generated by any funded research project. If we elect to exercise our right to obtain such a license, we will have a specified period of time to negotiate and enter into a mutually agreeable license agreement with Blumberg. This license agreement will include the following pre negotiated upfront, milestone and royalty payments: an upfront payment in the amount of \$100,000; up to \$8.1 million upon the achievement of specified development and regulatory milestones; up to \$92.5 million upon the achievement of specified commercialization milestones; and royalties at a low single to mid-single digit rates based upon the proportionate net sales of licensed products from any commercialized combination.

#### NeuroVive Pharmaceutical AB ("NeuroVive")

In September 2014, Arbutus Inc., our wholly owned subsidiary, entered into a license agreement with NeuroVive that granted us an exclusive, worldwide, sub-licensable license to develop, manufacture and commercialize, for the treatment of HBV, oral dosage form sanglifehrin based cyclophilin inhibitors (including OCB-030). Under this license agreement we have been granted a non-exclusive, royalty free right and license and right of reference to NeuroVive's relevant regulatory approvals and filings for the sole purpose of developing, manufacturing and commercializing licensed products for the treatment of HBV. Under this license agreement, we have (1) an option to expand our exclusive license to include treatment of viral diseases other than HBV and (2) an option, exercisable upon specified conditions, to expand our exclusive license to include development, manufacture and commercialization of non-oral variations of licensed products for treatment of viral diseases other than HBV. NeuroVive retains all rights with respect to development, manufacture and commercialization of licensed products and non-oral variations of licensed products for all indications (other than HBV) for which we have not exercised our option.

In partial consideration for this license, Arbutus Inc. paid NeuroVive a license fee of \$1 million. As described in "Overview", Arbutus Inc. became our wholly owned subsidiary by way of a Merger Agreement, which does not trigger any milestone payments. We have conducted significant research and analysis on the NeuroVive Product, OCB-030. Based on this research and analysis, we have decided to discontinue the OCB-030 development program. Otherwise, the license agreement and ongoing relationship with NeuroVive remains in full effect at this time.

### CRITICAL ACCOUNTING POLICIES AND ESTIMATES

**Share purchase warrant valuation** / The valuation of share purchase warrants is a critical accounting estimate due to the value of liabilities recorded and the many assumptions that are required to calculate the liability, resulting in the classification of our warrant liability as a level 3 financial instrument.

We classify warrants in our consolidated balance sheet as liabilities and revalue them at each balance sheet date. Any change in valuation is recorded in our statement of operations. We use the Black-Scholes pricing model to value the warrants. Determining the appropriate fair-value model and calculating the fair value of registered warrants requires considerable judgment. A small change in the estimates used may cause a relatively large change in the estimated valuation. Due to ongoing changes in our business and general stock market conditions, we continuously assess our warrant fair value assumptions. We adjust the estimated expected life as appropriate, based on the pattern of exercises of our warrants. As at December 31, 2014, for the purpose of calculating the fair value, the expected life of outstanding warrants was three months for warrants expiring in June 2016, and nine months for warrants expiring in February 2017. Based on the pattern of decreasing exercises of warrants, we increased the expected life to nine months and twelve months for outstanding warrants expiring in June 2016 and February 2017, respectively, effective January 1, 2015. During the nine months ended September 30, 2015, warrant exercise activity continued to decline; as a result, we increased the remaining expected life of outstanding warrants to nine months and seventeen months effective July 1, 2015. As at September 30, 2015, the remaining expected life is six months and fourteen months for outstanding warrants expiring in June 2016 and February 2017, respectively. For the three and nine month period ended September 30, 2015, we recorded a gain in earnings due to the decrease in fair value of warrant liability of \$1,976,000 and \$2,777,000 respectively.

**Business combination** / The purchase price allocation is a critical accounting estimate due to the many assumptions that are required to calculate the fair value of assets acquired and liabilities assumed during a business combination.

We account for our business combinations using the acquisition method. Under this method, the fair value of the consideration transferred is allocated to the fair values of assets acquired and liabilities assumed. In determining the fair value of the consideration transferred, the acquisition date market price of common shares issued was used. The total consideration transferred is comprised of common shares issued without subjects and common shares issued replacement awards, which are subject to repurchase provisions. As at the acquisition date, we determined the total fair value of the replacement awards and attributed a portion of the replacement awards to pre-combination service as part of the total acquisition consideration, and a portion to post-combination service, which is recognized as compensation expense over the expiry period of repurchase provision rights subsequent to the acquisition date. The fair value of the repurchase awards was determined using the Black-Scholes pricing model with assumed risk-free interest rate of 0.74%, volatility of 81%, a zero dividend yield and an expected life of 4 years. In July 2015, the expiration period of the repurchase rights have been amended, resulting in a prospective adjustment to recognize the remaining compensation expense on a straight-line basis over the revised expiration period.

In addition, we make estimates to determine the fair values of assets acquired and liabilities assumed, which include judgments in our determinations of acquired intangible assets and assessment of the fair value of existing property and equipment. Assumed liabilities can include other contingency reserves existing at the time of acquisition. Contingent consideration is recorded for cash payments due upon the completion of certain future development and performance milestones. This liability is recorded as at the acquisition date as the fair value of the contingent consideration, estimated using the income method which utilizes various inputs such as probability of success and risk-adjusted discount rates. In addition, contingent consideration is recorded at its fair value at subsequent reporting dates, with any change in fair value from the previous reporting date recorded in the statement of operations and comprehensive loss.

Goodwill is recognized on acquisition as the excess of the purchase price over the estimated fair values of net identifiable assets acquired and liabilities assumed. Acquisition related expenses are separately recognized from the business combination and are expensed as incurred.

When establishing fair values, we make significant estimates and assumptions, especially with respect to intangible assets. Intangible assets acquired and recorded by us may include patents, intellectual property, and in-process research and development. Estimates include, but are not limited to the forecasting of future cash flows and discount rates.

Our estimates for the fair values of assets acquired and liabilities assumed with respect to our acquisition of Arbutus Inc. are preliminary for the period ended September 30, 2015. We have engaged a third-party valuation specialist to assist us to determine the fair values. Our preliminary estimates of fair values are based upon assumptions that we believe to be reasonable, but which are inherently uncertain and unpredictable; therefore, actual results may differ from estimates, thereby impacting our earnings.

Goodwill and intangible assets – Impairment / Intangible assets classified as indefinite-lived and goodwill are not amortized, but are evaluated for impairment annually using a measurement date of November 30. In addition, if there is a major event indicating that the carrying value of an asset may not be recoverable, then management will perform an impairment test by comparing the discounted cash flow values to each asset's carrying value to determine if a write down is necessary. Such indicators include, but are not limited to on an ongoing basis: (a) industry and market considerations such as an increased competitive environment or an adverse change in legal factors including an adverse assessment by regulators; (b) an accumulation of costs significantly in excess of the amount originally expected for the development of the asset; (c) current period operating or cash flow loss combined with a history of operating or cash flow losses or a projection or forecast that demonstrates continuing losses associated with the use of the asset; and (d) if applicable, a sustained decrease in share price.

In assessing impairment, significant judgments are required by management to estimate future cash flows, appropriate discount rates, and other estimates and assumptions that could materially affect the determination of fair value. These judgments include the use of, but are not limited to: projected results of operations and forecast cash flows based on our corporate model as approved by our Board of Directors, third party forecasts and data and other macroeconomic indicators that forecasts market conditions and our estimated future revenues and growth.

In October 2015, we announced the discontinuance of the cyclophilin drug candidate, OCB-030. Although the final conclusion on discontinuance was made subsequent to period end, it reflected our best estimate as at September 30, 2015, and as such we recorded an estimated impairment charge of \$38.0 million in Q3 2015. We determined that the impairment on cyclophilins was a significant change in the business that would trigger an earlier evaluation of the recoverability of goodwill prior to the annual impairment testing date of November 30.

Goodwill is subject to a two-step impairment test. The first step compares the fair value of the reporting unit to the carrying amount, which includes goodwill. If the carrying amount exceeds the implied fair value of the goodwill, the second step measures the amount of the impairment loss. As part of the impairment evaluation of goodwill, we identified one reporting unit to which the total preliminary carrying amount of goodwill has been assigned. We used a valuation specialist to assist us in determining the fair value of the reporting unit under the income approach. For step one of the impairment test, we determined that the fair value of the reporting unit exceeded the preliminary carrying value of the reporting unit, and as such, step two was not required. In addition, we considered our market capitalization of approximately \$332.3 million, which exceeded our carrying value of \$553.8 million as at September 30, 2015. We reconciled the income approach determination of fair value with the market capitalization by considering macroeconomic factors, and as such we do not believe the market capitalization appropriately reflected the value of the reporting unit for the purpose of goodwill impairment testing. No impairment charge on goodwill was recorded for the period ended September 30, 2015.

There are no other changes to our critical accounting policies and estimates from those disclosed in our annual MD&A contained in our 2014 Annual Report filed on Form 10-K.

## RECENT ACCOUNTING PRONOUNCEMENTS

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board (FASB) or other standard setting bodies that are adopted by the Company as of the specified effective date. Unless otherwise discussed, the Company believes that the impact of recently issued standards that are not yet effective will not have a material impact on its financial position or results of operations upon adoption.

In September 2015, the FASB issued ASU 2015-16, Business Combinations (Topic 805): Simplifying the Accounting for Measurement-Period Adjustments. The update eliminates the requirement to retrospectively adjust the provisional amounts recognized at the acquisition date with a corresponding adjustment to goodwill during the measurement period when new information is obtained about the facts and circumstances that existed as of the acquisition date, that if known, would have affected the measurement of the amounts initially recognized or would have resulted in the recognition of additional assets or liabilities. The amendments in this update are effective for fiscal years beginning after December 15, 2015, which for the Company means January 1, 2016, and should be applied prospectively to adjustments to provisional amounts that occur after the effective date of this update. Early application permitted for financial statements that have not been issued. We do not plan to early adopt this update, and are currently assessing the impact of this adoption.

In May 2014, the FASB issued ASU 2014-09, Revenue from Contracts with Customers (ASC 606). The standard is intended to clarify the principles for recognizing revenue and to develop a common revenue standard for U.S. GAAP and IFRS by creating a new Topic 606, Revenue from Contracts with Customers. This guidance supersedes the revenue recognition requirements in ASC 605, Revenue Recognition, and supersedes some cost guidance included in Subtopic 605-35, Revenue Recognition – Construction-Type and Production-Type Contracts. The core principle of the accounting standard is that an entity recognizes revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those good or services. The amendments should be applied by either (1) retrospectively to each prior reporting period presented; or (2) retrospectively with the cumulative effect of initially applying this ASU recognized at the date of initial application. In August 2015, the FASB issued ASU 2015-14, Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date to defer the effective date of Update 2014-09 for all entities by one year. The new guidance would be effective for fiscal years beginning after December 15, 2017, which for us means January 1, 2018. Entities are permitted to adopt in accordance with the original effective date if they choose. We have not yet determined the extent of the impact of adoption.

In August 2014, the FASB issued ASU 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. The update is intended to provide guidance in GAAP about management's responsibility to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern and to provide related footnote disclosures. Under amendments to GAAP, the assessment period is within one year after the date that the financial statements are issued (or available to be issued). The amendments are effective for the annual period ending after December 15, 2016, which for us means January 1, 2017, and for annual periods and interim periods thereafter. Early application is permitted. We do not plan to early adopt this update. The extent on the impact of this adoption has not yet been determined.

## **SUMMARY OF QUARTERLY RESULTS**

The following table presents our unaudited quarterly results of operations for each of our last eight quarters. These data have been derived from our unaudited condensed consolidated financial statements, which were prepared on the same basis as our annual audited financial statements and, in our opinion, include all adjustments necessary, consisting solely of normal recurring adjustments, for the fair presentation of such information.

	Q3 2015	Q2 2015	Q1 2015	Q4 2014	Q3 2014	Q2 2014	Q1 2014	Q4 2013
D								
Revenue Collaborations and contracts:								
DoD	\$ 2.0 \$	1.8 \$	3.0 \$	2.8 \$	1.5 \$	0.9 \$	3.2 \$	2.6
Monsanto	0.3	0.3	0.3	0.3	0.3	0.9 \$	0.3	2.0
Dicerna	0.7	0.2	0.2	0.3	0.2	— U.Z	— —	
Other	<b>0.</b> 7	—	—	—	1.6	_	0.2	(0.1)
Circi					1.0		0.2	(0.1)
	3.0	2.3	3.5	3.4	3.6	1.1	3.7	2.6
Alnylam milestone payments	_	_	_	_	_	_	0.2	5.0
Monsanto licensing fees and								
milestone payments	0.7	0.8	0.8	0.9	0.7	0.6	0.5	_
Dicerna licensing fee	0.3	0.3	0.3	_	_	_	_	_
Spectrum milestone and royalty								
payments	0.1	0.1	0.1	0.1	0.1	0.0	0.0	0.0
Total revenue	4.1	3.4	4.7	4.4	4.4	1.8	4.4	7.6
Expenses	(62.2)	(17.9)	(22.7)	(15.1)	(11.2)	(11.2)	(10.4)	(9.9)
Other income (losses)	14.0	(0.5)	6.0	4.5	(1.8)	3.3	(12.0)	(0.2)
- 10	(44.0)	(110)	(42.0)	(6.0)	(0.0)	(0.4)	(40.0)	(2.6)
Loss before income taxes	(44.2)	(14.9)	(12.0)	(6.2)	(8.6)	(6.1)	(18.0)	(2.6)
Income tax benefit	15.2	_	_	_	_	_	_	_
Net loss	(29.0)	(14.9)	(12.0)	(6.2)	(8.6)	(6.1)	(18.0)	(2.6)
	. ,	, ,	, ,	, ,	, ,	, ,	3 1	
Basic and diluted net loss per shar	re\$ (0.57) \$	(0.27) \$	(0.40) \$	(0.27) \$	(0.39) \$	(0.28) \$	(0.91) \$	(0.15)

## **Quarterly Trends**

**Revenue** / Our revenue is derived from research and development collaborations and contracts, licensing fees, milestone and royalty payments. Over the past two years, our principal source of ongoing revenue has been our contract with the DoD to advance TKM-Ebola which began in July 2010. We expect revenue to continue to fluctuate particularly due to the development stage of the TKM-Ebola contract and the irregular nature of licensing and milestone receipts.

In Q3 2010 we signed a contract with the DoD to develop TKM-Ebola and have since incurred significant program costs related to equipment, materials and preclinical and clinical studies. These costs are included in our research, development, collaborations and contracts expenses. These costs are fully reimbursed by the DoD, and this reimbursement amount is recorded as revenue. DoD revenue from the TKM-Ebola program also compensates us for labor and overheads and provides an incentive fee. As described in our critical accounting policies in our Annual Report, we estimate the labor and overhead rates to be charged under our TKM-Ebola contract and update these rate estimates throughout the year. In April 2014, we signed a contract modification to increase the stage one targeted funding by \$2.1 million to \$43.8 million. The additional funding is to compensate us for unrecovered costs related to the temporary stop-work period that occurred in 2012 and to provide additional overhead funding should it be required. In O1 2014, we earned \$3.2 million in DoD revenue, due partially to an increase in activity as we moved into a Phase I Clinical Trial. In Q2 2014, we earned \$0.9 million in DoD revenue due to lower contract activity as our clinical trial data was with the FDA for review. DoD revenue increased in O3 2014 with an increase in activity as we prepared a response to the FDA's partial clinical hold on our Phase I Clinical Trial. In October 2014, the DoD exercised a contract option adding \$7.0 million to the contract for the scale-up and manufacture of TKM-Ebola-Guinea, our product targeting the Ebola-Makona (formerly known as Ebola-Guinea) strain responsible for the current outbreak in West Africa. DoD revenue increased in Q4 2014 and Q1 2015 as we purchased materials and manufactured TKM-Ebola-Guinea. In Q2 2015, material purchases and subcontract work related to TKM-Ebola-Guinea were less significant. In July 2015, we announced that activities have been suspended and in October 2015, we received formal notification from the DoD to terminate the TKM-Ebola-Guinea manufacturing and IND submission activities, subject to completion of our post-termination obligations. The TKM-Ebola portion of the contract is expected to complete before the end of 2015 at which point contract close out procedures will commence.

In January 2014, we signed an Option Agreement and a Services Agreement with Monsanto for the use of our proprietary delivery technology and related intellectual property in agriculture. Over the option period, which is expected to be approximately four years, Monsanto will make payments to us to maintain their option rights. In Q1 2014, we received \$14.5 million of the \$17.5 million near term payments, of which \$4.5 million relates to research services and \$10.0 million for the use of our technology. In June 2014 and October 2014, we received further payments of \$1.5 million each, following the completion of specified program developments. In 2015, we received an additional \$1.3 million related to research services. The payments are being recognized as revenue on a straight-line basis over the option period.

In November 2014, we signed a License Agreement and a Development and Supply Agreement with Dicerna for the use of our proprietary delivery technology and related technology intended to develop, manufacture, and commercialize products related to the treatment of PH1. In Q4 2014, we received an upfront payment of \$2.5 million, which is being recognized over the period over which we provide services to Dicerna, estimated to complete in Q1 2017. We recognized collaboration revenue of \$0.2 million in each of Q1 and Q2 2015, and \$0.7 million in Q3 2015, relating to inventory manufactured for and services provided to Dicerna in the period.

In Q4 2013 we earned a \$5.0 million milestone from Alnylam following their initiation of a Phase III trial enabled by our LNP technology.

In Q4 2013, we began to earn royalties from Spectrum with respect to the commercial sales of Marqibo.

Included in "other collaborations and contract revenue" is revenue from a BMS batch formulation agreement. In Q4 2013, we offered to extend the BMS agreement end date from May 2014 to December 2014. Extending the agreement would have given BMS more time to order LNP batches. Revenue recognized in 2013 has been reduced and the balance of deferred revenue as at December 31, 2013 has been increased to account for BMS potentially ordering more batches under the agreement. This agreement is reflected in the \$0.1 million of negative "other revenue" in Q4 2013 when the offer was made to extend the agreement and a cumulative revenue adjustment was recorded. In August 2014, we received notification from BMS that the extension would not occur. As such, the collaboration expired and both parties' obligations under the agreement ended. Revenue recognized in Q3 2014 relates to the release of the deferred revenue balance of \$1.6 million.

**Expenses** / Expenses consist primarily of clinical and pre-clinical trial expenses, personnel expenses, consulting and third party expenses, reimbursable collaboration expenses, consumables and materials, patent filing expenses, facilities, stock-based compensation and general corporate costs.

Our expenses have increased in the past eight quarters due to an increase in our research and development activities as we seek to move more products into the clinic. In Q1 2014, we dosed the first subject in human clinical trials of TKM-Ebola. In Q2 2014, we initiated a Phase I/II Clinical Trial for TKM-PLK1 in patients with HCC. In Q4 2014, we filed a Canadian Clinical Trial Application (CTA) for TKM-HBV and received clearance to conduct a Phase I Clinical Trial, as well as initiated manufacturing of TKM-Ebola-Guinea for emergency use in West Africa – see overview. In Q1 2015, we initiated a Phase I Clinical Trial for TKM-HBV and incurred significant material costs related to the TKM-Ebola-Guinea contract with the DoD. In addition, we incurred \$9.3 million in costs for professional fees related to completing the merger with Arbutus Inc. (formerly OnCore). In Q2 2015, we incurred an incremental \$2.9 million R&D expenses related to our HBV programs acquired through the merger with Arbutus Inc. In Q3 2015, we incurred \$5.5 million in incremental R&D expenses primarily related to an increase in HBV and HCC clinical trial expenses due to an increase in patient enrollment and a ramp up in spending on Arbutus Inc. HBV programs.

In Q3 2015, we recorded an estimated impairment charge of \$38.0 million as we discontinued our cyclophilin inhibitor program based on our conclusion that cyclophilins do not play a meaningful role in HBV biology. No impairment charges were recorded on any of our other intangible assets or on goodwill.

**Other income (losses)** / Other income (losses) consist primarily of changes in the fair value of our warrant liability, foreign exchange differences, as well as impairment on intangible assets. Other losses increased in Q3 2013, Q1 2014, and Q3 2014 due primarily to the increase in fair value of our warrant liability. Increases in our share price from the previous reporting date results in an increase in the fair value of our warrant liability, and vice versa. We expect to see future changes in the fair value of our warrant liability and these changes will largely depend on the change in the Company's share price, any change in our assumed rate of share price volatility, our assumptions for the expected lives of the warrants and warrant exercises.

In Q3 2015, we recorded \$11.8 million foreign exchange gain due to the appreciation of the U.S. dollar against the Canadian dollar from the previous period, as well as a \$2.0 million gain due to the decrease in the fair value of warrant liability for the period.

**Income tax benefit** / Income tax benefit relates to the decrease in deferred tax liability associated with the impairment charge recorded on acquired intangible assets. In Q3 2015, we recorded \$15.2 million of income tax benefit for the estimated impairment our cyclophilin inhibitor program, OCB-030.

**Net (loss) income** / Fluctuations in our net loss are explained by changes in revenue, expenses and other income (losses) as discussed above.

### RESULTS OF OPERATIONS

The following summarizes the results of our operations for the periods shown, in thousands (except for per share figures):

		Three Months Ended September 30,			Nine Months Ended September 30,			
	<u></u>	2015		2014		2015		2014
Total revenue	\$	4,065	\$	4,362	\$	12,187	\$	10,603
Operating expenses		62,203		11,206		102,751		32,828
Loss from operations		(58,138)		(6,844)		(90,564)		(22,225)
Net loss	\$	(28,982)	\$	(8,604)	\$	(55,857)	\$	(32,669)
Basic and diluted loss per share		(0.57)		(0.39)		(1.28)		(1.53)

**Revenue** / Revenue is summarized in the following table, in thousands:

		Three months ended	September 30,	
		% of		
	2015	Total	2014	% of Total
DoD	\$ 2,002	49 % \$	1,493	34%
Monsanto	309	8 %	283	6%
BMS	-	0 %	1,552	36%
Dicerna	724	18 %	250	6%
Total collaborations and contracts revenue	3,035	75 %	3,578	82%
Monsanto licensing fee and milestone payments	727	18 %	730	17%
Acuitas milestone payment	-	0 %	-	0%
Dicerna licensing fee	263	6 %	-	0%
Spectrum milestone and royalty payments	 40	1 %	54	1%
Total revenue	\$ 4,065	\$	4,362	
		Nine months ended	September 30,	
	2015	% of	2014	0/ - ( T 1
D D	 2015	Total	2014	% of Total
D <sub>0</sub> D	\$ 6,909	57 % \$	5,594	53%
Monsanto	826	7 %	809	8%
BMS	-	0 %	1,758	17%
Dicerna	1,130	9 %	250	2%

8,865

2,374

789

159

12,187

73 %

19 %

0 %

6 %

1 %

\$

8,411

1,901

150

141

10,603

79%

18%

1%

0%

## Revenue contracts are covered in more detail in the overview section of this discussion. DoD revenue

\$

In July 2015, we announced that Ebola related activities were being suspended and, in October 2015, we received formal notification from the DoD terminating the Ebola-Guinea manufacturing and IND submission statements of work, subject to the completion of certain post-termination obligations. The TKM-Ebola portion of the contract is expected to complete before the end of 2015 at which point contract close out procedures will commence. DoD revenues and related contract expenses were higher in Q3 2015 as compared to Q3 2014 as we incurred sub-contract close out costs related to Ebola-Guinea manufacturing. We do not expect to record much revenue from the DoD contract in Q4 2015 or beyond.

#### Monsanto revenue

Total collaborations and contracts revenue

Spectrum milestone and royalty payments

Acuitas milestone payment

Dicerna licensing fee

**Total revenue** 

Monsanto licensing fee and milestone payments

In January 2014, we received \$14.5 million, of which \$4.5 million relates to research services and \$10.0 million for the use of our technology. In June and October 2014, we received payments of \$1.5 million each, following the completion of specified program developments. In May 2015, we received \$1.05 million for research services. We are recognizing these payments on a straight-line basis over the option period of approximately four years. In the three and nine months ended September 30, 2015, we recorded an aggregate of \$1.0 million and \$3.2 million respectively in revenue for the use of our technology and for research activities.

### Dicerna revenue

In November 2014, we signed a License Agreement and a Development and Supply Agreement with Dicerna for the use of our proprietary delivery technology and related technology intended to develop, manufacture, and commercialize products related to the treatment of PH1. We recognized collaboration revenue of \$0.7 million and \$1.1 million respectively for the three and nine months ended September 30, 2015 earned on inventory manufactured for and services provided to Dicerna. In Q4 2014, we received an upfront payment of \$2.5 million, which is being recognized as licensing fee revenue over the period we provide services to Dicerna, estimated to complete in Q1 2017.

### Acuitas revenue

In Q1 2014, we recognized \$0.15 million in milestone revenue from Acuitas following their receipt of a milestone from Alnylam with the initiation of a Phase III trial enabled by our LNP technology.

#### BMS revenue

In May 2010 we signed a formulation agreement with BMS under which BMS paid us \$3.0 million to make a certain number of LNP formulations over the following four year period. The contract expired in 2014 with no further obligation for either party. Revenue recognized in Q1 2014 relates to the batches shipped to BMS during the period.

## Spectrum revenue

In September 2013, Spectrum announced that they had shipped the first commercial orders of Marqibo. We continue to earn royalties on the sales of Marqibo, which uses a license to our technology.

**Expenses** / Expenses are summarized in the following table, in thousands:

	Three months ended September 30,					
		2015	% of Total		2014	% of Total
Research, development, collaborations and contracts	\$	16,354	26%	\$	9,309	83%
General and administrative		7,706	12%		1,764	16%
Depreciation		153	*		133	1%
Acquisition costs		-	0%		-	0%
Impairment of intangible assets		37,990	61%		-	0%
Total operating expenses	\$	62,203		\$	11.206	

		Nine months end	led Septen	nber 30,	
	2015	% of Total	_ 2	2014	% of Total
Research, development, collaborations and contracts	\$ 36,601	36%	\$	26,811	82%
General and administrative	18,084	18%		5,601	17%
Depreciation	420	*		416	1%
Acquisition costs	9,656	9%		-	0%
Impairment of intangible assets	37,990	37%		-	0%
Total operating expenses	\$ 102,751		\$	32,828	

<sup>\*</sup> represents less than 1% of total

## Research, development, collaborations and contracts

Research, development, collaborations and contracts expenses consist primarily of clinical and pre-clinical trial expenses, personnel expenses, consulting and third party expenses, consumables and materials, as well as a portion of stock-based compensation and general corporate costs. R&D expenses increased during the three and nine months ended September 30, 2015 as compared to the three and nine months ended September 30, 2014 as we increased our spending on TKM-HBV for which Phase 1 clinical trials were initiated in 2015. We also continue to incur incremental costs related to an increase in activities for the preclinical HBV programs we acquired from our merger with Arbutus Inc. In addition, we increased research activities related to our collaboration contracts with the DoD, Monsanto, and Dicerna.

R&D compensation expense increased in the three and nine months ended September 30, 2015 as compared to the three and nine months ended September 30, 2014 due to an increase in the number of employees in support of our expanded portfolio of product candidates, as well as from our merger with Arbutus Inc. In addition, in the nine months ended September 30, 2015 we incurred a total of \$11.0 million, of incremental non-cash compensation expense related to the expiry of repurchase rights on shares issued as part of the consideration paid for the merger with Arbutus Inc. (refer to notes to the financial statements), of which \$2.8 million has been included as part of research, development, collaborations and contracts expense, and \$8.2 million included as part of general and administrative expense.

A significant portion of our research, development, collaborations and contracts expenses are not tracked by project as they benefit multiple projects or our technology platform and because our most-advanced programs are not yet in late-stage clinical development. However, our collaboration agreements contain cost-sharing arrangements pursuant to which certain costs incurred under the project are reimbursed. Costs reimbursed under collaborations typically include certain direct external costs and hourly or full-time equivalent labor rates for the actual time worked on the project. In addition, we have been reimbursed under government contracts for certain allowable costs including direct internal and external costs. As a result, although a significant portion of our research, development, collaborations and contracts expenses are not tracked on a project-by-project basis, we do, however, track direct external costs attributable to, and the actual time our employees worked on, our collaborations and government contracts.

### General and administrative

General and administrative expenses were higher in the three and nine months ended September 30, 2015 compared to of the three and nine months ended September 30, 2014 due largely to an increase in compensation expense linked to our increase in employee base and incremental corporate expenses to support the growth of the Company following the completion of our merger with Arbutus Inc. This includes an incremental non-cash compensation expense we incurred related to the expiry of repurchase rights on

shares issued as part of consideration paid for the merger with Arbutus Inc. (see above). Expenses were also higher in the nine months ended September 30, 2015 due to legal costs incurred in relation to the May 2015 arbitration hearing against Alnylam.

## Depreciation of property and equipment

In 2015, we spent \$1.1 million on property and equipment mostly related to lab equipment and information technology improvements to support integration following our merger with Arbutus Inc.

## Acquisition costs

In 2015, we incurred \$9.7 million in costs for professional fees related to completing the merger with Arbutus Inc. – see overview. This is a one-time cost specific to the merger with Arbutus Inc., and we do not expect to incur recurring acquisition costs.

## Impairment of intangible assets

In the three and nine months ended September 30, 2015, we recorded an estimated impairment charge of \$38.0 million based on our decision to discontinue cyclophilin inhibitors. The decision, which was finalized in October 2015, was based on extensive preclinical evaluations of OCB-030, and other competitive cyclophilin inhibitors, following the acquisition of Arbutus Inc., which concluded that cyclophilins do not play a meaningful role in HBV biology.

**Other income (losses)** / Other income (losses) are summarized in the following table, in thousands:

		Three Months Ended September 30,			Nine Months Ended September 30,			
		2015		2014		2015		2014
	4	4.00		201		400		
Interest income	\$	183	\$	304	\$	466	\$	708
Foreign exchange gains		11,801		3,076		16,268		1,791
Decrease (increase) in fair value of warrant liability		1,976		(5,140)		2,777		(12,943)
Impairment of intangible assets				-				-
Total other income (losses)	\$	13,960	\$	(1,760)	\$	19,511	\$	(10,444)

## Foreign exchange gains

For the three and nine months ended September 30, 2015, we recorded a foreign exchange gain of \$11.8 million and \$16.3 million respectively, which is primarily an unrealized gain related to an appreciation in the value of our U.S. dollar funds from the previous period, when converted to our functional currency of Canadian dollars. Cumulative translation adjustments, which result from converting from our functional currency of Canadian dollars to our reporting currency of U.S. dollars, do not impact our net loss calculation and are not included in foreign exchange gains (losses), but are included in cumulative translation adjustment in other comprehensive loss.

## Increase in fair value of warrant liability

In conjunction with equity and debt financing transactions in 2011 and an equity private placement that closed on February 29, 2012, we issued warrants to purchase our common share. We are accounting for the warrants under the authoritative guidance on accounting for derivative financial instruments indexed to, and potentially settled in, a company's own stock, on the understanding that in compliance with applicable securities laws, the registered warrants require the issuance of registered securities upon exercise and do not sufficiently preclude an implied right to net cash settlement. At each balance sheet date the warrants are revalued using the Black-Scholes model and the change in value is recorded in the consolidated statement of operations and comprehensive income (loss).

Generally, a decrease in our share price from the previous reporting date results in a decrease in the fair value of our warrant liability and vice versa.

We expect to see future changes in the fair value of our warrant liability and these changes will largely depend on the change in the Company's share price, any change in our assumed rate of share price volatility, our assumptions for the expected lives of the warrants and warrant issuances or exercises.

#### Income tax benefit

In the three and nine months ended September 30, 2015, we recorded an income tax benefit of \$15.2 million due to the decrease in deferred tax liability resulting from the estimated impairment charge we recorded for the discontinuance of our cyclophilin inhibitor program.

## LIQUIDITY AND CAPITAL RESOURCES

The following table summarizes our cash flow activities for the periods indicated, in thousands:

	Three Months Ended September 30,			nths Ended nber 30,
	2015	2014	2015	2014
Net loss for the period	\$ (28,928)	\$ (8,604)	\$ (55,857)	\$ (32,669)
Adjustments to reconcile net loss to net cash provided by (used	,	,	,	
in) operating activities	16,684	2,473	18,962	14,160
Changes in operating assets and liabilities	9,771	(589)	(1,273)	12,934
Net cash provided by (used in) operating activities	(2,527)	(6,720)	(38,168)	(5,575)
Net cash provided by (used in) investing activities	(17,733)	(443)	9,486	(44,016)
Net cash provided by financing activities	116	684	143,895	60,207
Effect of foreign exchange rate changes on cash & cash				
equivalents	(5,972)	(611)	(6,311)	(1,156)
Net increase (decrease) in cash and cash equivalents	(26,116)	(7,090)	108,902	9,460
Cash and cash equivalents, beginning of period	207,205	85,267	72,187	68,717
Cash and cash equivalents, end of period	181,089	78,177	181,089	78,177

Since our incorporation, we have financed our operations through the sales of shares, units, debt, revenues from research and development collaborations and licenses with corporate partners, interest income on funds available for investment, and government contracts, grants and tax credits.

At September 30, 2015, we had an aggregate of approximately \$206.1 million in cash and cash equivalents, short-term and long-term investments as compared to an aggregate of \$112.2 million in cash and cash equivalents and short-term investments at December 31, 2014.

For the nine months ended September 30, 2015, operating activities used \$38.2 million in cash as compared to \$5.6 million of cash used in the nine months ended September 30, 2014. The increase in cash used from operating activities is primarily related to the significant costs incurred related to the acquisition of Arbutus Inc. in March 2015, as well as cash received from Monsanto in January 2014. The impairment of intangible assets of \$38.0 million, with an offsetting income tax benefit of \$15.2 million, were both non-cash charges, and are reconciling adjustments for the three and nine-months ended September 30, 2015.

For the nine months ended September 30, 2015, investing activities provided \$9.5 million in cash as we sold the guaranteed investment certificates we acquired in 2014. In May 2015, we acquired a \$10.0 million long-term deposit and in August 2015, we acquired a \$15.0 million short-term guaranteed investment certificate

On March 25, 2015, we completed an underwritten public offering of 7,500,000 common shares, at a price of \$20.25 per share, representing gross proceeds of \$151.9 million. The cost of financing, including commissions and professional fees, was approximately \$9.7 million, which gave us net proceeds of \$142.2 million. We plan to use these proceeds to develop and advance product candidates through clinical trials, as well as for working capital and general corporate purposes.

Cash requirements / At December 31, 2014 we held \$72.2 million in cash and cash equivalents, \$40.0 in short-term investments, totaling \$112.2 million. On March 25, 2015, we raised net proceeds of \$142.2 million from a public offering. Our aggregate cash and short and long-term investment balance as at September 30, 2015 was \$206.1 million. We believe we have sufficient cash resources for at least the next 12 months. In the future, substantial additional funds will be required to continue with the active development of our pipeline products and technologies. In particular, our funding needs may vary depending on a number of factors including:

- . the need for additional capital to fund future business development programs;
- revenues earned form our current collaborative partnership and licensing agreements with Monsanto and Dicerna;
- . revenues earned from our DoD contract to develop TKM-Ebola and TKM-Ebola-Guinea;
- . revenues earned from our legacy collaborative partnerships and licensing agreements, including milestone payments from Alnylam and royalties from sales of Marqibo from Spectrum;
- . the extent to which we continue the development of our product candidates, add new product candidates to our pipeline, or form collaborative relationships to advance our products;
- . our decisions to in-license or acquire additional products or technology for development, in particular for our HBV and RNAi therapeutics programs;
- our ability to attract and retain corporate partners, and their effectiveness in carrying out the development and ultimate commercialization of our product candidates;
- . whether batches of drugs that we manufacture fail to meet specifications resulting in delays and investigational and remanufacturing costs;
- . the decisions, and the timing of decisions, made by health regulatory agencies regarding our technology and products;
- . competing technological and market developments; and
- costs associated with prosecuting and enforcing our patent claims and other intellectual property rights, including litigation and arbitration arising in the course of our business activities.

We will seek to obtain funding to maintain and advance our business from a variety of sources including public or private equity or debt financing, collaborative arrangements with pharmaceutical companies and government grants and contracts. There can be no assurance that funding will be available at all or on acceptable terms to permit further development of our products.

If adequate funding is not available, we may be required to delay, reduce or eliminate one or more of our research or development programs or reduce expenses associated with non-core activities. We may need to obtain funds through arrangements with collaborators or others that may require us to relinquish most or all of our rights to product candidates at an earlier stage of development or on less favorable terms than we would otherwise seek if we were better funded. Insufficient financing may also mean failing to prosecute our patents or relinquishing rights to some of our technologies that we would otherwise develop or commercialize.

**Material commitments for capital expenditures** / As at the date of this discussion we do not have any material commitments for capital expenditure.

#### **OFF-BALANCE SHEET ARRANGEMENTS**

We do not have any off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that is material to investors.

#### CONTRACTUAL OBLIGATIONS

Other than as disclosed elsewhere in this MD&A, there have not been any material changes to our contractual obligations from those disclosed in our Form 10-K for the year ended December 31, 2014.

## IMPACT OF INFLATION

Inflation has not had a material impact on our operations.

#### RELATED PARTY TRANSACTIONS

We have not entered into any related party transactions in the periods covered by this discussion.

#### **OUTSTANDING SHARE DATA**

At October 30, 2015, we had 54,569,791 common shares issued and outstanding, outstanding options to purchase an additional 2,475,259 common shares and outstanding warrants to purchase an additional 379,500 common shares.

### ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

There have been no material changes in our quantitative and qualitative disclosures about market risk from those disclosed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2014.

## ITEM 4. CONTROLS AND PROCEDURES

As of September 30, 2015, an evaluation of the effectiveness of our "disclosure controls and procedures" (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934) was carried out by our management, with the participation of our Chief Executive Officer (CEO) and Chief Financial Officer (CFO). The scope of the effectiveness of disclosure controls and procedures does not include disclosure controls and procedures of Arbutus Inc., which was acquired on March 4, 2015, that are also part of Arbutus Inc.'s internal control over financial reporting. Based upon this evaluation, the CEO and CFO have concluded that as of September 30, 2015, 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 is (i) recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission (the "Commission") rules and forms and (ii) accumulated and communicated to the management of the registrant, including the CEO and CFO, to allow timely decisions regarding required disclosure.

It should be noted that while the CEO and CFO believe that our disclosure controls and procedures provide a reasonable level of assurance that they are effective, they do not expect that our disclosure controls and procedures or internal control over financial reporting will prevent all errors and fraud. A control system, no matter how well conceived or operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

No change in our internal control over financial reporting (as defined in Rules 13a–15(f) and 15d–15(f) under the Exchange Act) occurred during the three months ended September 30, 2015 that has materially affected, or is reasonably likely to materially affect, our internal control overfinancial reporting.

#### PART II. OTHER INFORMATION

#### ITEM 1. LEGAL PROCEEDINGS

We are involved with various legal matters arising in the ordinary course of business. We make provisions for liabilities when it is both probable that a liability has been incurred and the amount of the loss can be reasonably estimated. Such provisions are reviewed at least quarterly and adjusted to reflect the impact of any settlement negotiations, judicial and administrative rulings, advice of legal counsel, and other information and events pertaining to a particular case. Litigation is inherently unpredictable. Although the ultimate resolution of these various matters cannot be determined at this time, we do not believe that such matters, individually or in the aggregate, will have a material adverse effect on our consolidated results of operations, cash flows, or financial condition.

## Alnylam Pharmaceuticals Inc. ("Alnylam")

On June 21, 2013, we transferred manufacturing process technology to Ascletis Pharmaceuticals (Hangzhou) Co., Ltd. ("Ascletis") to enable them to produce ALN-VSP, a product candidate licensed to them by Alnylam. We believe that under a licensing agreement with Alnylam, the technology transfer to Ascletis triggers a \$5 million milestone obligation from Alnylam to Arbutus. However, Alnylam has demanded a declaration that we have not yet met our milestone obligations. We dispute Alnylam's position. To remedy this dispute, the parties have commenced arbitration proceedings, as provided for under the agreement. In addition to seeking a declaration that we have met our obligations under the agreement, we have also stated a claim for breach of contract, breach of the implied covenant of good faith and fair dealing, and fraud. The hearing for this arbitration took place in May, 2015 and a decision is pending.

## University of British Columbia ("UBC")

Certain early work on lipid nanoparticle delivery systems and related inventions was undertaken at the University of British Columbia (UBC). These inventions are licensed to us by UBC under a license agreement, initially entered in 1998 as amended in 2001, 2006 and 2007. We have granted sublicenses under the UBC license to Alnylam as well as to Talon. Alnylam has in turn sublicensed back to us under the licensed UBC patents for discovery, development and commercialization of RNAi products. In mid-2009, we and our subsidiary Protiva entered into a supplemental agreement with UBC, Alnylam and AlCana Technologies, Inc., in relation to a separate research collaboration to be conducted among UBC, Alnylam and AlCana to which we have license rights. The settlement agreement signed in late 2012 to resolve the litigation among Alnylam, AlCana, Arbutus and Protiva provided for the effective termination of all obligations under such supplemental agreement as between and among all litigants.

On November 10, 2014, the University of British Columbia filed a demand for arbitration against Arbutus Biopharma Corp., BCICAC File No.: DCA-1623. We received UBC's Statement of Claims on January 16, 2015. In its Statement of Claims, UBC alleges that it is entitled to \$3.5 million in allegedly unpaid royalties based on publicly available information, and an unspecified amount based on non-public information. UBC also seeks interest and costs, including legal fees. We dispute UBC's allegation. No dates have been scheduled for this arbitration.

#### ITEM 1A. RISK FACTORS

There have been no material changes in our risk factors from those disclosed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2014.

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

None.

#### ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

#### ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

## ITEM 5. OTHER INFORMATION

In connection with our merger with OnCore Biopharma, Inc., we and Roivant Sciences Ltd., Patrick T. Higgins, Michael J. McElhaugh, Michael J. Sofia and Bryce A. Roberts (the "OnCore Holders"), entered into a registration rights agreement, dated as of January 11, 2015, under which we agreed, among other things, to file by the deadline stated in the registration rights agreement, a shelf registration statement under the Securities Act of 1933 to register the resale of our common shares issued in the merger to the OnCore Holders.

As of November 2, 2015, the parties to the registration rights agreement entered into an Amending Agreement, in connection with which our obligation to file a shelf registration statement was amended to replace the filing deadline contained in the original registration rights agreement with a requirement that we file a shelf registration statement within 30 days following a written request made by Roivant Sciences Ltd., and that we use our commercially reasonable efforts to cause that registration statement to

## ITEM 6. EXHIBITS

See the Exhibit Index hereto.

## **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 on November 5, 2015.

## TEKMIRA PHARMACEUTICALS CORPORATION

By: /s/ Mark Murray

Mark Murray

President and Chief Executive Officer

## **EXHIBIT INDEX**

Exhibit Number	Description
<u>10.1*†</u>	Letter Agreement between OnCore Biopharma, Inc. and Cytos Biotechnology AG, effective July 16, 2015
<u>10.2*†</u>	License Agreement between OnCore Biopharma, Inc. and Cytos Biotechnology Ltd. dated December 30, 2014
<u>10.3*</u>	Amending Agreement, dated as of November 2,2015, among Arbutus Biopharma Corporation, Roivant Sciences Ltd., Patrick T. Higgins, Michael J. McElhaugh, Michael J. Sofia and Bryce A. Roberts
31.1*	Certification of Chief Executive Officer pursuant to Rule 13a14 or 15d14 of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the SarbanesOxley Act of 2002
31.2*	Certification of Chief Financial Officer pursuant to Rule 13a14 or 15d14 of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the SarbanesOxley Act of 2002
32.1*	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the SarbanesOxley Act of 2002
<u>32.2*</u>	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the SarbanesOxley Act of 2002
101	Interactive Data Files

<sup>\*</sup> Filed herewith.
† Confidential treatment has been requested for specific portions of this exhibit.

Confidential treatment has been requested for portions of this exhibit. The copy filed herewith omits the information subject to the confidentiality request. Omissions are designated as [\*\*\*]. A complete version of this exhibit has been filed separately with the Securities and Exchange Commission.

#### LETTER AGREEMENT

THIS LETTER AGREEMENT ("Letter Agreement") is effective as of July 16, 2015 (the "Effective Date") and made between:

- (1) **OnCore Biopharma, Inc.,** a Delaware corporation having its principal place of business at 3805 Old Easton Road, Doylestown, PA 18902, USA ("**OnCore**"); and
- (2) CYTOS BIOTECHNOLOGY AG, having its principal place of business at Wagistrasse 25, CH-8952 Schlieren, Switzerland ("Cytos"),

Cytos and OnCore being herein referred to individually as a "Party" and collectively as the "Parties".

## **WHEREAS**

- (A) The Parties entered into that certain License Agreement dated December 30, 2014 (the "Agreement") regarding the development, manufacture and commercialization of Licensed Compounds and Licensed Products in the Field as set forth in the Agreement;
- (B) Closing of the Agreement is subject to the satisfaction or waiver of certain conditions as set forth in Article 2 of the Agreement;
- (C) The Parties have prepared the Technology and Program Transfer Plan referred to in Section 2.4.4 of the Agreement;
- (D) As part of the technology transfer set forth in the Technology and Program Transfer Plan, Cytos shall transfer to OnCore certain Licensor Materials as set forth in Schedule 1.43 of the Agreement.

#### NOW IT IS HEREBY AGREED AS FOLLOWS:

#### 1. Definitions and Interpretation

- 1.1. When used in this Letter Agreement, capitalized terms shall have the meaning as defined above and throughout this Letter Agreement. Any capitalized terms used in this Letter Agreement but not defined herein shall have the meaning as defined in the Agreement.
- 1.2. In the event of any conflict between the terms of this Letter Agreement and the Agreement, the terms of the Agreement shall govern and control. Nothing in this Letter Agreement shall be construed, by implication or otherwise, to modify or supersede any of the terms of the Agreement.

#### 2. Sale of Licensor Materials to OnCore

- 2.1. Cytos shall sell and assign to OnCore complete and unreserved ownership of items 2, 3 and 4 of the Licensor Materials as set forth in Schedule 1.43 of the Agreement. OnCore shall pay Cytos for such Licensor Materials the purchase price set forth in Schedule 1.43 of the Agreement, a total of US\$600,000, no later than thirty (30) Business Days after Closing, and Cytos shall provide whatever documentation of such sale and assignment as OnCore may reasonably request.
- 2.2. Promptly after receiving payment, Cytos shall provide a written notice of such sale and assignment to any third parties that are storing the Licensor Materials, and shall copy OnCore on each such notice.
- 2.3. OnCore shall be responsible for entering into the appropriate agreements with such third parties regarding the storage and further use of the Licensor Materials, though Cytos shall reasonably facilitate OnCore's efforts to secure such agreements at OnCore's request.
- 2.4. OnCore shall place [\*\*\*] in escrow with a mutually agreed upon escrow agent no later than [\*\*\*] after Closing and shall undertake to test relevant Licensor Materials ([\*\*\*] set forth in item 1 of Schedule 1.43), currently being stored by Cytos at third party facilities, against established shelf life specifications as set forth in Exhibit A attached hereto. In the event such Licensor Materials meet such specifications, the escrowed funds shall be released to Cytos and subsections 2.1 through 2.3 above shall then apply to such Licensor Materials. In the event such Licensor Materials do not meet such specifications at any time during the course of testing through [\*\*\*], OnCore shall so notify Cytos and the escrowed funds shall be returned to OnCore.

#### 3. Agreement to Technology and Program Transfer Plan

Upon the execution of this Letter Agreement, the Technology and Program Transfer Plan attached hereto as Exhibit B shall be deemed agreed upon by the parties and condition 2.4.4 of the Agreement shall be satisfied. Pursuant to Section 2.4.4 of the Agreement, such final Technology and Program Transfer Plan shall be appended as Schedule 1.69 to the Agreement.

[Signatures appear on following page]

For and on behalf of ONCORE BIOPHARMA, INC.

Signature

Name

Position

Date

For and on behalf of CYTOS BIOTECHNOLOGY AG

Signature

Name

Position

Position

IN WITNESS WHEREOF, the authorised representatives of the Parties have executed this Letter Agreement on the date written at

the top of this Agreement.

Date

# EXHIBIT A Shelf Life Specifications

[\*\*\*]

# EXHIBIT B Technology and Program Transfer Plan

[\*\*\*]

## CONFIDENTIAL Execution Version

Confidential treatment has been requested for portions of this exhibit. The copy filed herewith omits the information subject to the confidentiality request. Omissions are designated as [\*\*\*]. A complete version of this exhibit has been filed separately with the Securities and Exchange Commission.

## LICENSE AGREEMENT

Dated December 30, 2014

By and Between

Cytos Biotechnology Ltd

and

OnCore Biopharma, Inc.

### LICENSE AGREEMENT

THIS LICENSE AGREEMENT (the "Agreement") is dated as of December 30, 2014 (the "Execution Date") by and between Cytos Biotechnology Ltd, a Swiss company having a place of business at Wagistrasse 25, 8952 Schlieren, Switzerland ("Licensor"), and OnCore Biopharma, Inc., a Delaware corporation having a place of business at 3805 Old Easton Road, Doylestown, PA 18902, USA ("OnCore"). Licensor and OnCore may be referred to herein as a "Party" or, collectively, as "Parties".

#### **RECITALS:**

WHEREAS, Licensor is engaged in the development of products based on its Qb VLP platform technology and owns certain intellectual property covering Licensed Compounds and Licensed Products;

WHEREAS, OnCore is engaged in the research, development, and manufacturing of pharmaceutical products for the treatment of hepatitis and is interested in developing, manufacturing and commercializing Licensed Products for the treatment of hepatitis and potentially other viral infections; and

WHEREAS, OnCore desires to license from Licensor and Licensor wishes to license to OnCore, on an exclusive basis, the right to develop, manufacture and commercialize Licensed Compounds and Licensed Products in the Field.

Now, THEREFORE, in consideration of the various promises and undertakings set forth herein, the Parties agree as follows:

## ARTICLE 1 DEFINITIONS

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

- **1.1** "Additional Fields" mean the diagnosis, prevention and/or treatment of any viral infections other than influenza virus infections and hepatitis virus infections, with each viral infection representing a single "Additional Field."
- **1.2** "Adverse Event" means any serious untoward medical occurrence in a patient or subject who is administered Licensed Product, but only if and to the extent that such serious untoward medical occurrence is required under Laws to be reported to applicable Regulatory Authorities.
- **1.3** "**Affiliate**" means a Person that controls, is controlled by or is under common control with a Party, but only for so long as such control exists. For the purposes of this Section 1.3, the word "control" (including, with correlative meaning, the terms "controlled by" or "under the common control with") means the actual power, either directly or indirectly through one or more intermediaries, to direct the management and policies of such Person or entity, whether by the ownership of more than fifty percent (50%) of the voting stock of such entity, or by contract or otherwise.

- **1.4** "Baseline Data" means any and all *in vitro* or *in vivo* efficacy, safety or toxicology data, whether preclinical or clinical, relating in any way to the use of a product comprising a Qb VLP for the diagnosis, prevention and/or treatment of any and all viral infections for which an Offer Notice was provided, which is in the possession of Licensor and which Licensor may rightfully provide to OnCore. Licensor shall use its best efforts to obtain any and all data that would otherwise be Baseline Data but for Licensor's inability to rightfully provide it to OnCore.
- **1.5** "Business Day" means a day other than Saturday or Sunday on which banking institutions in New York, New York are open for business.
- **1.6** "Calendar Quarter" means each three (3) month period commencing January 1, April 1, July 1 or October 1 of any year; provided, however, that (a) the first Calendar Quarter of the Term shall extend from the Closing Date to the end of the first full Calendar Quarter thereafter, and (b) the last Calendar Quarter of the Term shall end upon the expiration or termination of this Agreement.
- **1.7** "Calendar Year" means the period beginning on the 1<sup>st</sup> of January and ending on the 31<sup>st</sup> of December of the same year; provided, however, that (a) the first Calendar Year of the Term shall commence on the Closing Date and end on December 31 of the same year and (b) the last Calendar Year of the Term shall commence on January 1 of the Calendar Year in which this Agreement terminates or expires and end on the date of termination or expiration of this Agreement.
- 1.8 "Change of Control" means, with respect to a Person: (a) a transaction or series of related transactions that results in the sale or other disposition of all or substantially all of such Person's assets; or (b) a merger or consolidation in which such Person is not the surviving corporation or in which, if such Person is the surviving corporation, the shareholders of such Person immediately prior to the consummation of such merger or consolidation do not, immediately after consummation of such merger or consolidation, possess, directly or indirectly through one or more intermediaries, a majority of the voting power of all of the surviving entity's outstanding stock and other securities and the power to elect a majority of the members of such Person's board of directors; or (c) a transaction or series of related transactions (which may include a tender offer for such Person's stock or the issuance, sale or exchange of stock of such Person) if the shareholders of such Person immediately prior to the initial such transaction do not, immediately after consummation of such transaction or any of such related transactions, own, directly or indirectly through one or more intermediaries, stock or other securities of the entity that possess a majority of the voting power of all of such Person's outstanding stock and other securities and the power to elect a majority of the members of such Person's board of directors.
- **1.9** "Claim" means any claim, action, lawsuit, legal proceeding, litigation, arbitration, inquiry, audit, investigation or action brought, conducted or heard by or before any Regulatory Authority.

- **1.10** "Combination Licensed Product" means a Licensed Product that includes one or more active ingredients in addition to a Licensed Compound, and is sold either as a fixed dose or as separate doses as one product.
- **1.11** "Commercialization" or "Commercialize" means any and all activities undertaken before and after Regulatory Approval of a Marketing Authorization Application for a Licensed Product and that relate to the marketing, promoting, distributing, importing or exporting for sale, offering for sale, and selling of Licensed Compounds or Licensed Products, and interacting with Regulatory Authorities regarding any of the foregoing.
- 1.12 "Commercially Reasonable Efforts" means: (a) with respect to the efforts to be expended by a Party with respect to any objective, such reasonable, diligent, and good faith efforts as such Party would normally use to accomplish a similar objective under similar circumstances; and (b) with respect to any objective relating to Development or Commercialization of Licensed Compound or Licensed Product by a Party, the application by such Party, consistent with the exercise of its prudent scientific and business judgment, of diligent efforts and resources to fulfill the obligation in issue, consistent with the level of efforts such Party would devote to a product at a similar stage in its product life as Licensed Compound or Licensed Product and having profit potential and strategic value comparable to that of Licensed Compound or Licensed Product, taking into account, without limitation, commercial, legal and regulatory factors, target product profiles, product labeling, past performance, the regulatory environment and competitive market conditions in the therapeutic area, safety and efficacy of the Licensed Compound or Licensed Product, the strength of its proprietary position and such other factors as such Party may reasonably consider, all based on conditions then prevailing. For clarity, Commercially Reasonable Efforts shall not mean that a Party guarantees that it shall actually accomplish the applicable task or objective.
  - **1.13** "Competing Product" means any product for use in the Field.
- **1.14** "Compulsory License" means a compulsory license under Licensor Technology obtained by a Third Party through the order, decree, or grant of a competent Regulatory Authority or court, authorizing such Third Party to develop, make, have made, use, sell, offer to sell or import a Licensed Product in the Field in any country in the Territory.
- **1.15** "Confidential Information" of a Party, means information relating to the business, operations or products of a Party or any of its Affiliates, including any Know-How, not known or generally available to the public, that such Party discloses to the other Party under this Agreement, or otherwise becomes known to the other Party by virtue of this Agreement.
- **1.16** "Controlled" means, with respect to (a) Intellectual Property or (b) biological, chemical or physical material, that a Party or one of its Affiliates owns or has a license or sublicense to such Patent Rights, Know-How or material (or in the case of material, has the right to physical possession of such material) and has the ability to grant a license or sublicense to, or assign its right, title and interest in and to, such Patent Rights, Know-How or material as provided for in this Agreement without violating the terms of any agreement or other arrangement with any Third Party.

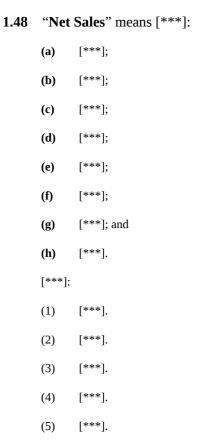
- **1.17** "Copyrights" means (a) all copyrights and works of authorship, whether registered, published or unpublished or unregistered throughout the world; (b) any registrations and applications therefor; (c) rights to databases of any kind under the Laws of any jurisdiction; (d) all extensions and renewals thereof; and (e) any moral rights in or to the foregoing if available by Law of the applicable jurisdiction.
- **1.18** "Cover", "Covering" or "Covered" means, with respect to Licensed Product, that the using, selling, or offering for sale of Licensed Product would, but for a license granted in this Agreement under the Licensor Patent Rights or OnCore Royalty Term Patent, infringe a Valid Claim of the Licensor Patent Rights or OnCore Royalty Term Patent in the country in which the activity occurs.
  - **1.19** "CYT003" means a Qb VLP as further described on Schedule 1.19.
- **1.20** "Development" or "Develop" means, with respect to a Licensed Compound or Licensed Product, the performance of all preclinical and clinical development (including efficacy, toxicology, pharmacology, test method development and stability testing, process development, formulation development, quality control development, statistical analysis), clinical trials, manufacturing and regulatory activities that are required to obtain Regulatory Approval of such Licensed Compound or Licensed Product in the Territory.
  - **1.21** "**EMA**" means the European Medicines Agency or a successor agency thereto.
- **1.22** "Encumbrance" means any pledge, charge, claim, encumbrance, security interest, mortgage, easement, lien, right of first refusal or similar restriction, including any restriction on use, transfer, receipt of income or exercise of any other attribute of ownership (whether arising by contract or by operation of Law).
- **1.23** "**European Commission**" means the authority within the European Union that has the legal authority to grant Regulatory Approvals in the European Union based on input received from the EMA or other competent Regulatory Authorities.
- **1.24** "Executive Officers" means, together, the Chief Executive Officer of OnCore and the Chief Executive Officer of Licensor.
- **1.25** "Existing Licenses" means the existing license agreements between Licensor and [\*\*\*], between Licensor and [\*\*\*], and between Licensor and [\*\*\*].
  - **1.26** "FDA" means the United States Food and Drug Administration or a successor federal agency thereto.
- **1.27** "**Field**" means the diagnosis, treatment and/or prevention of hepatitis viruses in humans and any Additional Fields included within this Agreement by exercise of the Field Option.
- **1.28** "First Commercial Sale" means, on a country-by-country basis, the first commercial transfer or disposition for value of a Licensed Product in such country to a Third Party by OnCore, or any of its Affiliates or Sublicensees after Regulatory Approval for such Licensed Product has been obtained in such country. Sales prior to receipt of Regulatory Approval for such Licensed Product, such as so-called "treatment IND sales," "named patient sales," and "compassionate use sales," shall not be construed as a First Commercial Sale.

- **1.29** "**Fiscal Year**" means OnCore's fiscal year as may be changed from time to time and which is currently from January 1 to December 31.
- **1.30** "GAAP" means generally accepted accounting principles of the United States (in the case of OnCore) or Switzerland (in the case of Licensor) from time to time in force and effect, applicable as of the date on which such accounting principles are to be applied or on which any calculation or determination is required to be made, or such other internationally recognized financial reporting standards, such as IFRS, as may be used by a Party in the preparation of its financial statements.
- **1.31** "Generic Competition" means the sale of Generic Product(s) in a country or other jurisdiction by one or more Third Parties.
- **1.32** "Generic Product" means, with respect to a Licensed Product, any product that (a) is sold by a Third Party that is not a licensee or Sublicensee of OnCore or its Affiliates, or any of their licensees or Sublicensees, (b) contains the Licensed Compound as an active ingredient, and (c) is approved in reliance, in whole or in part, on the prior approval (or on safety or efficacy data submitted in support of the prior approval) of such Licensed Product as determined by the applicable Regulatory Authority, including any product authorized for sale (i) in the U.S. pursuant to Section 505(b)(2) or Section 505(j) of the FFDCA (21 U.S.C. 355(b)(2) and 21 U.S.C. 355(j), respectively), (ii) in the European Union pursuant to a provision of Articles 10, 10a or 10b of Parliament and Council Directive 2001/83/EC as amended (including an application under Article 6.1 of Parliament and Council Regulation (EC) No 726/2004 that relies for its content on any such provision), or (iii) in any other country or jurisdiction pursuant to all equivalents of such provisions, including any amendments and successor statutes with respect to the subsections (i) through (iii) thereto. A Licensed Product licensed or produced by OnCore (i.e., an authorized generic product) shall not constitute a Generic Product.
- **1.33** "Intellectual Property" means all rights in (a) Patent Rights, (b) trademarks and service marks (whether registered or not), trademark and service mark applications and registrations, trade names, trade dress, logos, slogans, (c) Copyrights, (d) Know-How, and (e) technology, software, trade secrets, rights in domain names and web pages, rights in designs, and other intellectual property rights, other than off-the-shelf computer programs, in all cases whether or not registered or registrable and including registrations and applications for registrations of these and rights to apply for same and all rights and forms of protection of a similar nature or having equivalent or similar effect to any of these anywhere in the world.
- 1.34 "Know-How" means any: (a) scientific or technical information, results and data of any type whatsoever, in any tangible or intangible form whatsoever, that is not in the public domain or otherwise publicly known, including discoveries, inventions, trade secrets, devices, databases, practices, protocols, regulatory filings, methods, processes (including manufacturing processes, specification and techniques), techniques, concepts, ideas, specifications, formulations, formulae, data (including pharmacological, biological, chemical, toxicological, clinical and analytical information, quality control, trial and stability data), case report forms, medical records, data analyses, reports, studies and procedures, designs for experiments and tests and results of experimentation and testing (including results of research or development), summaries and information contained in submissions to and information from ethical committees, or Regulatory Authorities, and manufacturing process and development information, results and data, whether or not patentable, all to the extent not claimed or disclosed in a patent or patent application; and (b) compositions of matter, cells, cell lines, assays, animal models and physical, biological or chemical material, including drug substance samples, intermediates of drug substance samples, drug product samples and intermediates of drug product samples. The fact that an item is known to the public shall not be taken to exclude the possibility that compilation including the item, and/or a development relating to the item, is (and remains) not known to the public. "Know-How" includes any rights including copyright, database or design rights protecting such Know-How. "Know-How" excludes Patent Rights.

- **1.35** "Knowledge" means, with respect to a matter that is the subject of a given representation, or warranty of Licensor, the knowledge, information or belief of any officer or director of Licensor, or such other employee of Licensor who would reasonably be expected have knowledge of the matter in question, has, or should reasonably be expected to have, after making reasonable inquiry into the relevant subject matter. "Knowingly" means with Knowledge.
- **1.36** "Law" or "Laws" means any and all applicable laws of any jurisdiction which are applicable to any of the Parties or their respective Affiliates or (sub)licensees in carrying out activities hereunder or to which any of the Parties or their respective Affiliates or (sub)licensees in carrying out the activities hereunder is subject, that may be in effect from time to time, and shall include all statutes, enactments, acts of legislature, laws, ordinances, rules, regulations, notifications, guidelines, directions, directives and orders of any statutory authority, tribunal, board, or court or any central or state government or local authority or other governmental entity in such jurisdictions, including the International Conference on Harmonisation (ICH) guidance or other comparable regulation and guidance of any applicable Regulatory Authority in the Territory, as applicable.
  - **1.37** "Licensed Compound" means all Qb VLPs, including CYT003, containing least one of the following:
- (a) a TLR9 agonist encapsulated within said Qb VLP, and wherein said Qb VLP is not conjugated with any other molecule;
- **(b)** a TLR9 agonist encapsulated within said Qb VLP, and wherein said Qb VLP is conjugated with [\*\*\*], or with [\*\*\*];
- **(c)** a TLR7 agonist, including without limitation [\*\*\*], encapsulated within said Qb VLP, and wherein said Qb VLP is not conjugated with any other molecule;
- **(d)** a TLR7 agonist, including without limitation [\*\*\*], encapsulated within said Qb VLP, and wherein said Qb VLP is conjugated with [\*\*\*];

- **(e)** a RIG-I agonist encapsulated within said Qb VLP, and wherein said Qb VLP is not conjugated with any other molecule; or
  - (f) a RIG-I agonist encapsulated within said Qb VLP, and wherein said Qb VLP is conjugated with [\*\*\*].
- **1.38** "Licensed Compound Series" means any one of the Licensed Compounds in Section 1.37(a) 1.37(f) referred to individually.
- **1.39** "Licensed Product" means any product, in any dosage form, formulation, presentation or package configuration that is commercialized or undergoing research or preclinical or clinical development that contains or comprises one or more Licensed Compounds.
- **1.40** "Licensor Bankruptcy Event" means: (a) voluntary or involuntary proceedings by or against Licensor that are instituted in bankruptcy under any insolvency law, which proceedings, if involuntary, shall not have been dismissed within sixty (60) days after the date of filing; (b) a receiver or custodian is appointed for Licensor; (c) proceedings are instituted by or against Licensor for corporate reorganization, dissolution, liquidation or winding-up of Licensor, which proceedings, if involuntary, shall not have been dismissed within sixty (60) days after the date of filing; or (d) substantially all of the assets of Licensor are seized or attached and not released within sixty (60) days thereafter.
- **1.41** "**Licensor Copyrights**" means all Copyrights that are Controlled by Licensor or any of its Affiliates, as of the Execution Date or at any time thereafter during the Term and are necessary or useful in the research, Development, manufacture, use, or Commercialization of a Licensed Compound or Licensed Product.
- **1.42** "**Licensor Know-How**" means all Know-How that is Controlled by Licensor or any of its Affiliates, as of the Execution Date or at any time thereafter during the Term, and is necessary or useful in the research, Development, manufacture, use, or Commercialization of a Licensed Compound or Licensed Product. The Licensor Know-How shall include all KnowHow set forth on <u>Schedule 1.42</u>.
  - **1.43** "Licensor Materials" means the materials set forth on Schedule 1.43.
- **1.44** "Licensor Patents" means all Patent Rights that are Controlled by Licensor or any of its Affiliates, as of the Execution Date or at any time thereafter during the Term, and that are necessary or useful for the research, Development, manufacture, use, or Commercialization of a Licensed Compound or Licensed Product or that otherwise claim or cover the Licensor Know-How. Listed on Schedule 1.44 are all Licensor Patents existing as of the Effective Date; provided, that Licensor shall update Schedule 1.44 from time to time to include any new Patent Rights that come to be Controlled by Licensor or any of its Affiliates at any time during the Term on or following the Effective Date that are necessary or useful for the research, Development, manufacture, use, or Commercialization of a Licensed Compound or Licensed Product. Licensor Patents expressly exclude Patent Rights Controlled by an Affiliate of Licensor who becomes an Affiliate through a merger or acquisition by or of Licensor, which Patent Rights were Controlled by such Affiliate immediately prior to such merger or acquisition.

- **1.45** "**Licensor Technology**" means the Licensor Copyrights, Licensor Patents, the Licensor Know-How and the Licensor Materials, and all other Intellectual Property rights Controlled by Licensor or any of its Affiliates at any time during the Term on or following the Execution Date that are necessary or useful for the research, Development, manufacture, use, or Commercialization of a Licensed Compound or Licensed Product.
- **1.46** "**Marketing Authorization**" means all approvals from the relevant Regulatory Authority necessary to market and sell a Licensed Product in any country including pricing and pricing reimbursement approval.
- **1.47** "Marketing Authorization Application" or "MAA" shall mean an application or submission for Marketing Authorization of a pharmaceutical product filed with a Regulatory Authority to obtain marketing approval for such pharmaceutical product in a country or group of countries, including all additions, deletions or supplements thereto, and as any and all such requirements may be amended, or supplanted, at any time



**1.49** "New Drug Application" means a new drug application filed with the FDA under 21 U.S.C. § 505(b)(1) (including amendments and supplements thereto) to obtain Regulatory Approval in the United States.

- **1.50** "OnCore Competitor" means any company that (itself or through an Affiliate) is developing or commercializing a Competing Product that is, or could reasonably be expected to be, in competition with any product that OnCore (itself or through an Affiliate) is developing or commercializing.
- **1.51** "OnCore Royalty Term Patent" means any Patent Right owned by OnCore that claims inventions based on Licensor Know-How that is specifically described on <u>Schedule 1.42</u> made within [\*\*\*] years after the Execution Date.
- 1.52 "Patent Rights" means: (a) all national, regional and international patents and patent applications, including provisional patent applications, (b) all patent applications filed either from such patents, patent applications or provisional applications or from an application claiming priority from either of these, including divisionals, continuations, continuations-in-part, provisionals, converted provisionals and continued prosecution applications, (c) any and all patents that have issued or in the future issue from the foregoing patent applications ((a) and (b)), including utility models, petty patents and design patents and certificates of invention, and (d) any and all extensions or restorations by existing or future extension or restoration mechanisms, including revalidations, reissues, re-examinations and extensions (including any supplementary protection certificates and the like) of the foregoing patents or patent applications ((a), (b), and (c)).
- **1.53 "Person"** means any natural person, corporation, firm, business trust, joint venture, association, organization, company, partnership or other business entity, or any government or agency or political subdivision thereof.
- **1.54 "Phase 1b POC Trial"** means a clinical trial of a pharmaceutical product into infected patients with the primary purpose of determining safety, efficacy, metabolism, pharmacokinetic properties and clinical pharmacology of such product.
- **1.55 "Phase 1"** means a human clinical trial of a Licensed Product, the principal purpose of which is a preliminary determination of safety, tolerability, pharmacological activity or pharmacokinetics in healthy individuals or patients or similar clinical study prescribed by the Regulatory Authorities, including the trials referred to in 21 C.F.R. §312.21(a), as amended.
- **1.56** "**Phase 2**" means a human clinical trial of a Licensed Product, the principal purpose of which is a determination of safety and efficacy in the target patient population, which is prospectively designed to generate sufficient data that may permit commencement of pivotal clinical trials, or a similar clinical study prescribed by the Regulatory Authorities, from time to time, pursuant to applicable Law or otherwise, including the trials referred to in 21 C.F.R. §312.21(b), as amended.
- **1.57 "Phase 3"** means a human clinical trial of a Licensed Product on a sufficient number of subjects in an indicated patient population that is designed to establish that a or Licensed Product is safe and efficacious for its intended use and to determine the benefit/risk relationship, warnings, precautions, and adverse reactions that are associated with such product in the dosage range to be prescribed, which trial is intended to support marketing approval of such Licensed Product, including all tests and studies that are required by the FDA from time to time, pursuant to applicable Law or otherwise, including the trials referred to in 21 C.F.R. §312.21(c), as amended.

- **1.58** "**Price Approvals**" means, in those countries in the Territory where Regulatory Authorities may approve or determine pricing and/or pricing reimbursement for pharmaceutical products, such pricing and/or pricing reimbursement approval or determination.
  - **1.59** "**Qb VLP**" means a Q beta-derived virus like particle.
- **1.60** "**Regulatory Authority**" means: (a) in the US, the FDA; (b) in the EU, the EMA or the European Commission; or (c) in any other jurisdiction anywhere in the world, any regulatory body with similar regulatory authority over pharmaceutical or biotechnology products.
- **1.61** "**Regulatory Approval**" means any and all approvals, licenses, registrations, or authorizations of the relevant Regulatory Authority, including Price Approvals, necessary for the Development, manufacture, use, storage, import, transport or Commercialization of Licensed Product in a particular country or jurisdiction. For the avoidance of doubt, Regulatory Approval to Commercialize Licensed Product shall include Price Approval.
- 1.62 "Regulatory Documentation" means any and all applications, registrations, licenses, authorizations and approvals (including all Regulatory Approvals), and non-clinical and clinical study authorization applications or notifications (including all supporting files, writings, data, studies and reports) prepared for submission to a Regulatory Authority or research ethics committee with a view to the granting of any Regulatory Approval, and any correspondence to or with the EMEA or FDA or any other Regulatory Authority with respect to a Licensed Compound, a Licensed Product (including minutes and official contact reports relating to any communications with any Regulatory Authority), and all data contained in any of the foregoing, including all regulatory authorizations, regulatory drug lists, advertising and promotion documents, adverse event files and complaint files.
  - **1.63** "RIG-I agonist" means [\*\*\*] or any other molecule that activates retinoic acid-inducible gene I.
  - **1.64** "RIG-I Licensed Product" means a Licensed Product containing a RIG-I agonist.
- 1.65 "Royalty Term" means, on a Licensed Product-by-Licensed Product and country-by-country basis, the period from the First Commercial Sale of such Licensed Product in such country until the later of (a) the last date on which such Licensed Product is Covered by a Valid Claim within the Licensor Patents or any OnCore Royalty Term Patent in such country, (b) the date on which sale of such Licensed Product is no longer protected by regulatory data exclusivity in such country or (c) ten years following First Commercial Sale of such Licensed Product in such country; provided that this clause (c) shall only apply in the event that the Licensed Product is Covered by a Valid Claim within the Licensor Patents or any OnCore Royalty Term Patent at any time after the Execution Date.

- **1.66** "Senior Executive" means a member of senior management of a Party who is designated by such Party to resolve disputes under this Agreement.
- **1.67** "Sublicensee" means a Person other than an Affiliate of OnCore to which OnCore (or its Affiliate) has, pursuant to Section 4.2, granted sublicense rights under any of the license rights granted under Section 4.1; provided, that "Sublicensee" shall exclude distributors.
- **1.68** "Tax" or "Taxes" means any federal, state, local or foreign income, gross receipts, license, payroll, employment, excise, severance, stamp, occupation, premium, windfall profits, environmental, customs duties, capital stock, franchise, profits, withholding, social security, unemployment, disability, real property, personal property, sales, use, transfer, registration, value added, alternative or add-on minimum, estimated, or other tax of any kind whatsoever, including any interest, penalty, or addition thereto, whether disputed or not.
- **1.69 "Technology and Program Transfer Plan"** means the plan for the transfer of Licensor Know-How, Licensor Materials and Licensor's CYT003 program, an outline of which is set forth on <u>Schedule 1.69</u>.
  - **1.70** "**Territory**" means all the countries in the world.
  - **1.71 "Third Party"** means any Person other than Licensor, OnCore or any of their respective Affiliates.
- **1.72 "Third Party Action"** means any Action made by a Third Party against either Party that claims that a Licensed Compound or Licensed Product, or its use, Development, manufacture or sale infringes or misappropriates such Third Party's Intellectual Property rights.
- **1.73** "Third Party License Agreement" means any agreement entered into by a Party or its Affiliate with a Third Party, or any amendment or supplement thereto, in each case following the Effective Date, whereby royalties, fees or other payments are to be made by a Party or its Affiliate to such Third Party in connection with the grant of rights under intellectual property rights Controlled by such Third Party, which rights are necessary or useful to research, Develop, manufacture, have made, import, export, use or Commercialize a Licensed Compound or Licensed Product.
  - **1.74** "TLR agonist" means a molecule that activates Toll-like receptors.
  - **1.75** "TLR7 agonist" means single-stranded RNA or any other TLR agonist that activates Toll-like receptor 7.
  - **1.76** "TLR7 Licensed Product" means a Licensed Product containing a TLR7 agonist.
- **1.77** "**TLR9 agonist**" means unmethylated CpG Oligodeoxynucleotide DNA or any other TLR agonist that activates Toll-like receptor 9.
  - 1.78 "TLR9 Licensed Product" means a Licensed Product containing a TLR9 agonist.

- **1.79** "**United States**" or "**US**" means the United States of America, its territories and possessions.
- **1.80** "USD" or "\$" means the lawful currency of the United States.
- **1.81** "Valid Claim" means a claim (a) of an issued and unexpired patent which has not lapsed or been revoked, abandoned or held unenforceable or invalid by a final decision of a court or governmental or supra-governmental agency of competent jurisdiction, unappealable or unappealed within the time allowed for appeal, and which has not been disclaimed, denied or admitted to be invalid or unenforceable through reissue, reexamination or disclaimer or otherwise, or (b) of a patent application that is being diligently prosecuted and that has not been pending for more than [\*\*\*] from the earliest filing date from which such patent application is entitled to claim priority and which claim has not been revoked, cancelled, withdrawn, held invalid or abandoned.
- **1.82 Other Terms.** The definition of each of the following terms is set forth in the section of the Agreement indicated below:

Defined Term	Section
"Action"	8.5.2
"Agreement"	Preamble
"Closing"	2.1
"Closing Date"	2.1
"Controlling Party"	8.6.3
"Development Support"	5.2
"Effective Date"	Preamble
"Existing Licenses"	8.4.1
Field Option"	4.4.2
"Licensor"	Preamble
"Licensor Indemnitees"	11.1
"Manufacturing Support"	5.4
"No Shop Period"	3.3
"Offer Notice"	4.4.3
"OnCore"	Preamble
'OnCore Indemnitees"	11.2
'OnCore Patent"	8.4.4
"Option Exercise Notice"	4.4.2
'Net Sales-Based Milestone Payment"	7.4
'Net Sales-Based Milestone Table"	7.4
"Non-Escalable Dispute"	13.1
"Party" and "Parties"	Preamble
'Regulatory Support"	6.2
"Representatives"	5.2
'Right of First Refusal"	12.6.3
'Right of First Refusal Notice Period"	12.6.3(b)
'Rules"	13.3
'Term"	12.1

## ARTICLE 2 CLOSING

- **2.1 Closing.** The closing of the transactions contemplated hereby (the "**Closing**") shall take place on a date and at a time agreed by the Parties, but in no event later than the second Business Day following the date on which the conditions set forth in Section 2.3 below (other than those conditions that by their nature are to be satisfied at the Closing but subject to the fulfillment or waiver of those conditions) have been satisfied or waived, at the offices of [\*\*\*] (local time), or at such other place as the Parties hereto may mutually agree. The date on which the Closing occurs is referred to herein as the "**Closing Date**".
- **2.2 Deliveries at Closing.** On the terms and subject to the conditions set forth herein, at the Closing, each Party shall deliver to the other Party (at the delivering Party's cost and expense) such instruments and documents which the receiving Party may reasonably deem necessary or as may be required to consummate the transactions contemplated hereby, each in form and substance reasonably satisfactory to the delivering Party. Without limiting the foregoing, at the Closing, Licensor shall deliver to OnCore a copy of an interim balance sheet based on going-concern values reviewed by Licensor's independent auditor that confirms that Licensor is not overindebted in the sense of art. 725 para. 2 of the Swiss Code of Obligations as well as written confirmation of Licensor's independent auditor that Licensor is not so overindebted.
- **2.3 Conditions to the Obligations of OnCore**. The obligations of OnCore to consummate the Closing, shall, at the option of OnCore, be subject to the satisfaction or waiver, on or prior to the Closing Date, of the following conditions:
- **2.3.1 Representations and Warranties**. The representations and warranties of Licensor made in this Agreement shall be true and correct in all respects: (a) as of the date hereof; and (b) on and as of the Closing Date, as though made on such date, in each case, except for those representations and warranties which expressly refer to facts existing at a specific date (which shall be true and correct as of such date).
- **2.3.2 Covenants.** Licensor shall have performed or complied in all material respects with all obligations and covenants required by this Agreement to be performed or complied with by Licensor on or before the Closing Date.
  - **2.3.3 Bond Conversion**. All publicly traded bonds of Licensor shall have been converted into equity.
- **2.3.4 Certificate.** Licensor shall have delivered to OnCore a certificate dated the Closing Date and signed by an authorized officer of Licensor, to the effect that the conditions set forth in Sections 2.3.1, 2.3.2 and 2.3.3 have been satisfie.
- **2.3.5 Deliveries by Licensor**. Licensor shall have delivered to OnCore at Closing all of the items specified to be delivered in Section 2.2 hereof.

- **2.3.6 Technology and Program Transfer Plan**. The Parties shall have mutually agreed upon a final Technology and Program Transfer Plan, which plan shall be appended to <u>Schedule 1.69</u> hereof.
- **2.4 Conditions to the Obligations of Licensor.** The obligations of Licensor to consummate the Closing shall, at the option of Licensor, be subject to the satisfaction or waiver, on or prior to the Closing Date, of the following conditions:
- **2.4.1 Representations and Warranties**. The representations and warranties of OnCore made in this Agreement, without giving effect to any materiality or material adverse effect qualifications contained therein, shall be true and correct in all respects: (a) as of the date hereof; and (b) on and as of the Closing Date, as though made on such date, in each case, except for those representations and warranties which expressly refer to facts existing at a specific date (which shall be true and correct as of such date).
- **2.4.2 Covenants**. OnCore shall have performed or complied in all material respects with all obligations and covenants required by this Agreement to be performed or complied with by OnCore on or before the Closing Date.
- **2.4.3 Deliveries by OnCore**. OnCore shall have delivered to Licensor at Closing all of the items specified to be delivered by OnCore in Section 2.2 hereof.
- **2.4.4 Technology and Program Transfer Plan**. The Parties shall have mutually agreed upon a final Technology and Program Transfer Plan, which plan shall be appended to Schedule 1.69 hereof.

# ARTICLE 3 PRE-CLOSING COVENANTS

- **3.1** Access and Information. Without limiting Section 4.3 below, from and after the Execution Date until the earlier of the termination of this Agreement and the Closing, and in each case, subject to the confidentiality terms herein, Licensor shall afford OnCore and its representatives reasonable access, during regular business hours and upon reasonable advance notice, to the assets, books, records and employees relating to the Licensed Technology, Licensed Compounds and/or Licensed Products and/or all financial records of Licensor.
- **3.2 Conduct of Business.** From and after Execution Date until the earlier of the termination of this Agreement and the Closing, except as otherwise contemplated by this Agreement or as OnCore shall otherwise consent in writing (which consent OnCore shall not unreasonably withhold, condition or delay), Licensor shall not:
- **3.2.1** sell, lease, license, transfer or dispose of any Licensed Technology or otherwise disclose any Confidential Information relating thereto, or mortgage, pledge or impose any Encumbrance (other than under the Existing Licenses) on any of the Licensed Technology;
  - **3.2.2** dispose of or permit to lapse any rights in, to or for the use of any Licensed Technology;

- **3.2.3** cancel or compromise any material debt or claim owed to Licensor or waive any rights of material value relating to the Licensed Technology; or
  - **3.2.4** authorize any of, or commit or agree to take any of the foregoing actions.
- **3.3 No Shop**. From and after the Execution Date until the earlier of the termination of this Agreement and the Closing (the "**No Shop Period**"), Licensor shall not, and shall cause its Affiliates and its and their respective officers, directors, employees, representatives and agents (including any investment banking, legal or accounting firm retained by it or any of them and any individual member or employee of the foregoing) not to, initiate, solicit or encourage any inquiry, proposal or offer from, or engage in any negotiations or discussions regarding any such inquiry, proposal or offer with, any Third Party (other than OnCore) regarding any direct or indirect acquisition, transfer, license or other grant of rights with respect to the Licensor Technology in the Field.
- **3.4 Materials Prior to Closing.** Licensor shall provide OnCore, at OnCore's expense, with certain Licensor Materials prior to the Closing, including such quantities of CYT003 and the associated analytical methods, as may be reasonably requested by OnCore for the purpose of enabling OnCore's conduct of certain non-clinical research activities using such Licensor Materials. OnCore shall pay for such Licensor Materials according to the purchase price set forth in <u>Schedule 1.43</u> pro rata based on the amount of materials transferred to OnCore.

## ARTICLE 4 LICENSES AND OTHER RIGHTS

- **4.1 Grant of License to OnCore**. Subject to the terms and conditions of this Agreement, Licensor hereby grants to OnCore and its Affiliates, effective as of the Closing Date, an exclusive (even as to Licensor) worldwide right and license (with the right to sublicense, subject to the provisions of Section 4.2) under the Licensor Technology to research, Develop, manufacture, have manufactured, use and Commercialize Licensed Compounds and Licensed Products in the Territory in the Field. Notwithstanding that the licenses are not effective until the Closing Date, Licensor grants to OnCore and its Affiliates the foregoing licenses to the extent necessary for OnCore to exercise its rights pursuant to Section 3.4.
- **4.2 Right to Sublicense.** OnCore shall have the right, in its sole discretion, to grant sublicenses, in whole or in part, through multiple tiers of Sublicensees, under the licenses granted in Section 4.1, provided that no sublicense or other right may be granted with respect to Licensor Technology, Licensed Compounds or Licensed Products in any Additional Field for a period of two (2) years after the exercise of the Field Option for such Additional Field without the prior written consent of Licensor, such consent not to be unreasonably withheld, conditioned or delayed.
- 4.3 Technology Transfer. After the Closing Date, Licensor shall make available to OnCore the Licensor Know-How and Licensor Materials and undertake the other activities set forth in the Technology and Program Transfer Plan in the manner and according to the schedule set forth therein. OnCore shall be responsible for certain costs as set forth in the Technology and Program Transfer Plan; provided, however, that except as provided in Section 3.4, OnCore shall not be required to make payments for any Licensor Materials until the later of (i) March 31, 2015 and (ii) the Closing Date. The technology transfers set forth in the Technology and Program Transfer Plan shall occur in an orderly fashion and in a manner such that the value, usefulness and confidentiality of the transferred Licensor Know-How, Licensor Materials and Regulatory Documentation are preserved in all material respects. In addition to implementing the Technology and Program Transfer Plan, during the Term, Licensor shall provide to OnCore full and prompt disclosure, but in no event less frequently than semi-annually, of any Licensor Technology that becomes Controlled by Licensor or any of its Affiliates after the Closing Date and that is necessary or useful to OnCore to conduct its activities or exercise its rights as contemplated hereunder and shall, in the case of Licensor Know-How, promptly following such disclosure, transfer to OnCore such Licensor Know-How.

## 4.4 Field Option.

- **4.4.1** Licensor shall not, and shall cause its Affiliates not to, grant to any Third Party any rights to the Licensor Technology in the Additional Fields, except in accordance with Section 4.4.3.
- **4.4.2** Licensor hereby grants to OnCore the first option (the "**Field Option**") to expand the Field to include any Additional Fields in accordance with this Section 4.4. OnCore may, at any time during the Term and regardless of whether the Field Option has been previously exercised, give written notice (each an "**Option Exercise Notice**") to Licensor that OnCore wishes to exercise its Field Option to include under this Agreement any Additional Fields. The Option Exercise Notice shall set forth the Additional Fields to which the Field Option shall apply. Effective upon the date of the Option Exercise Notice, the definition of Field shall be deemed to include the Additional Fields that are the subject of the Option Exercise Notice.
- **4.4.3** If a Third Party requests that Licensor grant any rights to the Licensor Technology in any Additional Fields that have not already been included in the Field, Licensor shall provide OnCore with written notice (each an "Offer Notice") of such request. The Offer Notice shall set forth the Additional Fields requested by the Third Party and include all available Baseline Data. To the extent the Baseline Data is not sufficient for OnCore to make a reasonably informed decision regarding such Additional Field, OnCore shall so notify Licensor and the Parties shall confer regarding what additional data OnCore may reasonably require. OnCore shall have ninety (90) days from the later of (a) the effective date of the Offer Notice or (b) receipt of all Baseline Data (if not provided with the Offer Notice), in which to provide Licensor with an Option Exercise Notice covering such Additional Fields. Effective upon the date of the Option Exercise Notice, the definition of Field shall be deemed to include such Additional Fields. If OnCore does not provide such Option Exercise Notice within the ninety (90) day period, Licensor shall be free to grant a license to such Third Party under the Licensor Technology only with respect to the Additional Fields that were the subject of the Offer Notice and which are not already included within the Field.
- **4.4.4** Within [\*\*\*] months from providing the Option Exercise Notice, OnCore shall commence the Development of at least one Licensed Product with respect to each Additional Field for which OnCore has exercised the Field Option pursuant to a research or development plan that in the exercise of OnCore's prudent scientific and business judgment is consistent with the level of efforts OnCore would devote to a product at a similar stage in its product life and having profit potential and strategic value comparable to that of the Licensed Product for such Additional Field, taking into account, without limitation, commercial, legal and regulatory factors, target product profiles, product labeling, past performance, the regulatory environment and competitive market conditions in the therapeutic area, safety and efficacy of the Licensed Product in such Additional Field.

**4.5 Financial Reporting.** On or before March 31 and September 30 of each year of the Term, Licensor shall provide to OnCore full and prompt disclosure, of Licensor's financial condition, including a copy of an interim balance sheet based on going-concern values reviewed by Licensor's independent auditor.

# ARTICLE 5 DEVELOPMENT, MANUFACTURE AND COMMERCIALIZATION OF PRODUCT

- **5.1 Development of Licensed Product by OnCore**. After the Closing Date, OnCore shall have the exclusive right and decision-making authority to research and Develop the Licensed Compounds and Licensed Products in the Field and to conduct (either itself or through its Affiliates, agents, subcontractors and/or Sublicensees) all clinical trials and non-clinical studies OnCore believes appropriate to obtain Regulatory Approval for Licensed Products in the Field.
- **5.2 Licensor Support in Development**. After the Closing Date, Licensor shall assist OnCore with Development of the Licensed Compounds and Licensed Products by making its employees, consultants, contractors, advisors and agents ("**Representatives**") that are knowledgeable regarding the Licensor Technology, the Licensed Compounds or Licensed Products (including the properties and functions thereof), available to OnCore for scientific and technical explanations, advice and on-site support (collectively, the "**Development Support**"). All Development Support requested by OnCore shall be at OnCore's expense and at industry standard rates
- **5.3 Commercialization**. After the Closing Date, OnCore (or its Affiliates, Sublicensees or other Third Parties designated by OnCore) shall have the exclusive right and decision-making authority to Commercialize Licensed Products and Licensed Compounds in the Field.
- **5.4 Clinical and Commercial Manufacturing**. After the Closing Date, OnCore (or its Affiliates, Sublicensees or other Third Parties designated by OnCore) shall have the exclusive right to manufacture the Licensed Compounds and Licensed Products for use in the Field. After the Closing Date, Licensor shall make Representatives that are knowledgeable regarding the Licensor Technology, the Licensed Compounds or Licensed Products available to OnCore for scientific and technical explanations, advice and on-site support, that may reasonably be required by OnCore, relating to the manufacture of a Licensed Compound and Licensed Product (the "**Manufacturing Support**"), including manufacturing scale-up. All such Manufacturing Support shall be at OnCore's expense and at industry standard rates.

- 5.5 **Diligence by OnCore**. After the Closing Date, OnCore shall use Commercially Reasonable Efforts to Develop and Commercialize at least one Licensed Product in the Field and, to the extent OnCore exercises the Field Option for an Additional Field, in each Additional Field. OnCore shall have the exclusive right to determine, in its sole discretion, the launch strategy for a Licensed Product in the Field subject to its exercise of Commercially Reasonable Efforts and the availability of any necessary Third Party licenses or other rights. Activities by OnCore's Affiliates and Sublicensees shall be considered as OnCore's activities under this Agreement for purposes of determining whether OnCore has complied with its obligation to use Commercially Reasonably Efforts. OnCore shall be relieved of its diligence obligations under this Section 5.5 starting from the date OnCore provides Licensor with a termination notice pursuant to Section 12.3 or Section 12.4, subject to the terms and conditions described in Section 12.5.2(a)(vii) .
- **5.6 OnCore's Right to Subcontract**. OnCore may exercise any of its rights, or perform any of its obligations, under this Agreement (including any of the rights licensed in Section 4.1) by subcontracting the exercise or performance of all or any portion of such rights and obligations on OnCore's behalf. Any subcontract granted or entered into by OnCore as contemplated by this Section 5.6 of the exercise or performance of all or any portion of the rights or obligations that OnCore may have under this Agreement shall not relieve OnCore from any of its obligations under this Agreement.
- **5.7 Trade Marks**. After the Closing Date, as between Licensor and OnCore, OnCore shall have the sole authority to select trademarks for Licensed Products in the Field and shall own all such trademarks.
- **5.8 Reporting.** OnCore shall, within [\*\*\*] days of each anniversary of the Closing Date, provide Licensor with a written report summarizing in reasonable detail its major Development and, as applicable, Commercialization activities conducted since the last such report. All information and reports provided to Licensor pursuant to this Section 5.8 shall be treated as Confidential Information of OnCore hereunder. Notwithstanding the foregoing, OnCore's obligation to provide reports under this Section 5.8 shall expire: (a) with respect to Development, upon receipt of Regulatory Approval for Licensed Product, and (b) with respect to Commercialization, upon the third anniversary of the First Commercial Sale of Licensed Product hereunder.

# ARTICLE 6 REGULATORY MATTERS

- **6.1 Regulatory Filings**. After the Closing Date, as between OnCore and Licensor, OnCore shall own and maintain all regulatory filings and Regulatory Approvals for Licensed Products in the Field, including all INDs and Marketing Authorization Applications.
- 6.2 Communications with Regulatory Authorities. After the Closing Date, OnCore (or one of its Affiliates or Sublicensees) shall be responsible, and act as the sole point of contact, for communications with Regulatory Authorities in connection with the Development, Commercialization, and manufacturing of Licensed Compounds and Licensed Products in the Field. After the Closing Date, Licensor shall not initiate, with respect to any Licensed Compound or Licensed Product in the Field, any meetings or contact with Regulatory Authorities without OnCore's prior written consent. After the Closing Date, to the extent Licensor receives any written or oral communication from any Regulatory Authority relating to a Licensed Compound or Licensed Product in the Field, Licensor shall (a) refer such Regulatory Authority to OnCore, and (b) as soon as reasonably practicable (but in any event within twenty-four (24) hours), notify OnCore and provide OnCore with a copy of any written communication received by Licensor or, if applicable, complete and accurate minutes of such oral communication. After the Closing Date, at the request of OnCore, Licensor shall make available to OnCore a Representative knowledgeable regarding the Licensor Technology, the Licensed Compounds or Licensed Products, who shall, together with the representatives of OnCore, participate in and contribute to meetings with the Regulatory Authorities with respect to regulatory matters relating to the Licensor Technology ("Regulatory Support"). All such Regulatory Support shall be at OnCore's expense and at industry standard rates.

- **6.3** Adverse Event Reporting. The Parties agree to comply with any and all Laws that are applicable as of the Execution Date and thereafter during the Term in connection with Licensed Product safety data collection and reporting. After the Execution Date, if Licensor has or receives any information regarding any Adverse Event which may be related to the use of Licensed Product, then Licensor shall provide OnCore with all such information in English within such time that shall enable OnCore to comply with all Laws and relevant regulations and requirements. OnCore shall report to Licensor any Adverse Event culminating in death or permanent disability of a patient or subject who is administered Licensed Product.
- **6.4 Recalls**. After the Closing Date, OnCore shall have the sole right to determine whether and how to implement a recall or other market withdrawal of a Licensed Product in the Field.

## ARTICLE 7 FINANCIAL PROVISIONS

## 7.1 Development Milestones.

**7.1.1** In partial consideration of the rights granted by Licensor to OnCore and subject to the terms and conditions set forth in this Agreement, OnCore shall pay to Licensor a milestone payment within [\*\*\*] days after the achievement of each of the following milestones for the first Licensed Compound in a Licensed Compound Series developed and commercialized for diagnosis, prevention and treatment of hepatitis virus infections in humans and any additional virus infection included in the Field upon exercise of the Field Option, in each case only if such Licensed Compound was Covered by a Valid Claim within the Licensor Patents or any OnCore Royalty Term Patent at any time after the Execution Date:

Development Milestone	Payment (all in USD)
Upon enrollment of the first patient in the first Phase 1b POC Trial	[***]
Upon enrollment of the first patient in the first Phase 2 clinical trial	[***]
Upon enrollment of the first patient in the first Phase 3 clinical trial	[***]
Upon the first New Drug Application filing with the FDA for regulatory approval in the United States	[***]
Upon the first MAA filing for regulatory approval in the European Union	[***]
Upon the first New Drug Application or equivalent filing for regulatory approval in the first of: China, Japan, South Korea, Taiwan or Singapore	[***]
Upon the first approval of a New Drug Application in the United States	[***]
Upon the first approval of an MAA in the European Union	[***]
Upon the first approval of a New Drug Application or equivalent in the first of: China, Japan, South Korea, Taiwan or Singapore	[***]

- **7.1.2** Each milestone payment in this Section 7.1 shall be payable only upon the first achievement of such milestone in a particular indication for the first Licensed Product from the same Licensed Compound Series and no amounts shall be due for subsequent or repeated achievements of such milestone in such indication with Licensed Products from such Licensed Compound Series.
- **7.1.3** If the first Licensed Product in a Licensed Compound Series in a particular indication is abandoned for any reason prior to the First Commercial Sale and an additional Licensed Product in the same Licensed Compound Series for the same indication is advanced into clinical development, OnCore shall resume milestone payments starting at the event subsequent to the last milestone payment that was made with respect to the first Licensed Product in such Licensed Compound Series.
- **7.1.4** If a development milestone event based on the enrollment of the first patient in a particular clinical trial has not been achieved with a Licensed Product, but a subsequent development milestone event is achieved, then the milestone payment for the preceding milestone event shall become due and payable upon the achievement of such subsequent milestone event.
- **7.1.5** The maximum aggregate amount payable by OnCore pursuant to this Section for each Licensed Compound Series for a given indication is \$67 million and for all Licensed Products for a given indication is [\*\*\*].
- **7.2 Discontinuation Payment**. In the event that development of a Licensed Product that has successfully completed a Phase 1b POC Trial is terminated by OnCore for reason other than safety or efficacy and no other Licensed Product containing the same agonist (i.e., a TLR9 agonist, TLR7 agonist or RIG-I agonist) remains under development, OnCore shall pay Licensor a one-time discontinuation payment of [\*\*\*] within [\*\*\*] days of such discontinuation. OnCore shall make this discontinuation payment only once in the Field (as defined as of the Execution Date) regardless of the number of Licensed Products that are discontinued in the Field, and only once for each of the Additional Fields with respect to which OnCore has exercised the Field Option regardless of the number of Licensed Products that are discontinued in such Additional Field. If OnCore fails to initiate research or development activities in such Additional Field within [\*\*\*] months from providing the Option Exercise Notice, OnCore shall pay to Licensor a one-time discontinuation payment of [\*\*\*]. If a discontinuation payment is due with respect to an Additional Field, the licenses granted under this Agreement shall automatically terminate with respect to such Additional Field.

# 7.3 Royalty Payments for Licensed Product.

**7.3.1 Royalty Rate**. As further consideration for the rights granted to OnCore hereunder, subject to Sections 7.3.2, 7.3.3 and 7.3.4, during each applicable Royalty Term, OnCore shall pay to Licensor a royalty on Net Sales of each Licensed Product in the Territory (excluding Net Sales of each Licensed Product in any country in the Territory for which the Royalty Term for such Licensed Product in such country has expired) during each Calendar Year at the following rates:

Net Sales in the Territory of all Licensed Products in a Calendar Year	Royalty Rate
For that portion of aggregate Net Sales of all Licensed Products in the Territory during a Calendar Year less than [***]	[***]
For that portion of aggregate Net Sales of all Licensed Products in the Territory during a Calendar Year equal to or greater than [***] but less than [***]	[***]
For that portion of aggregate Net Sales of all Licensed Products in the Territory during a Calendar Year equal to or greater than [***]	[***]

- **7.3.2 Royalty Step-Down**. If, during the Royalty Term, there is (i) Generic Competition with a Licensed Product in a particular country, or (ii) no Valid Claim of a Licensor Patent or OnCore Royalty Term Patent covering a Licensed Product in a particular country, then, for such country, the royalties payable to Licensor for Net Sales of such Licensed Product in such country shall be reduced by [\*\*\*] of the applicable royalty rate(s) set forth in Section 7.3.1.
- **7.3.3 Compulsory License**. In the event that Licensor or OnCore receives a request for a Compulsory License anywhere in the world, it shall promptly notify the other Party. If any Third Party obtains a Compulsory License in any country, then Licensor or OnCore (whoever has first notice) shall promptly notify the other Party. Thereafter, as of the date the Third Party obtained such Compulsory License in such country, the royalty rate payable under Section 7.3.1 to Licensor for Net Sales in such country shall be adjusted to equal any lower royalty rate granted to such Third Party for such country with respect to the sales of such Licensed Product therein. In addition, should OnCore grant a Sublicense to a Third Party in any country to avoid the imposition of such a Compulsory License, the royalty rate payable under Section 7.3.1 to Licensor for Net Sales in such country shall also be adjusted to match any lower royalty rate payable by such Sublicensee for such country under such Sublicense.

- **7.3.4 Reductions for Third Party License Agreements.** If OnCore or any of its Affiliates enter into a Third Party License Agreement(s) required to avoid or settle an alleged infringement of such Third Party's Intellectual Property rights arising from the use, Development, manufacture or sale of a Licensed Compound or Mono Product, OnCore shall be entitled to deduct from any amount payable to Licensor under Section 7.3.1 [\*\*\*] of any amounts paid by OnCore or such Affiliates pursuant to such Third Party License Agreement(s) in respect of the Licensed Product which gave rise to the payment obligation under Section 7.3.1; provided, that in no event shall the foregoing deduction reduce the amount due to Licensor pursuant to Section 7.3.1 for any Calendar Quarter by more than [\*\*\*]. If, but for the proviso in the preceding sentence, the deduction under this Section 7.3.4 would have reduced a payment made by OnCore by more than [\*\*\*], then the amount of such deduction that exceeds [\*\*\*] will be carried over to subsequent payments until the full amount that OnCore would have been entitled to deduct (absent the above limitation) is deducted.
- **7.3.5 Timing of Payment**. Royalties payable under Section 7.3 shall be payable on actual Net Sales and shall accrue at the time the payment for the sale of Licensed Product is received. Royalty obligations that have accrued during a particular Calendar Quarter shall be paid, on a Calendar Quarter basis, within [\*\*\*] after the end of each Calendar Quarter during which the royalty obligation accrued.
- **7.3.6 Royalty Reports and Records Retention.** Within [\*\*\*] after the end of each Calendar Quarter during which Licensed Product has been sold, OnCore shall deliver to Licensor, together with the applicable royalty payment due for such Calendar Quarter, a written report, on a Licensed Product-by-Licensed Product and a country-by-country basis, of Net Sales subject to royalty payments for such Calendar Quarter. Such report shall be deemed "Confidential Information" of OnCore subject to the obligations of ARTICLE 9 of this Agreement. For one year (unless OnCore's, or any of its relevant Affiliate's, internal company procedures require a shorter period) after each sale of Licensed Product occurs, OnCore shall, and shall ensure that its Affiliates and Sublicensees, keep complete and accurate records of such sale in sufficient detail to confirm the accuracy of the royalty calculations hereunder.
- **7.4 Sales Performance Milestones**. In partial consideration of the license rights granted by Licensor to OnCore hereunder, in the event that the cumulative Net Sales in the Territory for all Licensed Products made by OnCore or any of its Affiliates or Sublicensees exceeds a threshold set forth in the left-hand column of the table immediately below (the "**Net Sales-Based Milestone Table**"), OnCore shall pay to Licensor a milestone payment (each, a "**Net Sales-Based Milestone Payment**") in the corresponding amount set forth in the right column of the Net Sales-Based Milestone Table. Each Net Sales-Based Milestone Payment shall be due upon the later of (a) [\*\*\*] after achievement of the applicable threshold or (b) for any payment other than the first Net Sales-Based Milestone Payment, the first Business Day of the next Fiscal Year following payment of the immediately preceding Net Sales-Based Milestone Payment. Each Net Sales-Based Milestone Payment is payable only on the first achievement of such milestone and the maximum aggregate amount payable by OnCore pursuant to this Section is [\*\*\*].

Net Sales Performance Threshold	<u>Payment</u>
Cumulative Net Sales ≥ [***]	[***]
Cumulative Net Sales ≥ [***]	[***]
Cumulative Net Sales ≥ [***]	[***]
Cumulative Net Sales ≥ [***]	[***]

- **7.5 Mode of Payment and Currency**. All payments to Licensor hereunder shall be made by deposit of USD in the requisite amount to such bank account as Licensor may from time to time designate by written notice to OnCore. With respect to sales not denominated in USD, OnCore shall convert applicable sales in foreign currency into USD by using the then current and reasonable standard exchange rate methodology applied to its external reporting or other standard practice used for the preparation of its audited financial statements. Based on the resulting sales in USD, the then applicable royalties shall be calculated. The Parties may vary the method of payment set forth herein at any time upon mutual written agreement, and any change shall be consistent with the local Law at the place of payment or remittance.
- **7.6 Legal Restrictions**. If at any time legal restrictions prevent the remittance by OnCore of all or any part of royalties due on Net Sales in any country, OnCore shall have the right and option to make such payment either by depositing the amount thereof in local currency to an account in the name of Licensor in a bank or other depository selected by Licensor in such country.

## 7.7 Audits.

- **7.7.1 Audits Generally**. During the Royalty Term and for one Calendar Year thereafter, and not more than once in each Calendar Year, OnCore shall permit, and shall cause its Affiliates to permit, an independent certified public accounting firm of nationally recognized standing selected by Licensor, and reasonably acceptable to OnCore, to have access to and to review, during normal business hours upon reasonable prior written notice, the applicable records of OnCore and its Affiliates to verify the accuracy of the royalty reports and payments under this ARTICLE 7. Such review may cover the records for sales made in any Calendar Year ending not more than one year prior to the date of such request. The accounting firm shall disclose to Licensor and OnCore only whether the royalty reports are correct or incorrect and the specific details concerning any discrepancies. No other information shall be provided to Licensor.
- **7.7.2 Audit-Based Reconciliation**. If such accounting firm concludes that additional amounts were owed during such period, and OnCore agrees with such calculation, OnCore shall pay the additional undisputed amounts within [\*\*\*] after the date Licensor delivers to OnCore such accounting firm's written report. If such accounting firm concludes that an overpayment was made, such overpayment shall be fully creditable against amounts payable in subsequent payment periods or, at OnCore's request, shall be promptly reimbursed to OnCore.

If OnCore disagrees with such calculation, it may retain its own independent certified public accounting firm of recognized standing and reasonably acceptable to Licensor, to conduct a review, and if such firm concurs with the other accounting firm, OnCore shall make the required payment within [\*\*\*] after the date OnCore receives the report of its accounting firm. If OnCore's accounting firm does not concur, OnCore and Licensor shall meet and negotiate in good faith a resolution of the discrepancies between the two firms. Licensor shall pay for the cost of any audit, unless OnCore has underpaid Licensor by at least [\*\*\*], in which case OnCore shall pay for the cost of the audit.

- **7.7.3 Audit Confidentiality**. Each Party shall treat all information that it receives under this Section 7.7 in accordance with the confidentiality provisions of ARTICLE 9 of this Agreement, and shall cause its accounting firm to enter into an acceptable confidentiality agreement with the other Party obligating such firm to retain all such financial information in confidence pursuant to such confidentiality agreement, except to the extent necessary for such Party to enforce its rights under this Agreement. The terms of this Section 7.7 shall apply *mutatis mutandis* with respect to OnCore's right to audit Licensor's records related to those Out-of-Pocket Expenses for which Licensor seeks reimbursement hereunder.
- 7.8 Withholding Tax. Licensor shall be responsible for the payment of any and all Taxes levied on account of the royalties and other payments paid to Licensor by OnCore or its Affiliates or Sublicensees under this Agreement. If Law requires that Taxes be deducted and withheld from royalties or other payments paid under this Agreement, OnCore shall (a) deduct those Taxes and interests and penalties assessed thereon from the payment or from any other payment owed by OnCore hereunder; (b) pay the Taxes to the proper governmental body; (c) send evidence of the obligation together with proof of Tax payment to Licensor within [\*\*\*] following such payment; (d) remit the net amount, after deductions or withholding made under this Section 7.8; and (e) cooperate with Licensor in any way reasonably requested by Licensor, to obtain available reductions, credits or refunds of such Taxes; provided, however, that Licensor shall reimburse OnCore for OnCore's reasonable and documented out-of-pocket expenses incurred in providing such assistance.

# ARTICLE 8 INVENTIONS AND PATENTS

- **8.1** Patent Listing under Public Health Services Act. Each Party shall immediately give written notice to the other Party of any certification of which they become aware filed pursuant to 42 USC. §262(1)(3) (or any amendment or successor statute thereto) claiming that any Licensor Patents covering Licensed Compound or Licensed Product, or the manufacture or use of each of the foregoing, are invalid or unenforceable, or that infringement shall not arise from the manufacture, use or sale of a product by a Third Party.
- **8.2 Listing of Patents.** OnCore shall have the sole right to determine which of the Licensor Patents, if any, shall be listed for inclusion in the Approved Drug Licensed Products with Therapeutic Equivalence Evaluations (commonly referred to as the Orange Book), or any successor Law in the United States, together with any comparable Laws in any other country.

**8.3 Further Assurances**. Licensor shall require all of its employees, and use its best efforts to require its contractors and agents, and any Affiliates and Third Parties working on its behalf under this Agreement (and their respective employees, contractors and agents), to assign to Licensor any Licensor Technology.

## 8.4 Patent Prosecution and Maintenance.

## 8.4.1 Licensor Patents.

- (a) OnCore shall have the first right to file, prosecute and maintain Licensor Patents in Licensor's name, using a mutually agreeable patent attorney or law firm. OnCore shall keep Licensor informed of the status of the filing and prosecution of Licensor Patents and related proceedings (e.g. interferences, oppositions, reexaminations, reissues, revocations or nullifications) in a timely manner, and shall take into consideration the advice and recommendations of Licensor. At OnCore's request, Licensor shall provide OnCore with reasonable assistance in prosecuting Licensor Patents to the extent possible, including providing such data in Licensor's Control that is, in OnCore's reasonable judgment, needed to support the prosecution of a Licensor Patent. The Parties acknowledge that the patents and patent applications set forth on Schedule 1.44 are the subject of the Existing Licenses. For so long as such Existing Licenses are in effect, such patents and patent applications are subject to certain priority and consent rights related to prosecution, enforcement and abandonment as provided in the Existing Licenses.
- **(b)** As of the Execution Date, OnCore shall bear the costs and expenses of filing, prosecuting and maintaining Licensor Patents; provided that, if Licensor grants rights to any Third Parties under any Licensor Patents in fields other than the Field, each such Third Party shall share equally with OnCore in such costs and expenses.
- **8.4.2 Election Not to file and Prosecute Licensor Patents.** If OnCore elects not to file or to continue to prosecute or maintain a Licensor Patent in Licensor's name in any country, then it shall notify Licensor in writing at least [\*\*\*] before any deadline applicable to the filing, prosecution or maintenance of such Licensor Patent, as the case may be, or any other date by which an action must be taken to establish or preserve such Licensor Patent in such country or possession. In such case, Licensor shall have the right to pursue the filing or support the continued prosecution or maintenance of such Licensor Patent and OnCore shall provide to Licensor all unpublished patent applications and any other information and documents necessary to permit Licensor to take such action to establish or preserve any such Licensor Patent in such country or possession.
- **8.4.3 Patent Term Extension**. OnCore shall be responsible, in Licensor's name, for obtaining patent term extensions wherever available for Licensor Patents. Licensor shall provide OnCore with all relevant information, documentation and assistance in this respect as may reasonably be requested by OnCore. In the event that any election with respect to obtaining patent term extensions is to be made, OnCore shall have the right to make such elections, and Licensor shall abide by all such elections.

**8.4.4 OnCore Patents**. OnCore shall own any Know-How developed by OnCore or any of its Affiliates or a Third Party on behalf of OnCore and shall have the right, but not the obligation, to file, prosecute and maintain Patent Rights covering or claiming any such Know-How ("**OnCore Patent**"). OnCore shall bear all costs and expenses of filing, prosecuting and maintaining OnCore Patents and Licensor shall have no particular rights with respect thereto.

## 8.5 Enforcement of Patents and Know-How.

#### 8.5.1 Notice.

- **(a)** The Parties acknowledge that the patents and patent applications set forth on <u>Schedule 1.44</u> are the subject of the Existing Licenses. For so long as such Existing Licenses are in effect, such patents and patent applications are subject to certain priority and consent rights related to prosecution, enforcement and abandonment as provided in the Existing Licenses.
- **(b)** If either Party knows or believes that an infringement, unauthorized use, misappropriation, ownership claim, threatened infringement or other similar activity by a Third Party exists or has occurred with respect to any Licensor Technology, or if a Third Party claims that any Licensor Patent is invalid or unenforceable, the Party possessing such knowledge or belief shall notify the other Party and provide it with all details that are known by such Party.
- **(c)** In the event that Licensor believes that an OnCore Patent, if any, is being infringed by a Third Party or if a Third Party claims that any OnCore Patent is invalid or unenforceable, Licensor shall notify OnCore and provide it with details of such infringement or claim.
- **8.5.2 Right to Bring an Action**. OnCore shall have the exclusive right to attempt to resolve any infringement or claim, including by filing an infringement suit, defending against such claim or taking other similar action, with respect to the use or practice of a Licensor Patent in the Field (each, an "**Action**") and to compromise or settle any such infringement or claim; provided, however, that in case such infringement also involves any product comprising IgE coupled to Qb VLPs or CYT003, then OnCore's right shall be subject to the permission of Novartis and Pfizer that OnCore may initiate or participate in legal actions against such infringement, which permission Licensor shall use Commercially Reasonable Efforts to obtain. At OnCore's request, Licensor shall immediately provide OnCore with all relevant documentation (as may be requested by OnCore) evidencing that OnCore is validly empowered by Licensor to take such an Action. Licensor is obligated to join OnCore in such Action if OnCore determines that it is necessary to demonstrate "standing to sue." If OnCore does not intend to prosecute or defend an Action, OnCore shall promptly inform Licensor.
- **8.5.3 Costs of an Action.** Subject to the respective indemnity obligations of the Parties set forth in ARTICLE 11, the Party taking an Action under Section 8.5.2 shall pay all costs associated with such Action, other than (subject to Section 8.5.5) the expenses of the other Party if the other Party elects to join such Action (as provided in the last sentence of this paragraph); provided that, if OnCore is the Party who is taking such Action, then OnCore shall have the right to deduct [\*\*\*] of its costs associated with such Action from any amounts due to Licensor pursuant to ARTICLE 7 hereof. Each Party shall have the right to join an Action relating to a Licensor Patent, at its own expense

- **8.5.4 Settlement.** Neither Party shall settle or otherwise compromise any Action by admitting that any Licensor Patent is invalid or unenforceable without the other Party's prior written consent and, in the case of Licensor, Licensor may not settle or otherwise compromise an Action in a way that adversely affects or would be reasonably expected to adversely affect OnCore's rights or benefits hereunder without OnCore's prior written consent.
- **8.5.5 Reasonable Assistance.** The Party not enforcing or defending Licensor Patents shall provide reasonable assistance to the other Party, including providing access to relevant documents and other evidence and making its employees available, subject to the other Party's reimbursement, on an on-going basis, of any reasonable out-of-pocket expenses incurred by the non-enforcing or non-defending Party in providing such assistance.
- **8.5.6 Distribution of Amounts Recovered.** Any amounts recovered by the Party taking an Action pursuant to this Section 8.5, whether by settlement or judgment, shall be allocated in the following order: (a) to reimburse the Party taking such Action for any costs incurred, which, if such Party is OnCore, shall be limited to those costs not deducted pursuant to Section 8.5.3 from amounts due to Licensor hereunder; (b) to reimburse Licensor, if it is the Party not taking such action for any costs deducted pursuant to Section 8.5.3 from the amounts due to Licensor hereunder; (c) to reimburse the Party not taking such Action for its costs incurred in such Action, if it joins such Action; and (d) the remaining amount of such recovery shall be allocated to OnCore and deemed to be Net Sales for the Calendar Quarter in which the amount is paid and OnCore shall pay to Licensor a royalty on such remaining amount based on the royalty rates set forth in Section 7.3.
- **8.5.7 OnCore Patents**. OnCore shall have the sole right and authority, but not the obligation, to enforce OnCore Patents against any Third Party infringer; provided that Licensor shall provide reasonable assistance to OnCore with respect thereto, including providing access to relevant documents and other evidence and making its employees available, subject to OnCore's reimbursement, on an on-going basis, of any out-of-pocket expenses incurred in providing such assistance.

# **8.6** Third Party Actions Claiming Infringement.

- **8.6.1 Notice.** If a Party becomes aware of any Third Party Action, such Party shall promptly notify the other Party of all details regarding such claim or action that is reasonably available to such Party.
- **8.6.2 Right to Defend**. OnCore shall have the right, at its sole expense, but not the obligation, to defend a Third Party Action and to compromise or settle such Third Party Action. If OnCore declines or fails to assert its intention to defend such Third Party Action within [\*\*\*] after sending (in the event that Licensor is the notifying Party) or receipt (in the event that OnCore is the notifying Party) of notice under Section 8.6.1 then Licensor shall have the right to defend such Third Party Action. The Party defending such Third Party Action shall have the sole and exclusive right to select counsel for such Third Party Action.

- **8.6.3 Consultation**. The Party defending a Third Party Action pursuant to Section 8.6.2 shall be the "**Controlling Party**." The Controlling Party shall consult with the non-Controlling Party on all material aspects of the defense. The non-Controlling Party shall have a reasonable opportunity for meaningful participation in decision-making and formulation of defense strategy. The Parties shall reasonably cooperate with each other in all such actions or proceedings. The non-Controlling Party shall be entitled to be represented by independent counsel of its own choice at its own expense.
- **8.6.4 Appeal**. In the event that a judgment in a Third Party Action is entered against the Controlling Party and an appeal is available, the Controlling Party shall have the first right, but not the obligation, to file such appeal. In the event the Controlling Party does not desire to file such an appeal, it shall promptly, in a reasonable time period (i.e., with sufficient time for the non-Controlling Party to take whatever action may be necessary) prior to the date on which such right to appeal shall lapse or otherwise diminish, permit the non-Controlling Party to pursue such appeal at such non-Controlling Party's own cost and expense. If Law requires the other Party's involvement in an appeal, the other Party shall be a nominal party of the appeal and shall provide reasonable cooperation to such Party at such Party's expense.
- **8.6.5 Costs of an Action.** Subject to the respective indemnity obligations of the Parties set forth in ARTICLE 11, the Controlling Party shall pay all costs associated with such Third Party Action other than the expenses of the other Party if the other Party elects to join such Third Party Action (as provided in the last sentence of this paragraph); provided, that, without limitation of Licensor's indemnification obligations under ARTICLE 11, if OnCore is the Controlling Party, OnCore shall have the right to deduct [\*\*\*] of its costs associated with such Third Party Action from any amounts due to Licensor pursuant to ARTICLE 7 hereof. Each Party shall have the right to join a Third Party Action defended by the other Party, at its own expense.
- **8.6.6 No Settlement Without Consent.** Neither Party shall settle or otherwise compromise any Third Party Action by admitting that any Licensor Patent is invalid or unenforceable without the other Party's prior written consent and, in the case of Licensor, Licensor may not settle or otherwise compromise a Third Party Action in a way that adversely affects or would be reasonably expected to adversely affect OnCore's rights and benefits hereunder without OnCore's prior written consent.

# ARTICLE 9 CONFIDENTIALITY

**9.1 Confidentiality Obligations**. Each Party agrees that, for the Term and for five (5) years thereafter, each Party shall, and shall ensure that its Representatives hold in confidence all Confidential Information disclosed to it by the other Party pursuant to this Agreement, unless such information:

- **9.1.1** is or becomes generally available to the public other than as a result of disclosure by the recipient;
- **9.1.2** is already known by or in the possession of the recipient at the time of disclosure by the disclosing Party;
- **9.1.3** is independently developed by recipient without use of or reference to the disclosing Party's Confidential Information; or
  - **9.1.4** is obtained by recipient from a Third Party that has not breached any obligations of confidentiality.
- **9.2 Permitted Disclosures**. The recipient shall not disclose any of the Confidential Information, except to Representatives of the recipient who need to know the Confidential Information for the purpose of performing the recipient's obligations, or exercise its rights, under this Agreement and who are bound by obligations of non-use and non-disclosure substantially similar to those set forth herein. The recipient shall be responsible for any disclosure or use of the Confidential Information by such Representatives. The recipient shall protect Confidential Information using not less than the same care with which it treats its own confidential information, but at all times shall use at least reasonable care. Each Party shall: (a) implement and maintain appropriate security measures to prevent unauthorized access to, or disclosure of, the other Party's Confidential Information; (b) promptly notify the other Party of any unauthorized access or disclosure of such other Party's Confidential Information; and (c) cooperate with such other Party in the investigation and remediation of any such unauthorized access or disclosure.

## 9.3 Permitted Use.

- **9.3.1** Notwithstanding Section 9.1, OnCore may use Licensor's Confidential Information for the purpose of performing its obligations, or exercising its rights, under this Agreement, including for purposes of:
  - **9.3.2** filing or prosecuting patent applications, subject to the terms of Section 8.3;
  - **9.3.3** prosecuting or defending litigation;
  - **9.3.4** conducting pre-clinical studies or clinical trials pursuant to this Agreement;
  - **9.3.5** seeking or maintaining Regulatory Approval of Licensed Products; or
- **9.3.6** complying with Law, including securities Law and the rules of any securities exchange or market on which OnCore's securities may be listed or traded.
- **9.3.7** In addition to the foregoing, OnCore may, in connection with the Development or Commercialization of Licensed Compounds and/or Licensed Products under this Agreement, disclose Confidential Information of Licensor to any Third Party, provided that such Third Party is bound by obligations of confidentiality at least as stringent as the ones herein.

- **9.3.8** In connection with any permitted filing by either Party of this Agreement with any governmental body, the filing Party shall endeavor to obtain confidential treatment of economic, trade secret information and such other information as may be requested by the other Party, and shall provide the other Party with the proposed confidential treatment request with reasonable time for such other Party to provide comments, and shall include in such confidential treatment request all reasonable comments of the other Party.
- **9.4 Required Disclosure**. The recipient may disclose the Confidential Information to the extent required by Law or court order; provided, however, that the recipient promptly provides to the disclosing party prior written notice of such disclosure and provides reasonable assistance in obtaining an order or other remedy protecting the Confidential Information from public disclosure.
- **9.5 Publications**. Licensor shall not publish any information relating to a Licensed Compound or Licensed Product without the prior written consent of OnCore (which consent may be withheld or given in OnCore's sole discretion), unless such information has already been publicly disclosed either prior to the Effective Date or after the Effective Date through no fault of Licensor or otherwise not in violation of this Agreement. OnCore shall have the right to make such publications as it chooses, in its sole discretion, without the approval of Licensor. Licensor shall submit to OnCore for OnCore's written approval (which approval be granted or denied in OnCore's sole discretion) any publication or presentation (including in any seminars, symposia or otherwise) of information related directly or indirectly to a Licensed Product for review and approval at least [\*\*\*] prior to submission for the proposed date of publication or presentation. Notwithstanding the foregoing, the terms and conditions of this Section 9.5 shall not apply with respect to Licensor's publication of abstracts, posters, and manuscripts relating to data from the completed Phase 2b clinical trial of CYT003 in patients with moderate to severe asthma.

## 9.6 Publicity.

- **9.6.1 Publicity and Use of Names.** In the event a Party desires to make a public disclosure announcing the transaction contemplated by this Agreement, such Party shall submit the proposed disclosure in writing to the other Party at least five Business Days prior to the date of disclosure to provide an opportunity to comment thereon. Only upon the approval of the other Party may such public disclosure be made. The Parties shall mutually agree on the timing and content of a joint press release regarding the execution and relevant details of this Agreement. Neither Party shall use the name of the other Party in any publicity, advertising or announcements or for any other commercial purpose without the prior written approval of the Party whose name is to be used.
- **9.6.2 Required Disclosure**. In the event that either Party believes it is required to issue a press release or make another public announcement to comply with Law it may issue such press release or announcement if (a) the other Party agrees; or (b) it obtains an opinion of legal counsel, from a reputable law firm, that it is required to make such disclosure to comply with Law and, after receiving such opinion, provides the text of such planned disclosure to the other Party no less than [\*\*\*] prior to disclosure.

# ARTICLE 10 REPRESENTATIONS, WARRANTIES AND COVENANTS

- **10.1 Representations and Warranties**. Each Party represents and warrants to the other Party that, as of the Execution Date and as of the Closing Date:
- **10.1.1** such Party is duly organized and validly existing under the Laws of the jurisdiction of its incorporation or organization;
- **10.1.2** such Party has taken all action necessary to authorize the execution and delivery of this Agreement and the performance of its obligations under this Agreement;
- 10.1.3 this Agreement is a legal and valid obligation of such Party, binding upon such Party and enforceable against such Party in accordance with the terms of this Agreement, except as enforcement may be limited by applicable bankruptcy, fraudulent conveyance, insolvency, reorganization, moratorium and other laws relating to or affecting creditors' rights generally and by general equitable principles. The execution, delivery and performance of this Agreement by such Party does not conflict with, breach or create in any Third Party the right to accelerate, terminate or modify any agreement or instrument to which such Party is a party or by which such Party is bound, and does not violate any Law of any governmental body having authority over such Party; and
- **10.1.4** such Party has all right, power and authority to enter into this Agreement, to perform its obligations under this Agreement.
- **10.2 Additional Representations and Warranties of Licensor**. Licensor represents and warrants to OnCore that, as of the Execution Date and as of the Closing Date:
- **10.2.1** no consent by any Third Party or governmental authority is required with respect to the execution and delivery of this Agreement by Licensor or the consummation by Licensor of the transactions contemplated hereby;
- **10.2.2** except for the claims detailed on <u>Schedule 10.2.2</u>, no claims have been asserted, or, to Licensor's Knowledge, threatened by any Person, (a) challenging the validity, effectiveness, or ownership of Licensor Technology, and/or (b) to the effect that the use, reproduction, modification, manufacturing, distribution, licensing, sublicensing, sale or any other exercise of rights in any of Licensor Technology infringes or shall infringe on any Intellectual Property right of any Person;
- **10.2.3** to the Knowledge of Licensor, there is no unauthorized use, infringement or misappropriation of any of Licensor Technology by any employee or former employee of Licensor, or any other Third Party;

- **10.2.4** to the Knowledge of Licensor, the Licensor Patents are not the subject of any litigation procedure, discovery process, interference, reissue, reexamination, opposition, appeal proceedings or any other legal dispute;
- **10.2.5** except as disclosed in <u>Schedule 10.2.5</u>, the Licensor Patents listed on <u>Schedule 1.44</u> constitute all Patent Rights owned or controlled by Licensor as of the Execution Date that are directly related to, or are necessary or useful for, the research, Development, manufacture, use or Commercialization of Licensed Compounds and Licensed Products in the Field;
- **10.2.6** the Licensor Patents are not now and have not at any time in the past been pledged, hypothecated or in any way used to secure a loan or debt of any kind whatsoever;
- **10.2.7** the Licensor Know-How constitutes all Know-How owned or controlled by Licensor as of the Execution Date that is directly related to, or are necessary or useful for, the research, Development, manufacture, use or Commercialization of Licensed Compounds and Licensed Products in the Field;
- **10.2.8** Licensor has not developed, subcontracted or licensed to a Third Party the right to develop or commercialize a Competing Product;
- **10.2.9** to the Knowledge of Licensor, no Third Party has filed, pursued or maintained or threatened in writing to file, pursue or maintain any claim, lawsuit, charge, complaint or other action alleging that any Licensor Patent is invalid or unenforceable:
- 10.2.10 to Licensor's Knowledge, without having made any inquiry with respect to the subject matter of this representation, OnCore's and its Affiliates' and Sublicensees' practice and use of the inventions claimed in the Licensor Patents as permitted herein will not infringe any intellectual property rights of any Third Party to Develop and Commercialize Licensed Compound and Licensed Product in the Field. In addition, and without limiting the foregoing, Licensor represents and warrants to OnCore that, to Licensor's Knowledge as of the Execution Date and as of the Closing Date, (a) OnCore's and its Affiliates' and Sublicensees' practice and use of the inventions claimed in the Licensor Patents as permitted herein will not infringe any intellectual property rights of any Third Party specifically directed to unconjugated CYT003 and Qb VLPs encapsulating [\*\*\*], and (b) the practice of the [\*\*\*] described and enabled in [\*\*\*] for the [\*\*\*] and [\*\*\*] will not infringe any intellectual property rights of any Third Party.
- **10.2.11** all issuance, renewal, maintenance and other material payments that are or have become finally due with respect to the Licensor Technology have been timely paid by or on behalf of Licensor;
  - **10.2.12** all Licensor Patents have been properly filed, prosecuted and maintained;
- **10.2.13** it has the full right to provide the Licensor Materials to OnCore and to transfer to OnCore all right, title and interest in and to the Licensor Material to be provided to OnCore pursuant to this Agreement;

- **10.2.14** all Representatives of Licensor who have performed any activities on its behalf in connection with research regarding Licensed Compound or Licensed Product have assigned to Licensor the whole of their rights in any Intellectual Property made, discovered or developed by them as a result of such research, and no Third Party has any rights to any such Intellectual Property;
- **10.2.15** Licensor has all right, title and interest in and to the Licensor Technology and Licensor Technology is free and clear of any liens, charges, encumbrances or rights of others to possession or use that would preclude OnCore's use of the Licensed Technology pursuant to the licenses granted in this Agreement;
- **10.2.16** Except as set forth in the Existing Licenses, Licensor has not previously licensed, assigned, transferred, or otherwise conveyed any right, title or interest in and to the Licensor Technology to any Third Party, including any rights with respect to Licensed Compound or Licensed Product, that would preclude OnCore's use of the Licensed Technology pursuant to the licenses granted in this Agreement;
- **10.2.17** Except as disclosed in <u>Schedule 10.2.5</u>, the Licensor Copyrights, Licensor Patents and Licensor Know-How constitutes all of the Intellectual Property Controlled by Licensor, which, to the Knowledge of Licensor as of the Effective Date, could reasonably be expected to be necessary or useful in the research, Development, manufacture, import, export, use or Commercialization of Licensed Compound or Licensed Product;
- **10.2.18** all tangible information and data provided by or on behalf of Licensor to OnCore on or before the Closing Date in contemplation of this Agreement was and is true, accurate in all material respects, and Licensor has not failed to disclose, or cause to be disclosed, any information or data that would cause the information and data that has been disclosed to be misleading in any material respect;
- **10.2.19** Licensor (and its Affiliates) has not employed or otherwise used in any capacity, and shall not employ or otherwise use in any capacity, the services of any Person debarred under United States law, including under Section 21 USC 335a or any foreign equivalent thereof, with respect to a Licensed Compound or Licensed Product;
- **10.2.20** all research and development related to Licensed Compounds and Licensed Products prior to the Effective Date has been conducted in all material respects in accordance with all applicable Laws; and
- **10.2.21** the materials to be provided to OnCore hereunder were (and at all times up until delivery of such materials hereunder shall remain) manufactured, packaged, labeled, tested, stored and handled in accordance with all Laws and specifications (including, to the extent applicable, release specifications as provided by Licensor to OnCore in writing prior to the Effective Date);
- **10.2.22** there are no (a) Claims relating to the Licensor Technology, the Licensed Compound or the Licensed Products pending or, to the Knowledge of Licensor, threatened against Licensor or any of its Affiliates; and (b) there are no Claims pending or, to the Knowledge of Licensor, threatened, that question the legality or propriety of the transactions contemplated by this Agreement or the consummation of the transactions contemplated herein or therein or which would reasonably be expected to prevent, hinder or delay the consummation of any of the transactions contemplated by this Agreement.

- **10.3 Covenant of Licensor.** Licensor hereby covenants and agrees that the Licensor Patents shall not at any time in future be pledged, hypothecated or in any way used to secure a loan or debt of any kind whatsoever.
- 10.4 Disclaimer of Warranties. EXCEPT FOR THE EXPRESS WARRANTIES SET FORTH IN THIS ARTICLE 10, LICENSOR MAKES NO REPRESENTATIONS AND GRANTS NO WARRANTIES, EXPRESS OR IMPLIED, EITHER IN FACT OR BY OPERATION OF LAW, BY STATUTE OR OTHERWISE, AND LICENSOR SPECIFICALLY DISCLAIMS ANY OTHER REPRESENTATIONS AND WARRANTIES, WHETHER WRITTEN OR ORAL, EXPRESS, STATUTORY OR IMPLIED, INCLUDING ANY WARRANTY OF QUALITY, MERCHANTABILITY OR FITNESS FOR A PARTICULAR USE OR PURPOSE OR ANY WARRANTY AS TO THE VALIDITY OF ANY PATENTS OR THE NON-INFRINGEMENT OF ANY INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES.

# ARTICLE 11 INDEMNIFICATION AND INSURANCE

- **11.1 Indemnification by OnCore**. OnCore shall indemnify, defend and hold Licensor and its Affiliates and each of their respective employees, officers, directors and agents (the "**Licensor Indemnitees**") harmless from and against any and all liability, damage, loss, cost or expense (including reasonable attorneys' fees) to the extent arising out of Third Party claims or suits related to: (a) OnCore's negligence or willful misconduct; (b) breach by OnCore of its representations or warranties set forth in this Agreement; or (c) the development of a Licensed Compound or Licensed Product by or on behalf of OnCore following the Closing Date; provided, however, that OnCore's obligations pursuant to this Section 11.1 shall not apply (i) to the extent such claims or suits result from the negligence or willful misconduct of any of the Licensor Indemnitees, or (ii) with respect to claims or suits arising out of breach by Licensor of its representations, warranties or covenants set forth in this Agreement.
- 11.2 Indemnification by Licensor. Licensor shall indemnify, defend and hold OnCore and its Affiliates and each of their respective agents, employees, officers and directors (the "OnCore Indemnitees") harmless from and against any and all liability, damage, loss, cost or expense (including reasonable attorneys' fees) to the extent arising out of Third Party claims or suits (including Third Party Actions) related to: (a) Licensor's negligence or willful misconduct; (b) breach by Licensor of its representations, warranties or covenants set forth in this Agreement; or (c) the development of a Licensed Compound or Licensed Product prior to the Closing Date or the development or commercialization of a Licensed Compound or Licensed Product outside of the Field; provided, however, that Licensor's obligations pursuant to this Section 11.2 shall not apply (i) to the extent that such claims or suits result from the negligence or willful misconduct of any of the OnCore Indemnitees or (ii) with respect to claims or suits arising out of a breach by OnCore of its representations or warranties set forth in ARTICLE 10.

- 11.3 No Consequential Damages. EXCEPT WITH RESPECT TO EACH PARTY'S INDEMNIFICATION OBLIGATIONS UNDER SECTION 11.1 OR SECTION 11.2, AS APPLICABLE, IN NO EVENT SHALL EITHER PARTY OR ANY OF ITS AFFILIATES BE LIABLE TO THE OTHER PARTY OR ANY OF ITS AFFILIATES FOR SPECIAL, INDIRECT, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES, INCLUDING LOSS OF PROFITS, WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE ARISING OUT OF OR RELATING TO THIS AGREEMENT, THE TRANSACTIONS CONTEMPLATED HEREIN OR ANY BREACH HEREOF. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS AGREEMENT SHALL LIMIT EITHER PARTY FROM SEEKING OR OBTAINING ANY REMEDY AVAILABLE UNDER LAW FOR ANY BREACH OF BY THE OTHER PARTY OF ITS CONFIDENTIALITY AND NON-USE OBLIGATIONS UNDER ARTICLE 9.
- 11.4 Notification of Claims; Conditions to Indemnification Obligations. As a condition to a Party's right to receive indemnification under this ARTICLE 11, it shall: (a) promptly notify the other Party as soon as it becomes aware of a claim or suit for which indemnification may be sought pursuant hereto; (b) cooperate, and cause the individual indemnitees to cooperate, with the indemnifying Party in the defense, settlement or compromise of such claim or suit; and (c) permit the indemnifying Party to control the defense, settlement or compromise of such claim or suit, including the right to select defense counsel. In no event, however, may the indemnifying Party compromise or settle any claim or suit in a manner which admits fault or negligence on the part of the indemnified Party or any indemnitee without the prior written consent of the indemnified Party. Each Party shall reasonably cooperate with the other Party and its counsel in the course of the defense of any such suit, claim or demand, such cooperation to include using reasonable efforts to provide or make available documents, information and witnesses. The indemnifying Party shall have no liability under this ARTICLE 11 with respect to claims or suits settled or compromised without its prior written consent.
- 11.5 Insurance. During the Term, each Party shall obtain and maintain, at its sole cost and expense, insurance (including any self-insured arrangements) in types and amounts that are reasonable and customary in the pharmaceutical and biotechnology industry for companies engaged in comparable activities in the countries in which such Party operates. It is understood and agreed that this insurance shall not be construed to limit either Party's liability with respect to its indemnification obligations hereunder. Each Party shall, except to the extent self-insured, provide to the other Party upon request a certificate evidencing the insurance such Party is required to obtain and keep in force under this Section 11.5.

# ARTICLE 12 TERM AND TERMINATION

**12.1 Term and Expiration**. The term of this Agreement (the "**Term**") shall commence on the Effective Date and, unless earlier terminated as provided in this ARTICLE 12, shall continue in full force and effect, on a country-by-country and Licensed Product-by-Licensed Product basis until the date on which the Royalty Term in such country with respect to such Licensed Product expires, at which time this Agreement shall expire in its entirety with respect to such Licensed Product in such country and the terms of Section 12.8 shall apply.

- **12.2 Pre-Closing Termination.** This Agreement may be terminated at any time prior to the Closing by OnCore, by giving written notice to Seller on or after [\*\*\*] after the date of this Agreement, if any of the conditions set forth in Section 2.3 is not satisfied or waived by such date or has become incapable of fulfillment, unless such satisfaction has been frustrated or made impossible by any act or failure to act by OnCore.
- **12.3 Termination of the Agreement for Convenience**. At any time after Closing, OnCore may, at its convenience, terminate this Agreement in its entirety, or on a Licensed Product-by-Licensed Product or country-by-country basis, upon [\*\*\*] prior written notice to Licensor.

# 12.4 Termination upon Material Breach.

- **12.4.1 Material Breach**. If a Party breaches any of its material obligations under this Agreement, the Party not in default may give to the breaching Party a written notice specifying the nature of the default, requiring it to cure such breach, and stating its intention to terminate this Agreement if such breach is not cured within [\*\*\*]. If such breach is not cured within [\*\*\*] after the receipt of such notice, the Party not in default shall be entitled to terminate this Agreement immediately by written notice to the other Party. For clarity, such material obligations may apply to the performance of either: (a) this Agreement in its entirety, in which case this provision shall apply to the entire Agreement; or (b) a specific Licensed Product or Licensed Product(s), in which case this provision shall apply only to such affected Licensed Product or Licensed Product(s).
- **12.4.2 Sole Remedy**. In the event that OnCore fails to fulfill its obligations under Section 5.5 (and does not cure such failure as provided in Section 12.4.1), Licensor's sole and exclusive remedy shall be to terminate this Agreement as provided in Section 12.4.1 on a Licensed Product-by-Licensed Product basis.
- **12.4.3 Material Breach Dispute**. Any dispute regarding an alleged material breach of this Agreement shall be resolved in accordance with ARTICLE 13 hereof.

#### 12.5 Effects of Termination.

**12.5.1 Pre Closing.** In the event of the termination of this Agreement in accordance with Section 12.2, this Agreement shall thereafter become void and have no effect, and neither party shall have any liability to the other party, except that the provisions of ARTICLE 9 (Confidentiality), ARTICLE 11 (Indemnification), this Section 12.5 (Effects of Termination), ARTICLE 13 (Dispute Resolution) and ARTICLE 14 (Miscellaneous Provisions), including the definitions incorporated in each of the foregoing provisions, shall remain in full force and effect. In addition, upon such termination, OnCore shall return to Licensor or, at OnCore's option, destroy, at Licensor's cost and expense, all Licensor Materials provided to OnCore as described in Section 3.4 and shall assign to Licensor any Intellectual Property rights generated by or on behalf of OnCore through the use or testing of such Licensor Materials.

# 12.5.2 Upon Termination At Will or for Material Breach.

- (a) Upon any termination of this Agreement pursuant to Section 12.3 or Section 12.4.1, the following terms and conditions shall apply with respect to such Licensed Product(s) and country(ies) as are the subject of such termination:
  - (i) all licenses granted to OnCore under Section 4.1 shall terminate;
- (ii) other than for termination by OnCore pursuant to Section 12.4.1, OnCore shall, upon written request by Licensor and subject to Licensor assuming legal responsibility for any clinical trials of such Licensed Product(s) then ongoing, transfer to Licensor at Licensor's cost and expense, all Regulatory Documentation and Regulatory Approvals prepared or obtained by or on behalf of OnCore prior to the date of such termination, to the extent solely related to such Licensed Product(s) and country(ies) and transferable, and OnCore shall have the right to retain one copy of such transferred documentation and Regulatory Approvals for record-keeping purposes;
- (iii) OnCore shall return to Licensor or, at OnCore's option, destroy, at Licensor's cost and expense, all relevant records and materials in its possession or control containing or comprising the Licensor Know-How and the Licensor Materials, or such other Confidential Information of Licensor, to the extent solely related to such Licensed Product(s) and country(ies); provided, however, that OnCore shall have the right to retain one copy of such Licensor Know-How and one sample of Licensor Materials and such other Confidential Information of Licensor.
- **(iv)** OnCore shall (i) destroy any and all chemical, biological or physical materials relating to or comprising such Licensed Product(s), including clinical supplies of such Licensed Product(s), that are Controlled by OnCore, or (ii) sell such materials (in whole or in part) to Licensor at a price equal to [\*\*\*], or (iii) sell such materials to a Third Party. Any clinical supplies of such Licensed Product(s) or other materials purchased by Licensor from OnCore shall be purchased on an "as is" basis with no representations or warranties.
- (v) To the extent not prohibited by Law, OnCore shall wind down any ongoing clinical trials with respect to such Licensed Product(s), or at Licensor's option, transfer such clinical trials to Licensor at Licensor's cost and expense, in which case Licensor shall purchase from OnCore the relevant clinical trial supplies of Licensed Product at [\*\*\*].

- **(vi)** OnCore and its Affiliates and Sublicensees shall be entitled, during the [\*\*\*] period following such termination, to sell any commercial inventory of such Licensed Product(s) which remains on hand as of the date of the termination, so long as OnCore pays to Licensor the royalties applicable to said subsequent sales in accordance with the terms and conditions set forth in this Agreement. Any commercial inventory remaining following [\*\*\*] period shall be offered for sale to Licensor at a price equal to [\*\*\*].
- (vii) Immediately following a notification of termination pursuant to Sections 12.3 or 12.4, the Parties shall agree upon a transition plan for the transition to Licensor of development and commercial activities then being conducted by OnCore to the extent solely related to such Licensed Product(s) and country(ies) and the wind-down of such activities by OnCore. Following such notification of termination, the diligence obligations in Section 5.5 shall no longer apply; provided, that OnCore uses Commercially Reasonable Efforts to carry out the activities assigned to it under the agreed upon transition plan provided that all activities conducted after the notice of termination in carrying out the transition plan shall be at the expense of Licensor and Licensor shall promptly reimburse OnCore for any such costs or expenses OnCore my incur.
- **(b)** Upon any termination of this Agreement, each of OnCore's Sublicensees shall continue to have the rights and license set forth in its sublicense agreements, which agreements shall be automatically assigned to Licensor (to the extent authorized therein); provided, however, that such Sublicensee is not then in breach of any of its material obligations under its sublicense agreement.

# 12.6 Rights on Bankruptcy or Insolvency; Right of First Negotiation.

- **12.6.1 Bankruptcy Code**. All rights and licenses granted under or pursuant to this Agreement by Licensor are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code, if applicable, licenses of right to "intellectual property" as defined under Section 101 of the U.S. Bankruptcy Code.
- **12.6.2 Continuing Rights.** The Parties agree that OnCore, as licensee of such rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the U.S. Bankruptcy Code. The Parties further agree that, in the event of Licensor Bankruptcy Event, OnCore shall be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property, which, if not already in OnCore's possession, shall be promptly delivered to it (a) following any such commencement of a bankruptcy proceeding upon OnCore's written request therefor, unless Licensor elects to continue to perform all of its obligations under this Agreement or (b) if not delivered under clause (a), following the rejection of this Agreement by Licensor upon written request therefor by OnCore.

- **12.6.3 Right of First Refusal**. In addition to the foregoing, in the event of a Licensor Bankruptcy Event, OnCore shall, to the extent allowed by Law, have a right of first refusal to purchase all of Licensor's interest in Licensed Products and the Licensor Technology (the "**Right of First Refusal**"). The Right of First Refusal shall operate as follows:
- **(a)** Licensor (or other authorized representative of Licensor, including a bankruptcy trustee) shall promptly send to OnCore a reasonably detailed written notification of any Licensor Bankruptcy Event.
- **(b)** Licensor (or other authorized representative of Licensor, including a bankruptcy trustee) shall promptly send to OnCore a written notification of any Third Party offer made on a Licensed Compound, Licensed Product or Licensor Technology. For a period of up to [\*\*\*] after OnCore receives such notice (such period, the "**Right of First Refusal Notice Period**"), it shall notify Licensor of its intention to exercise its Rights of First Refusal. In the event OnCore exercises its Right of First Refusal, the terms of the Third Party offer shall become binding upon OnCore and Licensor. For the avoidance of doubt, Licensor shall not enter into any agreement with a Third Party relating to Licensor's interest in Licensed Products or Licensor Technology during the Right of First Refusal Notice Period.

#### 12.7 Survival.

- **12.7.1** Notwithstanding the expiration or termination of this Agreement pursuant to Sections 12.3 or 12.4, the following provisions shall survive: ARTICLE 9, ARTICLE 11, ARTICLE 13 and ARTICLE 14; and Sections 10.4, 12.5, 12.7, 12.9 and any other provision that, by its terms or implication, is required to survive in order to give effect to any of the foregoing.
- **12.7.2** Expiration or termination of this Agreement shall not relieve the Parties of any liability that accrued hereunder prior to the effective date of such termination. In addition, termination of this Agreement shall not preclude either Party from pursuing all rights and remedies it may have hereunder or at Law or in equity with respect to any breach of this Agreement nor prejudice either Party's right to obtain performance of any obligation.
- **12.8 Effects of Expiration**. As of the effective date of expiration of the Royalty Term with respect to a given Licensed Product and country, the license from Licensor to OnCore under Section 4.1 shall convert to a fully paid, royalty free, irrevocable, perpetual, exclusive, and sublicensable license under the Licensor Technology to research, develop, manufacture, have manufactured, use and Commercialize Licensed Compound and such Licensed Product in the Field in such country.
- **12.9 Other Remedies**. Termination of this Agreement for any reason shall not release either Party from any liability or obligation that already has accrued prior to such termination. Termination of this Agreement for any reason shall not constitute a waiver or release of, or otherwise be deemed to prejudice or adversely affect or limit, any rights or remedies that otherwise may be available at Law or in equity.

# ARTICLE 13 DISPUTE RESOLUTION

- 13.1 Disputes. The Parties recognize that disputes as to certain matters may from time to time arise during the Term which relate to either Party's rights and/or obligations hereunder. It is the objective of the Parties to establish under this ARTICLE 13 procedures to facilitate the resolution of disputes arising under this Agreement (other than any disputes relating to matters which under this Agreement OnCore has sole decision-making authority and/or discretion regarding (each, a "Non-Escalable Dispute"), in which case, such matter shall be determined by OnCore and shall not be part of the dispute resolution procedure set forth in this ARTICLE 13) in an expedient manner by mutual cooperation and without resort to litigation. In the event that the Parties are unable to resolve such dispute through diligent review and deliberation by the Senior Executives within [\*\*\*] from the day that one Party had designated the issue as a dispute in written notice to the other Party, then either Party shall have the right to escalate such matter to the Executive Officers as set forth in Section 13.2.
- 13.2 Escalation to Executive Officers. Either Party may, by written notice to the other Party, request that a dispute (other than a Non-Escalable Dispute) that remains unresolved by the Senior Executives for a period of [\*\*\*] as set forth in Section 13.1 arising between the Parties in connection with this Agreement, or a dispute relating to material breach, be resolved by the Executive Officers, within [\*\*\*] after referral of such dispute to them. If the Executive Officers cannot resolve such dispute within [\*\*\*] after referral of such dispute to them, then, at any time after such [\*\*\*] period, either Party may proceed to enforce any and all of its rights with respect to such dispute.
- **13.3 Arbitration**. The Parties agree that, except as otherwise set forth in Section 13.1 or 13.2, any dispute, controversy or claim arising out of, related to or in connection with Agreement shall be finally determined by the American Arbitration Association in accordance with its Commercial Arbitration Rules (the "**Rules**"), except as modified herein.
- **13.4 Arbitrators**. Each Party shall select one arbitrator, and the two arbitrators so selected shall choose a third arbitrator. If a Party fails to nominate its arbitrator, or if the Parties' arbitrators cannot agree on the third arbitrator, such arbitrator(s) shall be appointed in accordance with the Rules. Once an arbitrator is appointed, neither Party shall have any *ex parte* communication with such arbitrator.
- **13.5 Location**. The arbitration proceedings shall be conducted in New York, NY, or such other location as may be agreed in writing by the Parties.
- **13.6 Language**. The arbitration proceedings and all pleadings and written evidence shall be in the English language. Any written evidence originally in another language shall be submitted in English translation accompanied by the original or a true copy thereof.
- **13.7 Making Employees Available**. Each Party agrees to use reasonable efforts to make all of its current employees available, if reasonably needed for the purposes of arbitration.
- 13.8 Award. Judgment upon an arbitral award may be entered in any competent court or application may be made to any competent court for judicial acceptance of such an award and order for enforcement. The arbitrators shall not have authority to: (a) make any award that could not be made by a court of competent jurisdiction; or (b) modify the limitations on liability set forth herein or make any award in violation thereof. If requested by either Party, each Party shall, as a condition of receiving any award from the arbitrators, be required to, on behalf of itself and its Affiliates, and its and their respective, Representatives, predecessors, successors and assigns, fully, finally and irrevocably relinquish, release and discharge the other Party and its Affiliates, and its and their respective Representatives, predecessors, successors and assigns, from any and all claims, damages, liabilities, obligations, and causes of action, including indemnification claims, known or unknown, suspected or unsuspected, in law or equity, that were asserted, or that could have been asserted by such Party and its Affiliates, and its and their respective Representatives, predecessors, successors and assigns under or in connection with this Agreement arising prior to the date of such release.

- **13.9 Fees and Costs**. The Parties shall: (a) share equally the fees and expenses of the arbitrators; and (b) bear their own attorneys' fees and associated costs and expenses associated with any arbitration; provided that if the arbitrators determine that a Party was frivolous in bringing a claim it may award the other Party such fees, expenses and costs.
- **13.10 Confidentiality**. At the request of either Party, the arbitrators shall enter an appropriate protective order to maintain the confidentiality of information produced or exchanged in the course of the arbitration proceedings. The arbitrators shall have the power to decide all questions of arbitrability.
- **13.11 Injunctive Relief**. Subject to Section 12.4.2 and notwithstanding anything to the contrary set forth in this ARTICLE 13, a Party shall not be required to use the foregoing dispute resolution procedures or otherwise follow the provisions of this ARTICLE 13 with respect to any dispute to which a Party is seeking purely injunctive relief (including a temporary restraining order) or specific performance and such Party shall be entitled to seek relief before any court having jurisdiction over such dispute and the Parties hereto.
- **13.12 Jurisdiction**. The Parties agree to accept the jurisdiction of, and not to contest the venue or forum of, the federal courts located in the State of Delaware for the purposes of enforcing awards entered on behalf of a Party pursuant to this ARTICLE 13 and for enforcing the agreements reflected in this ARTICLE 13, or to a state court in such jurisdiction if applicable Law precludes federal court jurisdiction. Notwithstanding anything in this Agreement to the contrary, each Party may also bring an action in any court of competent jurisdiction for purposes of causing the other Party to appear at, and submit to, arbitration or any court identified in this ARTICLE 13.

# ARTICLE 14 MISCELLANEOUS PROVISIONS

**14.1 Relationship of the Parties**. Nothing in this Agreement is intended or shall be deemed, for financial, tax, legal or other purposes, to constitute a partnership, agency, joint venture or employer-employee relationship between the Parties.

## 14.2 Assignment.

- **14.2.1 Limitation**. Subject to the provisions of this Section 14.2, neither this Agreement nor any of the rights and obligations of a Party under this Agreement shall be assigned to any person or entity, without the prior written consent of the other Party. Notwithstanding the foregoing, a Party may, without the consent of the other Party, assign this Agreement or its rights or obligations under this Agreement: (a) to an Affiliate; (b) in connection with the transfer or sale of all or substantially all of its assets to which this Agreement relates; or (c) in the event of its merger or consolidation or change in control or similar transaction.
- **14.2.2 Continuing Obligations**. This Agreement shall be binding upon, and inure to the benefit of, each Party, its Affiliates, and its permitted successors and assignees. Each Party shall be responsible for the compliance by its Affiliates with the terms and conditions of this Agreement, and for clarity, in the event of an assignment to an Affiliate, the assignor party shall remain as principal obligor for all or any obligations and liabilities assigned to such Affiliate under the terms of this Agreement.
  - **14.2.3 Void Assignments**. Any assignment not in accordance with this Section 14.2 shall be void.
- **14.2.4 Assignment of Licensor Technology**. Licensor shall not assign or transfer any Licensor Technology to any of its Affiliates or any Third Party without the prior written consent of OnCore.
- **14.3 Performance and Exercise by Affiliates**. OnCore shall have the right to have any of its obligations hereunder performed, or its rights hereunder exercised, by, any of its Affiliates and the performance of such obligations by any such Affiliate(s) shall be deemed to be performance by OnCore; provided, however, that OnCore shall be responsible for ensuring the performance of its obligations under this Agreement and that any failure of any Affiliate performing obligations of OnCore hereunder shall be deemed to be a failure by OnCore to perform such obligations. For clarity, the foregoing means that OnCore may designate an Affiliate to perform its obligations hereunder or to be the recipient of Licensor's performance obligations hereunder.
- **14.4 Change of Control.** In the event of a Change of Control of Licensor in which a OnCore Competitor acquires control (as defined in Section 1.3) of Licensor, then as from the date of such Change of Control, OnCore's reporting obligations under Section 5.8 shall be limited to such information as is reasonably necessary for Licensor to determine whether payment may be due under Section 7.1.1.
- **14.5 Further Actions**. Each Party agrees to execute, acknowledge and deliver such further instruments and to do all such other acts as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.
- **14.6 Accounting Procedures**. Each Party shall calculate all amounts, and perform other accounting procedures required, under this Agreement and applicable to it in accordance with GAAP.

- **14.7 Force Majeure**. Neither Party shall be liable to the other Party or be deemed to have breached or defaulted under this Agreement for failure or delay in the performance of any of its obligations under this Agreement for the time and to the extent such failure or delay is caused by or results from acts of God, earthquake, riot, civil commotion, terrorism, war, strikes or other labor disputes, fire, flood, failure or delay of transportation, omissions or delays in acting by a governmental authority, acts of a government or an agency thereof or judicial orders or decrees or restrictions or any other reason which is beyond the control of the respective Party. The Party affected by force majeure shall provide the other Party with full particulars thereof as soon as it becomes aware of the same (including its best estimate of the likely extent and duration of the interference with its activities), and shall use Commercially Reasonable Efforts to overcome the difficulties created thereby and to resume performance of its obligations hereunder as soon as practicable.
- **14.8 No Trademark Rights.** No right, express or implied, is granted by this Agreement to a Party to use in any manner the name or any other trade name or trademark of the other Party in connection with the performance of this Agreement or otherwise.
- **14.9 Entire Agreement of the Parties; Amendments.** This Agreement and the Schedules hereto constitute and contain the entire understanding and agreement of the Parties respecting the subject matter hereof and cancel and supersede any and all prior negotiations, correspondence, understandings and agreements between the Parties, whether oral or written, regarding such subject matter. No waiver, modification or amendment of any provision of this Agreement shall be valid or effective unless made in a writing referencing this Agreement and signed by a duly authorized officer of each Party.
- **14.10 Captions**. The captions to this Agreement are for convenience only, and are to be of no force or effect in construing or interpreting any of the provisions of this Agreement.
- **14.11 Governing Law**. This Agreement shall be governed by and interpreted in accordance with the laws of the State of New York, excluding application of any conflict of laws principles that would require application of the Law of a jurisdiction outside of the State of New York.
- **14.12 Notices and Deliveries**. Any notice, request, approval or consent required or permitted to be given under this Agreement shall be in writing and shall be deemed to have been sufficiently given if delivered in person, transmitted by facsimile (receipt verified) or by express courier service (signature required) to the Party to which it is directed at its address or facsimile number shown below or such other address or facsimile number as such Party shall have last given by notice to the other Party.

If to OnCore, addressed to:

OnCore Biopharma, Inc. 3805 Old Easton Road Doylestown, PA 18902

Attn: [\*\*\*] Email: [\*\*\*] With a copy to:

[\*\*\*] Attn: [\*\*\*] Email: [\*\*\*]

#### If to Licensor, addressed to:

Name: Cytos Biotechnology AG

Street: Wagistrasse 25
City: 8952 Schlieren
Country: Switzerland
Attn: CEO

#### With a copy to:

Name: [\*\*\*]
Street: [\*\*\*]
City: [\*\*\*]
Country: [\*\*\*]
Attn: [\*\*\*]
Email: [\*\*\*]

- **14.13 Waiver**. A waiver by either Party of any of the terms and conditions of this Agreement in any instance shall not be deemed or construed to be a waiver of such term or condition for the future, or of any other term or condition hereof. All rights, remedies, undertakings, obligations and agreements contained in this Agreement shall be cumulative and none of them shall be in limitation of any other remedy, right, undertaking, obligation or agreement of either Party.
- **14.14 Severability**. When possible, each provision of this Agreement shall be interpreted in such manner as to be effective and valid under Law, but if any provision of this Agreement is held to be prohibited by or invalid under Law, such provision shall be ineffective only to the extent of such prohibition or invalidity, without invalidating the remainder of this Agreement. The Parties shall make a good faith effort to replace the invalid or unenforceable provision with a valid one which in its economic effect is most consistent with the invalid or unenforceable provision.
- **14.15 No Implied License**. No right or license is granted to Licensor hereunder by implication, estoppel, or otherwise to any know-how, patent or other Intellectual Property right owned or controlled by OnCore or its Affiliates.
- **14.16 Interpretation**. The words "include," "includes" and "including" shall be deemed to be followed by the phrase "without limitation." All references herein to Articles, Sections, and Schedules shall be deemed references to Articles and Sections of, and Schedules to, this Agreement unless the context shall otherwise require. Unless the context otherwise requires, countries shall include territories.

**14.17 Counterparts.** This Agreement may be executed in counterparts, each of which shall be deemed an original, and all of which together shall be deemed to be one and the same instrument. A facsimile or a portable document format (PDF) copy of this Agreement, including the signature pages, shall be deemed an original.

# [SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF authorized officers as of the Effec	, the Parties have caused this Agreement to be executed and delivered by their respective duly tive Date.
CYTOS BIOTECHNOLOGY LTD	ONCORE BIOPHARMA INC.
By:	By:
Name:	Name:
Title:	Title:
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**SCHEDULE 1.19** 

# **CYT003 DESCRIPTION**

[\*\*\*]

# **SCHEDULE 1.42**

# LICENSOR KNOW-HOW

The Licensor Know-How will be compiled and mutually agreed by the Parties within [\*\*\*] after the completion of the last step of the Technology and Program Transfer Plan.

**SCHEDULE 1.43** 

# LICENSOR MATERIALS

**SCHEDULE 1.44** 

# LICENSOR PATENTS

# **SCHEDULE 1.69**

# OUTLINE OF TECHNOLOGY AND PROGRAM TRANSFER PLAN

- 1 [\*\*\*] TECHNOLOGY TRANSFER
- 1.1 Project Stakeholders and Contractual Status

- 1.2 Documents to be transfered
- 1.2.1 Documents to be transferred [\*\*\*]

1.2.4 Documents to be transferred for [\*\*\*]

[\*\*\*]

1.2.5 Preclinical reports on [\*\*\*]

1.2.5.1 Non-GLP reports

1.3 Material

- 2 [\*\*\*] TECHNOLOGY TRANSFER
- 2.1 Documents to be transfered
- 2.1.1 Documents to be transferred [\*\*\*]

2.1.2 Documents to be transferred [\*\*\*]

2.1.3 Documents to be transfered [\*\*\*]

[\*\*\*]

2.1.4 Preclinical GLP safety reports [\*\*\*]

# **Completed Clinical Studies:**

**SCHEDULE 10.2.2** 

# LICENSOR CLAIMS

None.

#### AMENDING AGREEMENT

THIS AMENDMENT (this "Amendment") is executed as of November 2, 2015, by and among Arbutus Biopharma Corporation (fka Tekmira Pharmaceuticals Corporation) (the "Company"), a British Columbia corporation, Roivant Sciences Ltd., Patrick T. Higgins, Michael J. McElhaugh, Michael J. Sofia and Bryce A. Roberts (such parties other than the Company being collectively referred to as the "OnCore Holders").

#### **RECITALS**

**WHEREAS,** the parties hereto entered into a Registration Rights Agreement, dated January 11, 2015 (the "Registration Rights Agreement"), pursuant to which the Company agreed in certain circumstances to register for resale under the Securities Act of 1933, as amended, certain common shares in the Company held by the OnCore Holders; and

**WHEREAS,** the parties hereto now wish to amend the terms of the Registration Rights Agreement in order to amend the provision thereof related to the filing of a shelf registration statement.

**NOW, THEREFORE**, in consideration of the mutual promises and covenants contained herein, the parties do hereby agree as follows:

- 1. <u>Defined Terms</u>. All capitalized terms used and not otherwise defined herein shall have the meaning ascribed thereto in the Registration Rights Agreement.
  - 2. Amendment. Section 1.2(a) of the Registration Rights Agreement is deleted in its entirety and replaced with the following:

"Upon the written request of Roivant Sciences Ltd. following the date hereof, the Company shall file a resale registration statement on Form S-3 within 30 days of such request (the "Resale Registration Statement") in accordance with and pursuant to Rule 415 promulgated under the Securities Act (or any successor rule then in effect) and shall effect any related qualification or compliance as would permit or facilitate the sale and distribution of all or any portion of the Registrable Securities owned by the Holders, including by naming such Holders as selling security holders, and shall use its commercially reasonable efforts to cause such Resale Registration Statement to become effective under the Act as promptly as practicable and otherwise no later than the date that is 120 days following the date that the request for such registration is received by the Company."

- 3. <u>Entire Agreement; Ratification</u>. This Amendment constitutes the entire agreement among the parties with respect to the subject matter hereof. Except as expressly amended hereby, the terms of the Registration Rights Agreement are each hereby confirmed and ratified in all respects by the parties hereto and remain in full force and effect.
- 4. <u>Binding Effect</u>. This Agreement shall be binding upon and inure to the benefit of the parties hereto, and any of their respective subsidiaries, affiliates, insurers, predecessors, successors, officers, directors, managers, employees, stockholders, members, agents, attorneys or assigns.

- 5. <u>Governing Law</u>. This Amendment shall be governed by and construed under the laws of the State of New York as applied to agreements among New York residents entered into and to be performed entirely within New York without giving effect to principles of conflicts of laws.
- 6. <u>Counterparts</u>. This Amendment may be signed in counterparts, each of which shall be deemed an original but all of which together shall constitute one and the same agreement.
- 7. <u>Necessary Action</u>. Each party shall perform any further acts and execute and deliver any documents that may be reasonably necessary to carry out the provisions of this Amendment.

[Signature pages to follow]

IN WITNESS WHEREOF, the parties have executed this Amendment as of the date first above written.

## ARBUTUS BIOPHARMA CORPORATION

By: <u>/s/ Bruce Cousins</u>

Name: Bruce Cousins

Title: Executive Vice President & Chief

Financial Officer

Address: 100 – 8900 Glenlyon Parkway

Burnaby, B.C. V5J 5J8

IN WITNESS WHEREOF, the parties have executed this Amendment as of the date first above written.

## ROIVANT SCIENCES LTD.

By: /s/ Marianne L. Romeo

Name: Marianne L. Romeo Title: Head, Global Transactions & Risk

Management Address: IN WITNESS WHEREOF, the parties have executed this Amendment as of the date first above written.

By: /s/ Patrick T. Higgins
Patrick T. Higgins

Address: \_\_\_\_\_

IN WITNESS WHEREOF, the parties have executed this Amendment as of the date first	st above written.
By: <u>/s/ Michael J. McElhaugh</u> Michael J. McElhaugh	1
Address:	

IN WITNESS WHEREOF, the parties have executed this Am	nendment as of the date first above written.
	By: <u>/s/ Michael J. Sofia</u> Michael J. Sofia
	Address:

IN WITNESS WHEREOF, the parties have executed this Amendme	ent as of the date first above written.
	A. Roberts
.A	Address:
	\ddress:

# CERTIFICATION PURSUANT TO RULE 13a-14 OR 15d-14 OF THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

### I, Mark Murray, certify that:

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

Date: November 5, 2015

/s/ Mark Murray

Name: Mark Murray

Title: President and Chief Executive Officer

# CERTIFICATION PURSUANT TO RULE 13a-14 OR 15d-14 OF THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

#### I, Bruce Cousins, certify that:

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

Date: November 5, 2015

/s/ Bruce Cousins

Name: Bruce Cousins

Title: Executive Vice President, Finance and

Chief Financial Officer

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

In connection with the Quarterly Report on Form 10-Q of Arbutus Biopharma Corporation (the "Company") for the quarter ended September 30, 2015, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I Mark Murray, President and Chief Executive 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 to the best of my knowledge:

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

Date: November 5, 2015

/s/ Mark Murray

Name: Mark Murray

Title: President and Chief Executive Officer

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

In connection with the Quarterly Report on Form 10-Q of Arbutus Biopharma Corporation (the "Company") for the quarter ended September 30, 2015, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I Bruce Cousins, Executive Vice President, Finance and 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 to the best of my knowledge:

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

Date: November 5, 2015

/s/ Bruce Cousins

Name: Bruce Cousins

Title: Executive Vice President, Finance and

Chief Financial Officer