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

## **FORM 10-Q**

X	QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SE	CURITIES E	XCH.	ANGE	E ACT OF 1934
	For the quarterly period ende	d September 3	30, 201	.1	
	Or				
	TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SE	CURITIES E	XCH A	ANGE	E ACT OF 1934
	For the transition period from	n to			
	Commission File Num	ber: 000-2108	8		
	VICAL INCOL	POR	Α,	TF	7 <b>D</b>
	(Exact name of registrant as				
	Delaware (State or other jurisdiction of incorporation or organization)	peemed in its	, chur	,	93-0948554 (I.R.S. Employer Identification No.)
	10390 Pacific Center Court San Diego, California (Address of principal executive offices)				92121 (Zip code)
	(858) 646-1 (Registrant's telephone numbe		code)		
	(Former name, former address and former fis	cal year, if chang	ed since	last rep	port)
	Indicate by check mark whether the registrant (1) has filed all reports required to be eding 12 months (or for such shorter period that the registrant was required to file such ass. Yes ⊠ No □				
	Indicate by check mark whether the registrant has submitted electronically and poster elitted and posted pursuant to Rule 405 of Regulation S-T (§232.405) during the precedit sost such files). Yes ⊠ No □				
of "la	Indicate by check mark whether the registrant is a large accelerated filer, an accelerated arge accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12th				filer or a smaller reporting company. See the definition
	Large accelerated filer $\square$	Smaller	report	ing co	ompany
	Indicate by check mark whether the registrant is a shell company (as defined in Rule	12b-2 of the E	Exchan	ige Ac	et). Yes □ No ⊠
	Indicate the number of shares outstanding of each of the issuer's classes of common	stock, as of the	e latest	t practi	ticable date.
	Total shares of common stock outstanding at October 31, 2011: 71,882,378				

## VICAL INCORPORATED

## FORM 10-Q

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## PART I. FINANCIAL INFORMATION

## ITEM 1. FINANCIAL STATEMENTS

# VICAL INCORPORATED BALANCE SHEETS (In thousands, except par value data) (Unaudited)

	September 30, 2011	December 31, 2010
ASSETS .		
Current assets:		
Cash and cash equivalents	\$ 41,068	\$ 47,320
Marketable securities, available-for-sale	11,565	5,037
Restricted cash	2,999	2,911
Receivables and other	2,642	940
Total current assets	58,274	56,208
Long-term investments	5,915	5,434
Property and equipment, net	6,654	7,560
Intangible assets, net	3,012	3,247
Other assets	192	458
Total assets	\$ 74,047	\$ 72,907
<u>LIABILITIES AND STOCKHOLDERS' EQUITY</u>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 5,484	\$ 6,334
Long-term liabilities:		
Deferred rent	2,036	2,211
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.01 par value, 5,000 shares authorized, none issued and outstanding	_	_
Common stock, \$0.01 par value, 160,000 shares authorized, 71,862 and 71,640 shares issued and outstanding at September 30,		
2011 and December 31, 2010, respectively	719	716
Additional paid-in capital	383,282	380,929
Accumulated deficit	(318,424)	(317,755)
Accumulated other comprehensive gain	950	472
Total stockholders' equity	66,527	64,362
Total liabilities and stockholders' equity	<u>\$ 74,047</u>	\$ 72,907

See accompanying notes to unaudited financial statements

## VICAL INCORPORATED STATEMENTS OF OPERATIONS (In thousands, except per share data) (Unaudited)

		onths Ended mber 30,		nths Ended nber 30,
	2011	2010	2011	2010
Revenues:				
Contract and grant revenue	\$ 1,360	\$ 1,573	\$ 2,607	\$ 3,538
License and royalty revenue	25,259	684	25,479	2,257
Total revenues	26,619	2,257	28,086	5,795
Operating expenses:				
Research and development	5,505	4,658	14,004	14,723
Manufacturing and production	2,343	2,307	7,697	8,543
General and administrative	2,379	2,102	7,161	6,473
Total operating expenses	10,227	9,067	28,862	29,739
Income (loss) from operations	16,392	(6,810)	(776)	(23,944)
Other income (expense):				
Investment and other income (expense), net	39	43	107	319
Net income (loss)	<u>\$16,431</u>	(6,767)	\$ (669)	(23,625)
Basic net income (loss) per share	\$ 0.23	\$ (0.12)	\$ (0.01)	\$ (0.42)
Diluted net income (loss) per share	\$ 0.22	\$ (0.12)	\$ (0.01)	\$ (0.42)
Weighted average shares used in computing basic net income (loss) per share	72,075	56,745	71,987	56,155
Weighted average shares used in computing diluted net income (loss) per share	73,739	56,745	71,987	56,155

See accompanying notes to unaudited financial statements

## VICAL INCORPORATED STATEMENTS OF CASH FLOWS (In thousands)

(Unaudited)

	Nine Mon Septem	iber 30,
	2011	2010
Cash flows from operating activities:  Net loss	e (((0)	0(22 (25)
	\$ (669)	\$(23,625)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:  Depreciation and amortization	1,746	2,106
Write-off of abandoned patents	1,740	2,100
Compensation expense related to stock options and awards	2,360	1,972
Changes in operating assets and liabilities:	2,300	1,772
Receivables and other	(1,703)	(326)
Other assets	267	_
Accounts payable, accrued expenses and other liabilities	(913)	(1,770)
Deferred revenue		(1,417)
Deferred rent	(112)	(48)
Net cash provided by (used in) operating activities	976	(23,100)
Cash flows from investing activities:		
Maturities of marketable securities	15,930	26,799
Purchases of marketable securities	(22,549)	(18,083)
Purchases of property and equipment	(290)	(296)
Patent expenditures	(315)	(298)
Net cash (used in) provided by investing activities	(7,224)	8,122
Cash flows from financing activities:	<del></del>	
Net proceeds from issuance of common stock	130	36,423
Payment of withholding taxes for net settlement of restricted stock units	(134)	(83)
Net cash (used in) provided by financing activities	(4)	36,340
Net (decrease) increase in cash and cash equivalents	(6,252)	21,362
Cash and cash equivalents at beginning of period	47,320	25,873
Cash and cash equivalents at end of period	\$ 41,068	\$ 47,235

See accompanying notes to unaudited financial statements

## VICAL INCORPORATED NOTES TO FINANCIAL STATEMENTS September 30, 2011 (Unaudited)

#### 1. GENERAL

Vical Incorporated, or the Company, a Delaware corporation, was incorporated in April 1987 and has devoted substantially all of its resources since that time to its research and development programs. The Company researches and develops biopharmaceutical products based on its patented DNA delivery technologies for the prevention and treatment of serious or life-threatening diseases.

All of the Company's potential products are in research and development phases. No revenues have been generated from the sale of any such products, nor are any such revenues expected for at least the next several years. The Company earns revenue from research and development agreements with pharmaceutical collaborators and grant and contract arrangements with government entities. Most of the Company's product candidates will require significant additional research and development efforts, including extensive preclinical and clinical testing. All product candidates that advance to clinical testing will require regulatory approval prior to commercial use, and will require significant costs for commercialization. There can be no assurance that the Company's research and development efforts, or those of its collaborators, will be successful. The Company expects to continue to incur substantial losses and not generate positive cash flows from operations for at least the next several years. No assurance can be given that the Company can generate sufficient product revenue to become profitable or generate positive cash flows from operations.

The unaudited financial statements at September 30, 2011, and for the three and nine months ended September 30, 2011 and 2010, have been prepared in accordance with the rules and regulations of the Securities and Exchange Commission, or SEC, and with accounting principles generally accepted in the United States applicable to interim financial statements. These unaudited financial statements have been prepared on the same basis as the audited financial statements and include all adjustments, consisting of only normal recurring accruals, which in the opinion of management are necessary to present fairly the Company's financial position as of the interim date and results of operations for the interim periods presented. Interim results are not necessarily indicative of results for a full year or future periods. The preparation of financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ materially from those estimates. These unaudited financial statements should be read in conjunction with the Company's audited financial statements for the year ended December 31, 2010, included in its Annual Report on Form 10-K filed with the SEC.

#### Cash, Cash Equivalents and Marketable Securities

Cash and cash equivalents consist of cash and highly liquid securities with original maturities at the date of acquisition of ninety days or less. Investments with an original maturity of more than ninety days are considered marketable securities and have been classified by management as available-for-sale. These investments are classified as current assets, even though the stated maturity date may be one year or more beyond the current balance sheet date. Such investments are carried at fair value, with unrealized gains and losses included as a separate component of stockholders' equity. Realized gains and losses from the sale of available-for-sale securities or the amounts reclassified out of accumulated other comprehensive income, if any, are determined on a specific identification basis.

#### Restricted Cash

The Company is required to maintain a letter of credit securing an amount equal to twelve months of the current monthly installment of base rent for the term of its primary facilities lease, which ends in August 2017. Under certain circumstances the Company may be able to eliminate the need for the letter of credit. As of September 30, 2011, and December 31, 2010, restricted cash of \$3.0 million and \$2.9 million, respectively, was pledged as collateral for this letter of credit.

#### Revenue Recognition

Revenue is recognized when the four basic criteria of revenue recognition are met: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services rendered; (3) the fee is fixed or determinable; and (4) collectability is reasonably assured.

Contract Manufacturing, Contract Services and Grant Revenue

The Company's contract manufacturing arrangements typically require the delivery of multiple lots of clinical vaccines. Prior to the revised multiple element guidance adopted by the Company on January 1, 2011, the Company analyzed its multiple element arrangements to determine whether the elements could be separated and accounted for individually as separate units of accounting. The evaluation was performed at the inception of the arrangement. The delivered item(s) were considered a separate unit of accounting if all of the following criteria were met: (1) the delivered item(s) has value to the customer on a standalone basis; (2) there is objective and reliable evidence of the fair value of the undelivered item(s); and (3) if the arrangement includes a general right of return relative to the delivered item, delivery or performance of the undelivered item(s) is considered probable and substantially in the Company's control. If the delivered item did not have standalone value or the Company did not have objective or reliable evidence of the fair value of the undelivered component, the amount of revenue allocable to the delivered item was deferred.

The Company recognizes revenues from contract services and federal government research grants during the period in which the related expenditures are incurred and related payments for those services are received or collection is reasonably assured.

#### License and Royalty Revenue

The Company's license and royalty revenues are generated through agreements with strategic partners. Prior to the revised multiple element and milestone method of revenue recognition guidance adopted by the Company on January 1, 2011 nonrefundable, up-front license fees and milestone payments with standalone value that are not dependent on any future performance by the Company under the agreements were recognized as revenue upon the earlier of when payments are received or collection is assured, but were deferred if the Company has continuing performance obligations. If the Company had continuing involvement through contractual obligations under such agreements, such up-front fees were deferred and recognized over the period for which the Company continued to have a performance obligation.

Effective January 1, 2011, for multiple deliverable agreements, including contract manufacturing, contract services and license agreements, the Company follows the provisions of ASU No. 2009-13. In order to account for the multiple-element arrangements, the Company identifies the deliverables included within the agreement and evaluates which deliverables represent separate units of accounting. Analyzing the arrangement to identify deliverables requires the use of judgment, and each deliverable may be an obligation to deliver services, a right or license to use an asset, or another performance obligation. A delivered item is considered a separate unit of accounting when the delivered item has value to the Partner on a standalone basis based on the consideration of the relevant facts and circumstances for each arrangement. Factors considered in this determination include the research capabilities of the partner and the availability of research expertise in this field in the general marketplace. In addition, if the arrangement includes a general right of return relative to the delivered item, delivery or performance of the undelivered item is considered probable and substantially in the Company's control. Arrangement consideration is allocated at the inception of the agreement to all identified units of accounting based on their relative selling price. The relative selling price for each deliverable is determined using vendor specific objective evidence ("VSOE"), of selling price or third-party evidence of selling price if VSOE does not exist. If neither VSOE nor third-party evidence of selling price exists, the Company uses its best estimate of the selling price for the deliverable. The amount of allocable arrangement consideration is limited to amounts that are fixed or determinable. The consideration received is allocated among the separate units of accounting, and the applicable revenue recognition criteria are applied to each of the separate units. Changes in the allocation of the sales price between delivered and undelivered elements can impact revenue recognition but do not change the total revenue recognized under any agreement. Upfront license fee payments are recognized upon delivery of the license if facts and circumstances dictate that the license has standalone value from the undelivered items, which generally include research and development services and the manufacture of drug products, the relative selling price allocation of the license is equal to or exceeds the upfront license fee, persuasive evidence of an arrangement exists, the Company's price to the partner is fixed or determinable, and collectability is reasonably assured. Upfront license fee payments are deferred if facts and circumstances dictate that the license does not have standalone value. The determination of the length of the period over which to defer revenue is subject to judgment and estimation and can have an impact on the amount of revenue recognized in a given period.

The terms of the Company's partnership agreements provide for milestone payments upon achievement of certain regulatory and commercial events. Effective January 1, 2011, the Company adopted on a prospective basis the Milestone Method. Under the Milestone Method, the Company recognizes consideration that is contingent upon the achievement of a milestone in its entirety as revenue in the period in which the milestone is achieved only if the milestone is substantive in its entirety. A milestone is considered substantive when it meets all of the following three criteria: 1) The consideration is

commensurate with either the entity's performance to achieve the milestone or the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from the entity's performance to achieve the milestone, 2) The consideration relates solely to past performance, and 3)The consideration is reasonable relative to all of the deliverables and payment terms within the arrangement. A milestone is defined as an event (i) that can only be achieved based in whole or in part on either the entity's performance or on the occurrence of a specific outcome resulting from the entity's performance, (ii) for which there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved and (iii) that would result in additional payments being due to the Company.

Reimbursements of research and development services are recognized as revenue during the period in which the services are performed as long as there is persuasive evidence of an arrangement, the fee is fixed or determinable and collection of the related receivable is probable. Revenue from the manufacture of drug product is recognized when the drug product has met all specifications required for partner acceptance and title and risk of loss have transferred to the partner. The Company does not directly control when any partner will request research and development services or supply of the drug product; therefore, the Company cannot predict when it will recognize revenues in connection with research and development services and supply drug product. Royalties to be received based on sales of licensed products by the Company's partners incorporating the Company's licensed technology will be recognized as earned.

#### Net Income (Loss) Per Share

Basic and diluted net income (loss) per share has been computed using the weighted-average number of shares of common stock outstanding during the period. The weighted average number of shares used to compute diluted net income per share also includes any assumed exercise of stock options under the treasury stock method, and the assumed issuance of common stock under restricted stock units, or RSUs. Common stock equivalents of 1.7 million for the three months ended September 30, 2011 were included in the calculation of diluted net income per share. The weighted average number of shares used to compute diluted net loss per share excludes any assumed exercise of stock options and warrants, and the assumed issuance of common stock under RSUs as the effect would be antidilutive. Common stock equivalents of 0.7 million for the three months ended September 30, 2010, were excluded from the calculation because of their antidilutive effect. Common stock equivalents of 1.3 million and 0.8 million for the nine months ended September 30, 2011 and 2010, respectively, were excluded from the calculation because of their antidilutive effect.

#### Recent Accounting Pronouncements

In June 2011, the Financial Accounting Standards Board, or FASB, issued authoritative guidance regarding comprehensive income. This newly issued accounting standard allows an entity to have the option to present the components of net income and comprehensive income in either one or two consecutive financial statements. The guidance eliminates the current option to report other comprehensive income and its components in the statement of changes in stockholders' equity. While the new guidance changes the presentation of comprehensive income, there are no changes to the components that are recognized in net income or other comprehensive income under current accounting guidance. The guidance is effective for fiscal years and interim periods beginning after December 15, 2011. While the new guidance will require us to change the manner in which we present other comprehensive income and its components on a retrospective basis, we do not believe our adoption of the guidance in the first quarter of 2012 will have a material impact on our financial position, results of operations or cash flows.

In June 2011, the FASB issued ASU No. 2011-05, Comprehensive Income (Topic 220): Presentation of Comprehensive Income. In ASU No. 2011-05, an entity has the option to present the total of comprehensive income, the components of net income, and the components of other comprehensive income either in a single continuous statement of comprehensive income or in two separate but consecutive statements. In both choices, an entity is required to present each component of net income along with total net income, each component of other comprehensive income along with a total for other comprehensive income, and a total amount for comprehensive income. ASU No. 2011-05 eliminates the option to present the components of other comprehensive income as part of the statement of changes in stockholders' equity. The amendments in ASU No. 2011-05 do not change the items that must be reported in other comprehensive income or when an item of other comprehensive income must be reclassified to net income. The amendments in ASU No. 2011-05 are effective for fiscal years, and interim period within those years, beginning after December 15, 2011. The Company does not expect the adoption of ASU No. 2011-05 to have a material impact on its consolidated financial position or results of operations.

In May 2011, the FASB issued authoritative guidance regarding common fair value measurements and disclosure requirements in U.S. Generally Accepted Accounting Principles and International Financial Reporting Standards. This newly issued accounting standard clarifies the application of certain existing fair value measurement guidance and expands the disclosures for fair value measurements that are estimated using significant unobservable inputs. This guidance is effective

on a prospective basis for annual and interim reporting periods beginning on or after December 15, 2011. The Company does not expect that the adoption of this standard will have a material impact on its financial position or results of operations.

In March 2010, the FASB ratified the milestone method of revenue recognition. Under this new standard, an entity can recognize contingent consideration earned from the achievement of a substantive milestone in its entirety in the period in which the milestone is achieved. A milestone is defined as an event (i) that can only be achieved based in whole or in part on either the entity's performance or on the occurrence of a specific outcome resulting from the entity's performance (ii) for which there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved and (iii) that would result in additional payments being due to the entity. This guidance is effective for annual periods beginning after June 15, 2010, but may be adopted earlier as of the beginning of an annual period. The Company adopted these provisions as of January 1, 2011. The adoption did not have a material impact on the Company's financial position or results of operations.

In September 2009, the FASB issued authoritative guidance regarding multiple-deliverable revenue arrangements. This guidance requires an entity to allocate arrangement consideration at the inception of an arrangement to all of its deliverables based on their relative selling prices. The guidance eliminates the use of the residual method of allocation and requires the relative-selling-price method in all circumstances in which an entity recognizes revenue for an arrangement with multiple deliverables. The Company adopted these provisions as of January 1, 2011. The adoption did not have a material impact on the Company's financial position or results of operations.

#### 2. STOCK-BASED COMPENSATION

Total stock-based compensation expense was allocated to research and development, manufacturing and production and general and administrative expense as follows (in thousands):

	Three Mo	Three Months Ended		ths Ended
	Septe	mber 30,	Septen	iber 30,
	2011	2010	2011	2010
Research and development	\$ 229	\$ 190	\$ 727	\$ 544
Manufacturing and production	43	75	125	222
General and administrative	<u>475</u>	421	1,508	1,206
Total stock-based compensation expense	<u>\$ 747</u>	\$ 686	\$2,360	\$1,972

During the nine months ended September 30, 2011 and 2010, the Company granted stock-based awards with a total estimated value of \$3.8 million and \$4.4 million, respectively. At September 30, 2011, total unrecognized estimated compensation expense related to unvested stock-based awards granted prior to that date was \$3.4 million, which is expected to be recognized over a weighted-average period of 1.4 years. Stock-based awards granted during the nine months ended September 30, 2011 and 2010, were equal to 3.6% and 3.0%, respectively, of outstanding shares of common stock at the end of the applicable period.

#### 3. COMPREHENSIVE GAIN (LOSS)

Comprehensive gain (loss) consists of net income (loss) and certain changes in equity that are excluded from net income (loss). Accumulated other comprehensive gain (loss) represents net unrealized gain (loss) on marketable securities. For the three months ended September 30, 2011 and 2010, other comprehensive gain was \$0.3 million and \$0.1 million, respectively, and total accumulated comprehensive gain (loss) was \$16.8 million and \$(6.7) million, respectively. For the nine months ended September 30, 2011 and 2010, other comprehensive gain was \$0.5 million and \$33,000, respectively, and total accumulated comprehensive loss for each period was \$0.2 million and \$23.6 million, respectively.

#### 4. OTHER BALANCE SHEET ACCOUNTS

Accounts payable and accrued expenses consisted of the following (in thousands):

	September 30, 2011	December 31, 2010
Clinical trial accruals	\$ 1,804	\$ 2,338
Employee compensation	2,818	2,730
Accounts payable	138	752
Other accrued liabilities	724	514
Total accounts payable and accrued expenses	\$ 5,484	\$ 6,334

#### 5. SHORT-TERM MARKETABLE SECURITIES

The following is a summary of short-term marketable securities classified as available-for-sale (in thousands):

	Amortizeu	Unreanzeu	Unreanzeu	Market
September 30, 2011_	Cost	Gain	Loss	Value
U.S. treasuries	\$ 1,012	\$ 2	<u>s — </u>	\$ 1,014
Government-sponsored enterprise securities	6,202	_	3	6,199
Corporate bonds	3,515	_	1	3,514
Certificates of deposit	838			838
	<u>\$ 11,567</u>	\$ 2	\$ 4	\$11,565
	<del></del>			
	Amortized	Unrealized	Unrealized	Market
December 31, 2010	Cost	Gain	Loss	Value
U.S. treasuries	\$ 1,002	<u> </u>	<u> </u>	\$1,002
Government-sponsored enterprise securities	2,999	1	_	3,000
Certificates of deposit	1,035	_	_	_1,035

Amortized

Unraalizad

Unrealized

Market

At September 30, 2011, \$4.0 million of these securities were scheduled to mature outside of one year. The Company did not realize any gains or losses on sales of available-for-sale securities for the nine months ended September 30, 2011. As of September 30, 2011, none of the securities had been in a continuous unrealized loss position longer than one year.

#### 6. LONG-TERM INVESTMENTS

As of September 30, 2011, the Company held \$6.5 million (at par value) of auction rate securities which were classified as long-term investments. With the liquidity issues experienced in global credit and capital markets, these auction rate securities have experienced multiple failed auctions as the amount of securities submitted for sale has exceeded the amount of purchase orders, and as a result, these affected securities are currently not liquid. All of the Company's auction rate securities are secured by either student loans or municipal bonds. The student loans are backed by the full faith and credit of the federal government (up to approximately 98% of the value of the student loan). At September 30, 2011, the auction rate securities the Company held maintained Standard and Poor's credit ratings of BBB or AAA. All of these securities continue to pay interest according to their stated terms. While it is not the Company's intent to hold these securities until their stated ultimate maturity dates, these investments are scheduled to ultimately mature between 2038 and 2043.

The valuation of the Company's auction rate security investment portfolio is subject to uncertainties that are difficult to predict. The fair values of these securities are estimated utilizing a discounted cash flow analysis. The key drivers of the valuation model include the expected term, collateralization underlying the security investments, the creditworthiness of the counterparty, the timing of expected future cash flows, discount rates, liquidity and the expected holding period. These securities were also compared, when possible, to other observable market data for securities with similar characteristics. Based on the valuation of the individual securities, the Company has recognized cumulative losses of \$1.5 million as of September 30, 2011, none of which was realized during the three or nine months ended September 30, 2011. The losses when

incurred are included in investment and other income. The market value of these securities has partially recovered. Included in other comprehensive income are unrealized gains of \$0.5 million and \$49,000 for the nine months ended September 30, 2011 and 2010, respectively. As of September 30, 2011, the Company had recorded cumulative unrealized gains of \$1.0 million. The resulting carrying value of the auction rate securities at September 30, 2011, was \$5.9 million which is included in long-term investments. Any future decline in market value may result in additional losses being recognized.

At present, in the event the Company needs to liquidate its auction rate securities that are in an illiquid state, it may not be able to do so without the possible loss of principal until a future auction for these investments is successful, another secondary market evolves for these securities, they are redeemed by the issuer or they mature. If the Company is unable to sell these securities in the market or they are not redeemed, then the Company could be required to hold them to maturity. The Company does not have a need to access these funds for operational purposes in the foreseeable future. The Company will continue to monitor and evaluate these investments on an ongoing basis for impairment.

#### 7. FAIR VALUE MEASUREMENTS

The current guidance related to fair value measurements, among other things, defines fair value, establishes a consistent framework for measuring fair value and expands disclosure for each major asset and liability category measured at fair value on either a recurring or nonrecurring basis. The guidance clarifies that fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, the guidance establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

- Level 1: Observable inputs such as quoted prices in active markets;
- · Level 2: Inputs, other than the quoted prices in active markets, that are observable either directly or indirectly; and
- · Level 3: Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions.

Cash, cash equivalents, marketable securities, restricted cash and long-term investments measured at fair value as of September 30, 2011, are classified in the table below in one of the three categories described above (in thousands):

		Fair Value Measurements		
	Level 1	Level 2	Level 3	Total
Demand deposits	\$27,511	\$ —	\$ —	\$27,511
Certificates of deposit	838			838
Money market funds	16,556	_	_	16,556
U.S. treasuries	1,014			1,014
Corporate bonds	_	3,514	_	3,514
Government-sponsored enterprise securities	_	6,199		6,199
Auction rate securities			5,915	5,915
	\$45,919	\$9,713	\$5,915	\$61,547

The Company's investments in U.S. treasuries, certificates of deposits and money market funds are valued based on publicly available quoted market prices for identical securities as of September 30, 2011. The Company's investments in government-sponsored entities and corporate bonds are valued by a third party using proprietary valuation models and analytical tools. The inputs to these models include market pricing for similar instruments that are both objective and publicly available. The Company's investments in auction rate securities are valued internally as more fully described in Note 6.

Activity for assets measured at fair value using significant unobservable inputs (Level 3) is presented in the table below (in thousands):

	Ended
	ember 30, 2011
Balance at December 31, 2010	\$ 5,434
Total net unrealized losses included in earnings	_
Total net unrealized gains included in other comprehensive income	481
Net transfers in and/out of Level 3	 
Balance at September 30, 2011	\$ 5,915
Total gains or losses for the period included in net loss attributable to the change in unrealized gains or losses relating to assets still held at the reporting	
date	\$ 

Nine Months

#### 8. COMMITMENTS AND CONTINGENCIES

The Company prosecutes its intellectual property estate vigorously to obtain the broadest valid scope for its patents. Due to uncertainty of the ultimate outcome of these matters, their impact on future operating results or the Company's financial condition is not subject to reasonable estimates.

In the ordinary course of business, the Company may become a party to lawsuits involving various matters. The Company is unaware of any such lawsuits presently pending against it which, individually or in the aggregate, are deemed to be material to the Company's financial condition or results of operations.

#### 9. STOCKHOLDERS' EQUITY

In September 2010, the Company sold 15.0 million shares of its common stock in a public offering at a price to the public of \$2.25 per share. Net proceeds from the offering, after deducting underwriting discounts and commissions and other offering expenses payable by the Company, totaled \$31.5 million. In October 2010, the Company sold an additional 368,662 shares pursuant to the exercise of the underwriters' overallotment option at a price of \$2.25 per share. Net proceeds from the overallotment option, after deducting underwriting discounts and commissions and other offering expenses payable by the Company, totaled \$0.7 million. All of the shares of common stock were offered pursuant to an effective shelf registration statement.

During 2010, certain of the Company's investors exercised warrants to purchase an aggregate of 2,365,644 shares of common stock that were issued in connection with the Company's May 2009 registered direct offering. The Company received net proceeds of \$5.0 million as a result of these exercises.

#### 10. ASTELLAS AGREEMENTS

In July 2011, the Company entered into license agreements with Astellas Pharma Inc., or Astellas, granting Astellas exclusive, worldwide, royalty-bearing licenses under certain of the Company's know-how and intellectual property to develop and commercialize certain products containing plasmids encoding certain forms of glycoprotein B and/or phosphoprotein 65, including TransVax™ but excluding CyMVectin™. Under the agreements, Astellas is responsible for the worldwide development and commercialization of products in the licensed field, at its expense, and has agreed to use commercially reasonable efforts to develop, obtain regulatory approval for and commercialize at least one Product for use in certain immunocompromised patients in the licensed field in the United States and certain other major markets.

Under the terms of the license agreements, Astellas paid a nonrefundable upfront license fee of \$25.0 million. The Company is entitled to receive an additional \$10.0 million upon finalization of the trial design for a Phase 3 registration trial of  $TransVax^{TM}$  in hematopoietic stem cell transplant recipients. The Company is also entitled to receive additional cash payments potentially totaling \$95.0 million for achievement of certain milestones through commercial launch and to receive double-digit royalties on net sales of products and has an option to co-promote  $TransVax^{TM}$  in the United States. Under the terms of a supply and services agreement entered into by the Company and Astellas on the same date, the Company agreed to perform certain development and regulatory activities, at Astellas' expense, and to supply Products, to Astellas at Astellas' expense, for use in development and initial commercialization activities in the licensed field.

The Company identified the deliverables at the inception of the agreements. The Company has determined that the license and the related know-how, development and regulatory services and drug product supply individually represent separate units of accounting, because each deliverable has standalone value. The estimated selling prices for these units of accounting was determined based on market conditions, the terms of comparable collaborative arrangements for similar technology in the pharmaceutical and biotechnology industry and entity-specific factors, such as the terms of the Company's previous collaborative agreements, the Company's pricing practices and pricing objectives and the nature of the research and development services to be performed for the partners.

The arrangement consideration was allocated to the deliverables based on the relative selling price method. Based on the results of the Company's analysis, the Company determined that the upfront payment was earned upon the granting of the exclusive right to the Company's technology and the transfer of the related know-how. However, the amount of allocable arrangement consideration is limited to amounts that are fixed or determinable; therefore, the amount allocated to the licenses at September 30, 2011 was only to the extent of cash received. As a result, during the three months ended September 30, 2011, the Company recognized \$25.1 million related to the license fee and know-how. The Company will recognize reimbursements for research and development services as revenues under the agreements as the related services are delivered. During the three months ended September 30, 2011, the Company recognized \$1.2 million of revenue related to contract services delivered. The Company will recognize revenue from sales of drug product when the drug product has met all required specifications and the related title and risk of loss and damages have passed to Astellas.

The Company is eligible to receive additional cash payments upon the achievement of specified regulatory and commercial milestones. The Company has determined that each of the regulatory and commercial milestones meets the definition of a milestone and that each milestone is substantive in accordance with the milestone method of revenue recognition. Accordingly, the Company expects to recognize such regulatory and commercial milestone payments as revenues under the agreements upon achievement of each milestone.

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

This Quarterly Report on Form 10-Q, or Report, contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1934, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, including statements regarding our business, our financial position, the research and development of biopharmaceutical products based on our patented DNA delivery technologies, the funding of our research and development efforts, and other statements describing our goals, expectations, intentions or beliefs. Such statements reflect our current views and assumptions and are subject to risks and uncertainties, particularly those inherent in the process of developing and commercializing biopharmaceutical products based on our patented DNA delivery technologies. Actual results could differ materially from those projected herein. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in our Annual Report on Form 10-K for the year ended December 31, 2010, and in our other filings with the SEC, and those identified in Part II, Item 1A entitled "Risk Factors" beginning on page 23 of this Report. As a result, you are cautioned not to rely on these forward-looking statements. We disclaim any duty to update any forward-looking statement to reflect events or circumstances that occur after the date on which such statement is made.

#### Overview

We research and develop biopharmaceutical products based on our patented DNA delivery technologies for the prevention and treatment of serious or life-threatening diseases. We believe the following areas of research offer the greatest potential for near-term commercialization for us and our partners:

- Vaccines for use in high-risk populations for infectious disease targets for which there are significant needs;
- Vaccines for general pediatric, adolescent and adult populations for infectious disease applications;
- Cancer vaccines or immunotherapies which complement our existing programs and core expertise; and
- Gene-based delivery of therapeutic proteins, such as angiogenic growth factors, for treatment of cardiovascular diseases.

We currently have four active independent clinical and preclinical development programs in the areas of infectious disease and cancer including:

- A fully enrolled ongoing Phase 3 clinical trial using our Allovectin® immunotherapeutic in patients with metastatic melanoma which has been funded, up to certain limits, by AnGes MG, Inc., or AnGes, through cash payments and equity investments under a research and development agreement;
- A completed Phase 1 clinical trial using our H1N1 pandemic influenza DNA vaccine formulated with our proprietary Vaxfectin adjuvant;
- A completed preclinical program, with an allowed investigational new drug application, using our CyMVectin™ prophylactic vaccine formulated with our proprietary Vaxfectin® adjuvant to prevent CMV infection before and during pregnancy; and
- A preclinical program with therapeutic and prophylactic vaccines for herpes simplex virus type 2 formulated with our proprietary Vaxfectin adjuvant.

We have leveraged our patented technologies through licensing and collaboration arrangements, such as our licensing arrangements with Astellas, Merck & Co., Inc., or Merck, Sanofi, AnGes, Aqua Health Ltd. of Canada, or Aqua Health, an affiliate of Novartis Animal Health, and Merial Limited, or Merial, a subsidiary of Sanofi, among other biopharmaceutical companies.

In addition, we have licensed complementary technologies from leading research institutions and biopharmaceutical companies. We also have granted non-exclusive, academic licenses to our DNA delivery technology patent estate to 11 leading research institutions including Stanford, Harvard, Yale and the Massachusetts Institute of Technology. The non-exclusive academic licenses allow university researchers to use our technology free of charge for educational and internal, non-commercial research purposes. In exchange, we have the option to exclusively license from the universities potential commercial applications arising from their use of our technology on terms to be negotiated.

## **Product Development**

We, together with our licensees and collaborators, are currently developing a number of DNA-based vaccines and therapeutics for the prevention or treatment of infectious diseases, cancer and cardiovascular diseases. The table below summarizes our independent programs and corporate and government collaborations.

Product/Concept	Intended Use	Development Status 1	Lead Developer
Independent Programs			
Allovectin® cancer immunotherapeutic	First-line treatment for metastatic melanoma	Phase 3	Vical
Prophylactic vaccine for H1N1 pandemic influenza virus	Prevent infection, disease, and/or viral shedding	Phase 1 complete	Vical
CyMVectin <sup>™</sup> prophylactic vaccine for cytomegalovirus	Prevent infection before pregnancy to preclude fetal transmission	Preclinical complete	Vical
Therapeutic vaccine for herpes simplex type 2 virus	Protect against recurring flare-ups, reduce viral shedding and transmission	Preclinical	Vical
Corporate Collaborations			
TransVax™ therapeutic vaccine for cytomegalovirus	Protect against CMV infection after stem cell transplants	Phase 3 preparation	Astellas
TransVax <sup>™</sup> therapeutic vaccine for cytomegalovirus	Protect against CMV infection after solid organ transplants	Phase 2 preparation	Astellas
Collategene™ angiogenic therapy encoding Hepatocyte Growth Factor	Induce local growth of blood vessels to restore blood flow to limbs affected by critical limb ischemia	Phase 3 preparation	AnGes
Apex®-IHN prophylactic vaccine for infectious hematopoietic necrosis virus	Prevent infection and disease in farm-raised salmon when exposed to infected wild salmon	Approved in Canada	Aqua Health (Novartis)
ONCEPT <sup>TM</sup> therapeutic cancer vaccine encoding human tyrosinase	Adjunct treatment to increase survival time of dogs with oral melanoma	Approved in the United States	Merial
Government Collaboration			
Prophylactic and/or therapeutic HIV vaccine	Prevent and/or treat infection, disease, and/or viral shedding	Phase 2b	NIH

<sup>&</sup>quot;Research" indicates exploration and/or evaluation of a potential product candidate in a nonclinical laboratory setting. "Preclinical" indicates that a specific product candidate in a nonclinical setting has shown functional activity that is relevant to a targeted medical need, and is advancing toward initial human clinical testing. "Phase 1" clinical trials are typically conducted with a small number of patients or healthy subjects to evaluate safety, determine a safe dosage range, identify side effects, and, if possible, gain early evidence of effectiveness. "Phase 2" clinical trials are conducted with a larger group of patients to evaluate effectiveness of an investigational product for a defined patient population, and to determine common short-term side effects and risks associated with the product candidate. "Phase 3" clinical trials involve large scale, multi-center, comparative trials that are conducted with patients afflicted with a target disease to evaluate the overall benefit-risk relationship of the investigational product and to provide an adequate basis for product labeling.

#### **Recent Events**

The following events have recently occurred with respect to our business and our development programs:

#### Continued Progress in our Melanoma Program

• We recently announced encouraging animal data demonstrating a synergistic (more than additive) reduction of tumor growth and a positive trend in survival using a combination of our Allovectin® immunotherapy with an anti-CTLA-4 antibody. The synergy became evident about 12 days after treatment initiation, suggesting a likely two-step process in which Allovectin® first directs T cells to target the melanoma tumor and anti-CTLA-4 antibody then maximally activates these T cells. The study was conducted in a well-accepted melanoma mouse model using a standard mouse equivalent of human anti-CTLA-4 antibodies such as ipilimumab.

#### Continued Progress in our HSV-2 Program

We recently announced that our Vaxfectin®-formulated plasmid DNA vaccines against herpes simplex virus type-2, or HSV-2, provided complete protection in
guinea pigs against both primary and recurrent HSV-2 disease. The vaccines also significantly reduced genital lesion recurrence and viral shedding as well as
latent infection in the central nervous system. These data expanded on previous results from repeated studies in mice showing that the vaccines provided complete
protection against lethal challenge, provided sterilizing immunity and inhibited viral counts at both the primary and latent infection sites.

#### Patent Update

We were recently issued Canadian Patent No. 2,365,416 and Japanese Patent No. 4,800,485 covering our novel cationic lipid/co-lipid adjuvant, Vaxfectin.
 Specific claims include composition of the Vaxfectin® adjuvant, composition of Vaxfectin®-formulated vaccines, and methods for their use. The new patents add to our existing U.S. and European patent coverage for Vaxfectin® and to our family of core technology patents broadly covering gene-based vaccines and therapeutics.

#### Research, Development and Manufacturing Programs

To date, we have not received revenues from the sale of our independently developed pharmaceutical products and have received minimal revenues from the sale of commercially marketed products by our licensees. We earn revenues by performing services under research and development and manufacturing contracts, from grants and from licensing access to our proprietary technologies. Since our inception, we estimate that we have received approximately \$196.3 million in revenues from these sources. Revenues by source were as follows (in millions):

	Three Months Ended September 30,		Nine Months Ended September 30,	
Source	2011	2010	2011	2010
Astellas supply and services contract	\$ 1.2	\$ —	\$ 1.2	\$ —
RapidResponse <sup>TM</sup> DNA manufacturing grant	_	0.5	0.9	1.3
IPPOX HIV contract	_	0.5	_	0.5
Navy H1N1 contract	_	0.3	_	1.2
HSV-2 grant	_	0.3	0.2	0.5
Other contract and grants	0.2		0.3	
Total contract and grant revenues	1.4	1.6	2.6	3.5
Astellas license	\$ 25.1	\$ —	\$ 25.1	\$ —
AnGes licenses	_	0.6	_	1.9
Other royalties and licenses	0.1	0.1	0.4	0.4
Total royalty and license revenues	25.2	0.7	25.5	2.3
Total revenues	\$ 26.6	\$ 2.3	\$ 28.1	\$ 5.8

Research, development, manufacturing and production costs by major program, as well as other costs, were as follows (in millions):

	Three Months				
	End	Ended September 30,		Nine Months Ended September 30,	
	Septem				
<u>Program</u>	2011	2010	2011	2010	
Allovectin®	\$ 4.7	\$3.8	\$13.9	\$12.3	
CMV	2.4	1.2	5.1	5.1	
Pandemic influenza	_	0.3	0.1	1.8	
Other research, development, manufacturing and production	0.7	1.7	2.6	4.1	
Total research, development, manufacturing and production	<u>\$ 7.8</u>	<u>\$7.0</u>	<u>\$21.7</u>	\$23.3	

Since our inception through September 30, 2011, we estimate that we have spent approximately \$436 million on research, development, manufacturing and production. Our current independent development focus is on our cancer immunotherapeutic Allovectin\*, novel DNA vaccines for CMV and pandemic influenza, and other clinical and preclinical targets.

We are conducting a Phase 3 clinical trial using Allovectin® in patients with recurrent metastatic melanoma which has been funded, up to certain limits, by AnGes through cash payments and equity investments under a research and development agreement. We are also developing vaccine candidates for our CMV products, TransVax<sup>TM</sup> and CyMVectin<sup>TM</sup>, and pandemic influenza and these programs, excluding TransVax<sup>TM</sup> which we recently licensed to Astellas, will require significant additional funds to advance through development to commercialization. From inception through September 30, 2011, we have spent approximately \$147 million on our Allovectin® program, \$62 million on our CMV programs, and \$25 million on our pandemic influenza programs.

We have other product candidates in the research stage. It can take many years to develop product candidates from the initial decision to screen product candidates, perform preclinical and safety studies, and perform clinical trials leading up to possible approval of a product by the FDA or comparable foreign agencies. The outcome of the research is unknown until each stage of the testing is completed, up through and including the registration of clinical trials. Accordingly, we are unable to predict which potential product candidates we may proceed with, the time and cost to complete development, and ultimately whether we will have a product approved by the FDA or comparable foreign agencies.

As a result, we expect to incur substantial operating losses for at least the next several years, due primarily to the advancement of our research and development programs, the cost of preclinical studies and clinical trials, spending for outside services, costs related to maintaining our intellectual property portfolio, costs due to manufacturing activities, costs related to our facilities, and possible advancement toward commercialization activities.

#### **Critical Accounting Policies and Estimates**

The preparation of financial statements in accordance with accounting principles generally accepted in the United States requires that management make a number of assumptions and estimates that affect the reported amounts of assets, liabilities, revenues and expenses in our financial statements and accompanying notes. Management bases its estimates on historical information and assumptions believed to be reasonable. Although these estimates are based on management's best knowledge of current events and circumstances that may impact us in the future, actual results may differ from these estimates.

Our critical accounting policies are those that affect our financial statements materially and involve a significant level of judgment by management. Our critical accounting policies regarding revenue recognition are in the following areas: license and royalty agreements, manufacturing contracts, contract services and grant revenues. Our critical accounting policies also include recognition of research and development expenses and the valuation of long-lived and intangible assets.

#### Revenue Recognition

Revenue is recognized when the four basic criteria of revenue recognition are met: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services rendered; (3) the fee is fixed or determinable; and (4) collectability is reasonably assured.

Contract Manufacturing Revenue. Our contract manufacturing arrangements typically require the delivery of multiple lots of clinical vaccines. Prior to the revised multiple element guidance adopted by us on January 1, 2011, we analyzed our multiple element arrangements to determine whether the elements can be separated and accounted for individually as separate units of accounting. The evaluation was performed at the inception of the arrangement. The delivered item(s) were considered a separate unit of accounting if all of the following criteria were met: (1) the delivered item(s) have standalone value to the customer; (2) there is objective and reliable evidence of the fair value of the undelivered item(s); and (3) if the arrangement includes a general right of return relative to the delivered item, delivery or performance of the undelivered item(s) is considered probable and substantially in our control. If the delivered item did not have standalone value or we did not have objective or reliable evidence of the fair value of the undelivered component, the amount of revenue allocable to the delivered item was deferred.

Contract Services and Grant Revenue. We recognize revenue from contract services and federal government research grants during the period in which the related expenditures are incurred and related payments for those services are received or collection is reasonably assured.

License and Royalty Revenue. Our license and royalty revenues are generated through agreements with strategic partners. Prior to the revised multiple element and milestone method of revenue recognition guidance adopted by us on January 1, 2011 nonrefundable, up-front license fees and milestone payments with standalone value that are not dependent on any future performance by us under the agreements were recognized as revenue upon the earlier of when payments are received or collection is assured, but were deferred if we have continuing performance obligations. If we had continuing involvement through contractual obligations under such agreements, such up-front fees were deferred and recognized over the period for which we continued to have a performance obligation.

Effective January 1, 2011, for multiple deliverable agreements, including contract manufacturing, contract services and license agreements, we follow the provisions of ASU No. 2009-13. In order to account for the multiple-element arrangements, we identify the deliverables included within the agreement and evaluate which deliverables represent separate units of accounting. Analyzing the arrangement to identify deliverables requires the use of judgment, and each deliverable may be an obligation to deliver services, a right or license to use an asset, or another performance obligation. A delivered item is considered a separate unit of accounting when the delivered item has value to the partner on a standalone basis based on the consideration of the relevant facts and circumstances for each arrangement. Factors considered in this determination include the research capabilities of the partner and the availability of research expertise in this field in the general marketplace. In addition, if the arrangement includes a general right of return relative to the delivered item, delivery or performance of the undelivered item is considered probable and substantially in our control. Arrangement consideration is allocated at the inception of the agreement to all identified units of accounting based on their relative selling price. The relative selling price for each deliverable is determined using VSOE of selling price or third-party evidence of selling price if VSOE does not exist. If neither VSOE nor third-party evidence of selling price exists, we use our best estimate of the selling price for the deliverable. The amount of allocable arrangement consideration is limited to amounts that are fixed or determinable. The consideration received is allocated among the separate units of accounting, and the applicable revenue recognition criteria are applied to each of the separate units. Changes in the allocation of the sales price between delivered and undelivered elements can impact revenue recognition but do not change the total revenue recognized under any agreement. Upfront license fee payments are recognized upon delivery of the license if facts and circumstances dictate that the license has standalone value from the undelivered items, which generally include research and development services and the manufacture of drug products, the relative selling price allocation of the license is equal to or exceeds the upfront license fee, persuasive evidence of an arrangement exists, our price to the partner is fixed or determinable, and collectability is reasonably assured. Upfront license fee payments are deferred if facts and circumstances dictate that the license does not have standalone value. The determination of the length of the period over which to defer revenue is subject to judgment and estimation and can have an impact on the amount of revenue recognized in a given period.

The terms of our partnership agreements provide for milestone payments upon achievement of certain regulatory and commercial events. Effective January 1, 2011, we adopted on a prospective basis the Milestone Method. Under the Milestone Method, we recognize consideration that is contingent upon the achievement of a milestone in its entirety as revenue in the period in which the milestone is achieved only if the milestone is substantive in its entirety. A milestone is considered substantive when it meets all of the following three criteria: 1) The consideration is commensurate with either the entity's performance to achieve the milestone or the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from the entity's performance to achieve the milestone, 2) The consideration relates solely to past performance, and 3) The consideration is reasonable relative to all of the deliverables and payment terms within the arrangement. A milestone is defined as an event (i) that can only be achieved based in whole or in part on either the entity's performance or on the occurrence of a specific outcome resulting from the entity's performance, (ii) for which there is

substantive uncertainty at the date the arrangement is entered into that the event will be achieved and (iii) that would result in additional payments being due to us.

Reimbursements of research and development services are recognized as revenue during the period in which the services are performed as long as there is persuasive evidence of an arrangement, the fee is fixed or determinable and collection of the related receivable is probable. Revenue from the manufacture of drug product is recognized when the drug product has met all specifications required for partner acceptance and title and risk of loss have transferred to the partner. We do not directly control when any partner will request research and development services or supply of drug product; therefore, we cannot predict when we will recognize revenues in connection with research and development services and the supply of drug product. Royalties to be received based on sales of licensed products by our partners incorporating our licensed technology will be recognized as earned.

#### Research and Development Expenses

Research and development expenses consist of expenses incurred in performing research and development activities including salaries and benefits, facilities and other overhead expenses, clinical trials, contract services and other outside expenses. Research and development expenses are charged to operations as they are incurred.

We assess our obligations to make milestone payments that may become due for licensed or acquired technology to determine whether the payments should be expensed or capitalized. We charge milestone payments to research and development expense when:

- The technology is in the early stage of development and has no alternative uses;
- There is substantial uncertainty of the technology or product being successful;
- There will be difficulty in completing the remaining development; and
- There is substantial cost to complete the work.

#### Capitalization and Valuation of Long-Lived and Intangible Assets

Intangible assets with finite useful lives consist of capitalized legal costs incurred in connection with patents, patent applications pending and technology license agreements. Payments to acquire a license to use a proprietary technology are capitalized if the technology is expected to have alternative future use in multiple research and development projects. We amortize costs of approved patents, patent applications pending and license agreements over their estimated useful lives, or terms of the agreements, whichever are shorter.

For patents pending, we amortize the costs over the shorter of a period of twenty years from the date of filing the application or, if licensed, the term of the license agreement. We re-assess the useful lives of patents when they are issued, or whenever events or changes in circumstances indicate the useful lives may have changed. For patents and patent applications pending that we abandon, we charge the remaining unamortized accumulated costs to expense.

Intangible assets and long-lived assets are evaluated for impairment at least annually or whenever events or changes in circumstances indicate that their carrying value may not be recoverable. If the review indicates that intangible assets or long-lived assets are not recoverable, their carrying amount would be reduced to fair value. Factors we consider important that could trigger an impairment review include the following:

- · A significant change in the manner of our use of the acquired asset or the strategy for our overall business; and/or
- A significant negative industry or economic trend.

In the event we determine that the carrying value of intangible assets or long-lived assets is not recoverable based upon the existence of one or more of the above indicators of impairment, we may be required to record impairment charges for these assets. As of September 30, 2011, our largest group of intangible assets with finite lives includes patents and patents pending for our DNA delivery technology, consisting of intangible assets with a net carrying value of approximately \$2.8 million.

## **Recent Accounting Pronouncements**

For information on the recent accounting pronouncements which may impact our business, see Note 1 of the Notes to Financial Statements included in this Report.

#### **Results of Operations**

#### Three Months Ended September 30, 2011, Compared with Three Months Ended September 30, 2010

Total Revenues. Total revenues increased \$24.4 million, or 1,079.4%, to \$26.6 million for the three months ended September 30, 2011, from \$2.3 million for the three months ended September 30, 2010. This increase was primarily the result of the recognition of \$25.1 million of license revenue related to the license of our TransVax™ program to Astellas in 2011 which was partially offset by a decrease in license revenue of \$0.6 million related to our Allovectin® license agreement with AnGes.

Research and Development Expenses. Research and development expenses increased \$0.8 million, or 18.2%, to \$5.5 million for the three months ended September 30, 2011, from \$4.7 million for the three months ended September 30, 2010. This increase was primarily due to a sub-license payment we made to the City of Hope related to the license of our TransVax™ program to Astellas which was partially offset by lower costs related to our clinical trials for TransVax™ and Allovectin® during the three months ended September 30, 2011.

Manufacturing and Production Expenses. Manufacturing and production expenses increased \$36,000, or 1.6%, to \$2.3 million for the three months ended September 30, 2011, from \$2.3 million for the three months ended September 30, 2010. This increase was primarily related to the timing of equipment maintenance.

General and Administrative Expenses. General and administrative expenses increased \$0.3 million, or 13.2%, to \$2.4 million for the three months ended September 30, 2011, from \$2.1 million for the three months ended September 30, 2010. This increase was primarily the result of higher overall wages.

#### Nine Months Ended September 30, 2011, Compared with Nine Months Ended September 30, 2010

Total Revenues. Total revenues increased \$22.3 million, or 384.7%, to \$28.1 million for the nine months ended September 30, 2011, from \$5.8 million for the nine months ended September 30, 2010. This increase was primarily the result of the recognition of \$25.1 million of license revenue related to the license of our TransVax™ program to Astellas in July 2011 which was partially offset by a decrease in license revenue of \$1.9 million related to our Allovectin® license agreement with AnGes.

Research and Development Expenses. Research and development expenses decreased \$0.7 million, or 4.9%, to \$14.0 million for the nine months ended September 30, 2011, from \$14.7 million for the nine months ended September 30, 2010. This decrease was primarily due to lower costs related to our clinical trials for TransVax<sup>TM</sup> and Allovectin® during the nine months ended September 30, 2011 which was partially offset by a sub-license payment we made to the City of Hope related to the license of our TransVax<sup>TM</sup> program in 2011.

Manufacturing and Production Expenses. Manufacturing and production expenses decreased \$0.8 million, or 9.9%, to \$7.7 million for the nine months ended September 30, 2011, from \$8.5 million for the nine months ended September 30, 2010. This decrease was primarily the result of the recognition of capitalized costs during the nine months ended September 30, 2010 related to the shipment of a vaccine we manufactured for the U.S. Navy.

General and Administrative Expenses. General and administrative expenses increased \$0.7 million, or 10.6%, to \$7.2 million for the nine months ended September 30, 2011, from \$6.5 million for the nine months ended September 30, 2010. This increase was primarily the result of higher overall wages and higher consulting costs during the nine months ended September 30, 2011.

### Liquidity and Capital Resources

Since our inception, we have financed our operations primarily through private placements of preferred and common stock, public offerings of common stock, and revenues from our operations. From our inception through September 30, 2011, we have received approximately \$196.3 million in revenues from performing services under research and development and manufacturing contracts, from grants and from licensing access to our proprietary technologies, and we have raised net proceeds of approximately \$370.9 million from the sale of equity securities. Cash, cash equivalents, marketable securities, and long-term investments, including restricted cash, totaled \$61.5 million at September 30, 2011, compared with \$60.7 million at December 31, 2010. The increase in our cash, cash equivalents and marketable securities for

the nine months ended September 30, 2011, was primarily the result of the receipt of \$25.0 million related to the license of our TransVax<sup>TM</sup> program to Astellas in 2011, offset by the use of cash to fund our operations.

Net cash provided by (used in) operating activities was \$1.0 million and \$(23.1) million for the nine months ended September 30, 2011 and 2010, respectively. The increase in net cash provided by operating activities for the nine months ended September 30, 2011, compared with the prior year period, was primarily the result of the receipt of \$25.0 million related to the license of our TransVax<sup>TM</sup> program to Astellas in 2011.

Net cash used in investing activities was \$7.2 million and \$8.1 million for the nine months ended September 30, 2011 and 2010, respectively. The increase in net cash used in investing activities for the nine months ended September 30, 2011, compared with the prior year period, was primarily the result of an increase in net purchases of investments.

Net cash (used in) provided by financing activities was \$(4,000) and \$36.3 million for the nine months ended September 30, 2011 and 2010, respectively. The decrease in net cash provided by financing activities for the nine months ended September 30, 2011, compared with the prior year period, was the result of net proceeds received from the sale of common stock and the exercise of warrants during the nine months ended September 30, 2010.

A discussion of our exposure to auction rate securities is included in Part 1, Item 3 of this Report under the heading "Quantitative and Qualitative Disclosures About Market Risk."

We expect to incur substantial additional research and development expenses, manufacturing and production expenses, and general and administrative expenses, including continued increases in costs related to personnel, preclinical and clinical testing, outside services, facilities, intellectual property and possible commercialization. Our future capital requirements will depend on many factors, including continued scientific progress in our research and development programs, the scope and results of preclinical testing and clinical trials, the time and costs involved in obtaining regulatory approvals, the costs involved in filing, prosecuting, enforcing and defending patent claims, the impact of competing technological and market developments, the cost of manufacturing scale-up and validation, and possible commercialization activities and arrangements. We may seek additional funding through research and development relationships with suitable potential corporate collaborators, such as Astellas. We have received \$25.0 million and expect to receive an additional \$10.0 million in near-term payments from Astellas as a result of the license agreements entered into in July 2011. We may also seek additional funding through public or private financings. We have on file two effective shelf registration statements that collectively allow us to raise up to an additional \$105.6 million from the sale of common stock, preferred stock, debt securities and/or warrants and we have also entered into an equity line of credit with Azimuth pursuant to which we may sell up to \$25.0 million of our common stock, subject to certain conditions, until January 2012. However, additional financing may not be available on favorable terms or at all. If additional funding is not available, we anticipate that our available cash and existing sources of funding will be adequate to satisfy our cash needs at least through December 31, 2013.

### Contractual Obligations

Under our Merck, Sanofi, AnGes, Merial and Aqua Health agreements, we are required to pay up to 10% of certain initial upfront monetary payments, and a small percentage of some royalty payments, to the Wisconsin Alumni Research Foundation and/or the University of Michigan. Under our license agreements with Astellas, we are required to make certain payments to the City of Hope and CytRx in connection with the development and commercialization of our products licensed by Astellas. In addition, certain technology license agreements require us to make other payments if we or our sublicensees advance products through clinical development. For programs developed with the support of U.S. government funding, the U.S. government may have rights to resulting products without payment of royalties to us.

We may be required to make future payments to our licensors based on the achievement of milestones set forth in various in-licensing agreements. In most cases, these milestone payments are based on the achievement of development or regulatory milestones, including the exercise of options to obtain licenses related to specific disease targets, commencement of various phases of clinical trials, filing of product license applications, approval of product licenses from the FDA or a foreign regulatory agency, and the first commercial sale of a related product. Payment for the achievement of milestones under our in-license agreements is highly speculative and subject to a number of contingencies.

The aggregate amount of additional milestone payments that we could be required to pay under all of our in-license agreements in place at September 30, 2011, is approximately \$23.1 million, of which approximately \$15.2 million is related to our independent programs and corporate and government collaborations which are currently in clinical development. These amounts assume that all remaining milestones associated with the milestone payments are met. In the event that product license approval for any of the related products is obtained, we may be required to make royalty payments in addition

to these milestone payments. Although we believe that some of the milestones contained in our in-license agreements may be achieved, it is highly unlikely that a significant number of them will be achieved. Because the milestones are highly contingent and we have limited control over whether the development and regulatory milestones will be achieved, we are not in a position to reasonably estimate how much, if any, of the potential milestone payments will ultimately be paid, or when. Additionally, under the inlicense agreements, many of the milestone events are related to progress in clinical trials which will take several years to achieve.

In addition, we have undertaken certain commitments under license agreements with collaborators, and under indemnification agreements with our officers and directors. Under the license agreements with our collaborators, we have agreed to continue to maintain and defend the patent rights licensed to the collaborators and, in the case of our agreements with Astellas, have agreed to undertake certain development and manufacturing activites. Under the indemnification agreements with our officers and directors, we have agreed to indemnify those individuals for any expenses and liabilities in the event of a threatened, pending or actual investigation, lawsuit, or criminal or investigative proceeding.

We have employment agreements that contain severance arrangements with each of our three executive officers and three of our other executives. Under the agreements with the executive officers we are obligated to pay severance if we terminate the executive officer's employment without "cause," or if the executive officer resigns for "good reason," as defined in the agreements, within the periods set forth therein. The severance for the executive officers consists of continued base salary payments at the then-current rate, including the payment of health insurance premiums, for the period specified in each agreement, which ranges from 12 to 18 months, plus a payment equal to between one and one and a half times the executive's cash bonus in the previous year. In addition, the executive officers receive accelerated vesting on all their unvested stock awards as if they had remained employed by us for between 12 and 18 months from the date of termination. In the event that the termination occurs within 24 months of a "change in control," as defined in the agreements, the severance for the executive officers consists of lump sum payments equal to between 18 and 24 months of base salary at the then-current rate, the payment of health insurance premiums for the period specified in each agreement, which ranges from 12 to 18 months, plus a payment equal to between one and one and a half times the executive's cash bonus in the previous year. In addition, all outstanding unvested stock awards will vest immediately. The severance for the other executive consists of continued payments at the then-current base compensation rate for a period of six months. All of the agreements specify that any earnings from employment or consulting during this period will offset any salary continuation payments due from us. The maximum payments due under these employment agreements would have been \$3.1 million if each such executive officer and other executive were terminated at September 30, 2011.

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

We are subject to interest rate risk. Our investment portfolio is maintained in accordance with our investment policy which defines allowable investments, specifies credit quality standards and limits the credit exposure of any single issuer. Our investment portfolio consists of cash equivalents, both restricted and non-restricted, marketable securities and long-term investments. The average maturity of our investments, excluding our auction rate securities, is approximately four months. Our investments are classified as available-for-sale securities.

To assess our interest rate risk, we performed a sensitivity analysis projecting an ending fair value of our cash equivalents and current marketable securities using the following assumptions: a 12-month time horizon, a 9-month average maturity and a 150-basis-point increase in interest rates. This pro forma fair value would have been \$0.1 million lower than the reported fair value of our investments at September 30, 2011.

All of our investment securities are classified as available-for-sale and therefore reported on the balance sheet at market value. Our investment securities consist of high-grade auction rate securities, corporate debt securities and government agency securities. As of September 30, 2011, our long-term investments included (at par value) \$6.5 million of auction rate securities secured by municipal bonds and student loans. At September 30, 2011, the auction rate securities we held maintained Standard and Poor's credit ratings of BBB or AAA. Our auction rate securities are debt instruments with a long-term maturity and with an interest rate that is reset in short intervals through auctions. The recent conditions in the global credit markets have prevented some investors from liquidating their holdings of auction rate securities because the amount of securities submitted for sale has exceeded the amount of purchase orders for such securities. If there is insufficient demand for the securities at the time of an auction, the auction may not be completed and the interest rates may be reset to predetermined higher rates. When auctions for these securities fail, the investments may not be readily convertible to cash until a future auction of these investments is successful or they are redeemed or mature.

Since February 2008, there has been insufficient demand at auction for all of our auction rate securities held at September 30, 2011. As a result, these affected securities are currently not liquid, and we could be required to hold them until

they are redeemed by the issuer or to maturity. As of September 30, 2011, we had recognized \$1.5 million of losses related to those auction rate securities by adjusting their carrying value. The market value of these securities has partially recovered from the lows that created the losses. As of September 30, 2011, we had recorded cumulative unrealized gains of \$1.0 million. Any future decline in market value may result in additional losses being recognized.

The valuation of our auction rate security investment portfolio is subject to uncertainties that are difficult to predict. The fair values of these securities are estimated utilizing a discounted cash flow analysis or other type of valuation model as of September 30, 2011. The key drivers of the valuation model include the expected term, collateralization underlying the security investments, the creditworthiness of the counterparty, the timing of expected future cash flows, discount rates, and the expected holding period. These securities were also compared, when possible, to other observable market data for securities with similar characteristics.

In the event we need to access the funds that are not currently liquid, we will not be able to do so without the possible loss of principal, until a future auction for these investments is successful or they are redeemed by the issuer or they mature. If we are unable to sell these securities in the market or they are not redeemed, then we may be required to hold them to maturity. We do not anticipate a need to access these funds for operational purposes for the foreseeable future. We will continue to monitor and evaluate these investments on an ongoing basis for impairment. Based on our ability to access our cash and other short-term investments, our expected operating cash flows, and our other sources of cash, we do not anticipate that the potential illiquidity of these investments will affect our ability to execute our current business plan.

#### ITEM 4. CONTROLS AND PROCEDURES

#### Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the design and operation of our disclosure controls and procedures, as such term is defined in Rule 13a-15(e) promulgated under the Securities Exchange Act of 1934, as amended, as of the end of the period covered by this Report. Based on this evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective and were operating at the reasonable assurance level as of September 30, 2011.

#### **Changes in Internal Control over Financial Reporting**

In connection with entering two new collaborative agreements during the three months ended September 30, 2011, we have developed additional internal controls over our revenue recognition process. Except for the additional internal controls over revenue recognition, there were no significant changes in our internal control over financial reporting that occurred during the three months ended September 30, 2011, that have materially affected, or are reasonably likely to materially affect our internal control over financial reporting.

#### PART II. OTHER INFORMATION

#### ITEM 1A. RISK FACTORS

You should consider carefully the risks described below, together with all of the other information included in this Report, and in our other filings with the SEC, before deciding whether to invest in or continue to hold our common stock. The risks described below are all material risks currently known, expected or reasonably foreseeable by us. If any of these risks actually occurs, our business, financial condition, results of operations or cash flow could be seriously harmed. This could cause the trading price of our common stock to decline, resulting in a loss of all or part of your investment.

The risk factors set forth below with an asterisk (\*) next to the title are new risk factors or risk factors containing changes, including any material changes, from the risk factors previously disclosed in Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2010, as filed with the SEC.

(\*)None of our independently developed product candidates has been approved for sale, and we have a limited number of independently developed product candidates in clinical trials. If we do not develop commercially successful products, we may be forced to curtail or cease operations.

All of our independently developed product candidates are either in research or development. We must conduct a substantial amount of additional research and development before any U.S. or foreign regulatory authority will approve any of our product candidates. Limited data exist regarding the efficacy of DNA vaccines or therapeutics compared with conventional vaccines or therapeutics. Results of our research and development activities may indicate that our product candidates are unsafe or ineffective. In this case, regulatory authorities will not approve them.

For example, our independently developed product candidates currently in clinical development include Allovectin®, for which we announced the completion of enrollment of a Phase 3 clinical trial in 2010, and a completed Phase 1 clinical study of our H1N1 pandemic influenza vaccine. We have completed preclinical work on CyMVectin™. We may not meet the primary endpoint of the Allovectin® trial for which a Special Protocol Assessment agreement is in place with the FDA. We may not conduct additional H1N1 pandemic influenza vaccine trials or conduct a Phase 1 CyMVectin™ trial, and the future trials, if any, may not demonstrate sufficient efficacy to support further product development.

Additionally, we are in early stages of development with other product candidates. These product candidates will require significant costs to advance through the development stages. If such product candidates are advanced through clinical trials, the results of such trials may not support approval by the FDA or comparable foreign agencies. Even if approved, our products may not be commercially successful, particularly if they do not gain market acceptance among physicians, patients, healthcare payers and relevant medical communities. If we fail to develop and commercialize our products, we may be forced to curtail or cease operations.

(\*) We are dependent on our license agreements with Astellas to further develop and commercialize TransVa₹<sup>M</sup>. The failure to maintain these agreements, or the failure of Astellas to perform its obligations under these agreements, could negatively impact our business.

Pursuant to the terms of our license agreements with Astellas, we granted to Astellas exclusive worldwide rights to develop and commercialize certain products, including TransVax<sup>TM</sup> but excluding CyMVectin<sup>TM</sup>, for the control and prevention of CMV infection in immunocompromised patients, including transplant recipients and transplant donors, and pursuant to the terms of our supply and services agreement with Astellas, we are obligated to perform certain development activities and supply Astellas with its product requirements for development and initial commercialization activities. Consequently, our ability to generate any revenues from TransVax<sup>TM</sup> depends on Astellas' ability to develop, obtain regulatory approvals for and successfully commercialize TransVax<sup>TM</sup>. We have limited control over the amount and timing of resources that Astellas will dedicate to these efforts.

We are subject to a number of other risks associated with our dependence on our license agreements with Astellas, including:

- Astellas may not comply with applicable regulatory guidelines with respect to developing or commercializing TransVax<sup>TM</sup>, which could adversely impact sales or future development of TransVax<sup>TM</sup>,
- · We and Astellas could disagree as to future development plans and Astellas may delay, fail to commence or stop future clinical trials or other development;
- There may be disputes between us and Astellas, including disagreements regarding the license agreements, that may result in (1) the delay of or failure to achieve developmental, regulatory and commercial objectives that would result in milestone or royalty payments, (2) the delay or termination of any future development or commercialization of TransVax<sup>TM</sup>, and/or (3) costly litigation or arbitration that diverts our management's attention and resources;
- Astellas may not provide us with timely and accurate information regarding development, sales and marketing activities or supply forecasts, which could
  adversely impact our ability to comply with our service and supply obligations to Astellas and manage our own inventory of TransVax™, as well as our ability to
  generate accurate financial forecasts;
- Business combinations or significant changes in Astellas' business strategy may adversely affect Astellas' ability or willingness to perform its obligations under our license agreements;
- Astellas may not properly defend our intellectual property rights, or may use our proprietary information in such a way as to invite litigation that could jeopardize
  or invalidate our intellectual property rights or expose us to potential litigation;

- The royalties we are eligible to receive from Astellas may be reduced based upon Astellas' and our ability to maintain or defend our intellectual property rights and the presence of generic competitors;
- Limitations on our or an acquiror's ability to maintain or pursue development or commercialization of products that are competitive with TransVax<sup>TM</sup> could deter a potential acquisition of us that our stockholders may otherwise view as beneficial; and
- If Astellas is unsuccessful in developing, obtaining regulatory approvals for or commercializing TransVax<sup>TM</sup>, we may not receive any additional milestone or royalty payments under the license agreements and our business prospects and financial results may be materially harmed.

The license agreements and supply and services agreement are subject to early termination, including through Astellas' right to terminate upon advance notice to us if Astellas reasonably determines that further development and/or commercialization will not be beneficial for Astellas. If the agreements are terminated early, we may not be able to find another collaborator for the commercialization and further development of TransVax<sup>TM</sup> on acceptable terms, or at all, and we may be unable to pursue continued development or commercialization of TransVax<sup>TM</sup> on our own.

(\*) Our revenues partially depend on the development and commercialization of products in collaboration with others to whom we have licensed our technologies. If our other collaborators or licensees do not successfully develop and commercialize products covered by these arrangements, or if we are unable to find collaborators or licensees in the future, we may not be able to derive revenues from these arrangements, we may lose opportunities to validate our DNA delivery technologies, or we may be forced to curtail our development and commercialization efforts in these areas.

In addition to our license agreements with Astellas, we have licensed, and may continue to license, our technologies to corporate collaborators and licensees for the research, development and commercialization of specified product candidates. Our revenues partially depend upon the ability of these collaborators and licensees to successfully develop and commercialize products covered by these arrangements. In addition, our licensees Astellas and AnGes have product candidates in advanced stage of clinical development, for which we believe regulatory approval would provide important further validation of our DNA delivery technologies. The development and commercialization efforts of our collaborators and licensees are subject to the same risks and uncertainties described above with respect to our independently developed product candidates.

Some collaborators or licensees may not succeed in their product development efforts. It is possible that AnGes or any of our other collaborators or licensees may be unable to obtain regulatory approval of product candidates using our technologies or successfully market and commercialize any such products for which regulatory approval is obtained. In September 2010, AnGes announced that after a series of extensive consultations with the Japanese Pharmaceuticals and Medical Devices Agency, it would be withdrawing its NDA in Japan. Also in September 2010, another one of our licensees, Sanofi announced that NV1FGF, an angiogenic growth factor therapeutic for which Sanofi had licensed our DNA delivery technology, did not meet the primary endpoint in a global Phase 3 trial. Other collaborators or licensees may not devote sufficient time or resources to the programs covered by these arrangements, and we may have limited or no control over the time or resources allocated by these collaborators or licensees to these programs. The occurrence of any of these events may cause us to derive little or no revenue from these arrangements, lose opportunities to validate our DNA delivery technologies, or force us to curtail or cease our development and commercialization efforts in these areas.

Our collaborators and licensees may breach or terminate their agreements with us, including some that may terminate their agreements without cause at any time subject to certain prior written notice requirements, and we may be unsuccessful in entering into and maintaining other collaborative arrangements for the development and commercialization of products using our technologies. If we are unable to maintain existing collaboration arrangements or enter into new ones, our ability to generate licensing, milestone or royalty revenues would be materially impaired.

Some of our independent product candidates and some of those under development by our sublicensees incorporate technologies we have licensed from others. If we are unable to retain rights to use these technologies, we or our sublicensees may not be able to market products incorporating these technologies on a commercially feasible basis, if at all.

We have licensed certain technologies from corporate collaborators and research institutions, and sublicensed certain of such technologies to others, for use in the research, development and commercialization of product candidates. Our product development efforts and those of our sublicensees partially depend upon continued access to these technologies. For

example, we or our licensors may breach or terminate our agreements, or disagree on interpretations of those agreements, which could prevent continued access to these technologies. If we were unable to resolve such matters on satisfactory terms, or at all, we or our sublicensees may be unable to develop and commercialize our products, and we may be forced to curtail or cease operations.

#### (\*)We have a history of net losses. We expect to continue to incur net losses and we may not achieve or maintain profitability.

To date, we have not sold, or received approval to sell, any pharmaceutical products. We do not expect to sell any pharmaceutical products for at least the next several years. Our net losses were approximately \$30.4 million, \$28.6 million and \$36.9 million for the years ended December 31, 2010, 2009 and 2008, respectively. As of September 30, 2011, we had incurred cumulative net losses totaling approximately \$318.4 million. Moreover, we expect that our net losses will continue and may increase for the foreseeable future. We may not be able to achieve projected results if we generate lower revenues or receive lower investment income than expected, or we incur greater expenses than expected, or all of the above. We may never generate sufficient product revenue to become profitable. We also expect to have quarter-to-quarter fluctuations in revenues, expenses, and losses, some of which could be significant.

#### We may need additional capital in the future. If additional capital is not available, we may have to curtail or cease operations.

We may need to raise more money to continue the research and development necessary to bring our products to market and to establish marketing and additional manufacturing capabilities. We may seek additional funds through public and private stock offerings, government contracts and grants, arrangements with corporate collaborators, borrowings under lease lines of credit or other sources. We have on file two effective shelf registration statements that collectively allow us to raise up to an additional \$105.6 million from the sale of common stock, preferred stock, debt securities and/or warrants. However, we may not be able to raise additional funds on favorable terms, or at all. Conditions in the credit markets and the financial services industry may make equity and debt financing more difficult to obtain, and may negatively impact our ability to complete financing transactions. To the extent that we raise additional funds by issuing equity securities, our stockholders may experience significant dilution. Any debt financing, if available, may involve restrictive covenants, such as limitations on our ability to incur additional indebtedness and other operating restrictions that could adversely impact our ability to conduct our business.

In January 2010, we entered into a committed equity line of credit with Azimuth, under which we may sell to Azimuth, subject to certain limitations, up to \$25.0 million of our common stock over a 24-month period. Azimuth will not be obligated to purchase shares under the equity line of credit unless specified conditions are met, which include a minimum price of \$1.50 for our common stock. If we are unable to meet the specified conditions with respect to any sale of shares under the Azimuth equity line of credit, we may be unable to access this source of financing. Azimuth is also permitted to terminate the equity line of credit under certain circumstances.

If we are unable to obtain additional funds, we may have to scale back our development of new products, reduce our workforce or license to others products or technologies that we otherwise would seek to commercialize ourselves. The amount of money we may need would depend on many factors, including:

- The progress of our research and development programs;
- The scope and results of our preclinical studies and clinical trials; and
- The time and costs involved in: obtaining necessary regulatory approvals; filing, prosecuting and enforcing patent claims; scaling up our manufacturing capabilities; and the commercial arrangements we may establish.

(\*) The regulatory approval process is expensive, time consuming and uncertain, which may prevent us and our collaborators and licensees from obtaining required approvals for the commercialization of our products.

Our product candidates under development and those of our collaborators and licensees, including Astellas, are subject to extensive and rigorous regulations by numerous governmental authorities in the United States and other countries. The regulatory approval process takes many years and will require us to expend substantial resources. For example, the FDA has provided only limited guidelines concerning the size and scope of clinical trials required for gene-based therapeutic and vaccine products.

Therefore, U.S. or foreign regulations could prevent or delay regulatory approval of our products or limit our and our collaborators and licensees' ability to develop and commercialize our products. Delays could:

- · Impose costly procedures on our activities and those of our collaborators and licensees;
- Delay or prevent our receipt of developmental or commercial milestones from our collaborators and licensees;
- Diminish any competitive advantages that we or our products attain; or
- · Otherwise negatively affect our results of operations and cash flows.

We have no experience in filing a Biologics License Application, or BLA, or NDA, with the FDA. Because a BLA or NDA must be submitted to and approved by the FDA before any of our product candidates may be commercialized, our lack of experience may impede our ability to obtain FDA approval in a timely manner, if at all, which in turn would delay or prevent us from commercializing those products. Similarly, our lack of experience with respect to obtaining regulatory approvals in countries other than the United States may impede our ability to commercialize our products in those countries.

We believe that the FDA and comparable foreign regulatory bodies will regulate separately each product containing a particular gene depending on its intended use. Presently, to commercialize any product we and our collaborators and licensees must file a regulatory application for each proposed use. We and our collaborators and licensees must conduct clinical studies to demonstrate the safety and efficacy of the product necessary to obtain FDA or foreign regulatory authority approval. The results obtained so far in our clinical trials and those of our collaborators and licensees may not be replicated in ongoing or future trials, or the results may be subject to varying interpretation on whether they are sufficient to support approval for commercialization. This may prevent any of our product candidates from receiving approval for commercial sale.

We use recombinant DNA molecules in our product candidates, and therefore we and our collaborators and licensees also must comply with guidelines instituted by the NIH and its Office of Biotechnology Activities. The NIH could restrict or delay the development of our product candidates.

If any of our product candidates receive regulatory approval, the FDA or other foreign regulatory agencies may still impose significant restrictions on the indicated uses or marketing of our product candidates or impose ongoing requirements for potentially costly post-approval studies. In addition, regulatory agencies subject a product, its manufacturer and the manufacturer's facilities to continual review and periodic inspections. If a regulatory agency discovers previously unknown problems with a product or a product class, including adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product or product class, our collaborators and licensees or us, including requiring withdrawal of a product from the market. Our product candidates will also be subject to ongoing FDA and other foreign regulatory agency requirements for the labeling, packaging, storage, advertising, promotion, record-keeping and submission of safety and other post-market information on the product. If we or our collaborators and licensees fail to maintain regulatory compliance after receiving marketing approval, we or our collaborators and licensees may be unable to market our products and our business could suffer.

Adverse events or the perception of adverse events in the field of gene therapy, or with respect to our product candidates, may negatively impact regulatory approval or public perception of our products.

The commercial success of some of our product candidates will depend in part on public acceptance of the use of gene therapy for preventing or treating human diseases. Serious adverse events, including patient deaths, have occurred in clinical trials utilizing viral delivery systems to deliver therapeutic genes to the patient's targeted cells. Although none of our current products or studies utilize viral delivery systems, these adverse events, as well as any other adverse events in the field of gene therapy that may occur in the future, may negatively influence public perception of gene therapy in general. If public perception is influenced by claims that gene therapy is unsafe, our product candidates may not be accepted by the general public or the medical community.

Future adverse events in gene therapy or the biotechnology industry could also result in greater governmental regulation, stricter labeling requirements and potential regulatory delays in the testing or approval of our potential products. Any increased scrutiny could delay or increase the costs of our product development efforts or clinical trials. In addition, any adverse events that may occur in our clinical trials and any resulting publicity may cause regulatory delays or otherwise affect our product development efforts or clinical trials.

Some of our potential products may be administered to patients who are suffering from, or are vulnerable to, serious diseases or other conditions which can themselves be life-threatening and often result in the death of the patient. For example, one patient in our Allovectin® Phase 2 trial conducted in 2000, died from progressive disease more than two months after receiving Allovectin® and other cancer therapies. The death was originally reported as unrelated to the treatment. Following an autopsy, the death was reclassified as "probably related" to the treatment because the possibility could not be ruled out. We do not believe Allovectin® was a significant factor in the patient's death. Patient deaths in our clinical trials, even if caused by pre-existing diseases or conditions, could negatively affect the perception of our product candidates. In addition, in our TransVax<sup>TM</sup> Phase 2 trial, we administered TransVax<sup>TM</sup> to patients who were at risk of CMV reactivation. Although we do not believe our vaccine candidates could cause the diseases they are designed to protect against, a temporal relationship between vaccination and disease onset could be perceived as causal. Some of our products are designed to stimulate immune responses, and those responses, if particularly strong or uncontrolled, could result in local or systemic adverse events, including latent adverse events.

#### (\*)Our patents and proprietary rights may not provide us with any benefit and the patents of others may prevent us from commercializing our products.

As of September 30, 2011, we were the assignee or co-assignee of 71 issued U.S. and foreign patents. We maintain our issued patents by paying maintenance fees to the patent office in each country when due. Where appropriate, we participate in legal proceedings to vigorously defend against the revocation or withdrawal of our patents. The scope and nature of these proceedings generally differ depending on the country in which they are initiated. If we are not successful in defending our patents, we may lose all or part of our proprietary rights related to those patents in these geographic regions.

As of September 30, 2011, we were also prosecuting 63 pending patent applications in the United States and in foreign countries that cover various aspects of our proprietary technologies, not including patent applications for which we are a co-assignee and that are being prosecuted by our partners.

We may not receive any patents from our current patent applications. Issued patents provide exclusivity for only a limited time period, after which they no longer serve to protect proprietary technologies or to provide any commercial advantage. Moreover, if patents are issued to us, governmental authorities may not allow claims sufficient to protect our technologies and products. Others may also challenge or seek to circumvent or invalidate our patents. In that event, the rights granted under our patents may be inadequate to protect our proprietary technologies or to provide any commercial advantage.

In addition, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was recently signed into law and includes a number of significant changes to United States patent law. These include changes in the way patent applications will be prosecuted and may also affect patent litigation. The U.S. Patent and Trademark Office is currently developing regulations and procedures to administer the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act will not become effective until one year or 18 months after its enactment. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the cost of prosecuting our patent applications, our ability to obtain patents based on our patent applications and our ability to enforce or defend our issued patents. An inability to obtain, enforce and defend patents covering our proprietary technologies would materially and adversely affect our business prospects and financial condition.

Some components of our gene-based product candidates are, or may become, patented by others. As a result, we may be required to obtain licenses to conduct research, to manufacture, or to market such products. Licenses may not be available on commercially reasonable terms, or at all, which may impede our ability to commercialize our products.

The NIH and the FDA jointly developed the Genetic Modification Clinical Research Information System, or GeMCRIS, an Internet-based database of human gene transfer trials. GeMCRIS enables individuals to easily view information on particular characteristics of clinical gene transfer trials. Although GeMCRIS includes special security features designed to protect patient privacy and confidential commercial information, these security features may be inadequately designed or enforced, potentially resulting in disclosure of confidential commercial information. In addition, the NIH, in collaboration with the FDA, has developed an Internet site, ClinicalTrials.gov, which provides public access to information on clinical trials and their results for a wide range of diseases and conditions. Future disclosures of such confidential commercial information may result in loss of advantage of competitive secrets.

(\*)The legal proceedings to obtain and defend patents, and litigation of third-party claims of intellectual property infringement, could require us to spend money and could impair our operations.

Our and our collaborators', including Astellas', success will depend in part on our, or our collaborators', ability to obtain patent protection for our products and processes, both in the United States and in other countries. The patent positions of biotechnology and pharmaceutical companies, however, can be highly uncertain and involve complex legal and factual questions. Therefore, it is difficult to predict the breadth of claims allowed in the biotechnology and pharmaceutical fields.

We also rely on confidentiality agreements with our corporate collaborators, employees, consultants and certain contractors to protect our proprietary technologies. However, these agreements may be breached and we may not have adequate remedies for such breaches. In addition, our trade secrets may otherwise become known or independently discovered by our competitors.

Protecting intellectual property rights can be very expensive. Litigation may be necessary to enforce patents issued to us or to determine the scope and validity of third-party proprietary rights. If we or, as applicable, our commercialization partners, including Astellas pursuant to its first right to enforce patents licensed to it under our license agreements, choose to go to court to stop someone else from using our inventions, that individual or company has the right to ask the court to rule that the underlying patents are invalid and/or should not be enforced against that third party. Moreover, if a competitor were to file a patent application claiming technology also invented by us or our collaborators or licensees, we would have to participate in an interference proceeding before the U.S. Patent and Trademark Office to determine the priority of the invention. We or our collaborators or licensees may be drawn into interferences with third parties or may have to provoke interferences ourselves to unblock third-party patent rights to allow us or our collaborators or licensees to commercialize products based on our technologies. Litigation could result in substantial costs and the diversion of management's efforts regardless of the results of the litigation. An unfavorable result in litigation could subject us to significant liabilities to third parties, require disputed rights to be licensed or require us to cease using some technologies.

Our products and processes may infringe, or be found to infringe, patents not owned or controlled by us. Patents held by others may require us to alter our products or processes, obtain licenses, or stop activities. If relevant claims of third-party patents are upheld as valid and enforceable, we or our collaborators or licensees could be prevented from practicing the subject matter claimed in the patents, or may be required to obtain licenses or redesign our products or processes to avoid infringement. In addition, we or our collaborators or licensees could be required to pay money damages. A number of genetic sequences or proteins encoded by genetic sequences that we are investigating are, or may become, patented by others. As a result, we or our collaborators or licensees may have to obtain licenses to test, use or market these products. Our business will suffer if we or our collaborators or licensees are not able to obtain licenses at all or on terms commercially reasonable to us or them and we or they are not able to redesign our products or processes to avoid infringement.

We have incurred costs in several legal proceedings involving our intellectual property rights in Europe, Japan and Canada. We may continue to incur costs to defend and prosecute patents and patent applications in these and other regions.

#### Competition and technological change may make our product candidates and technologies less attractive or obsolete.

We compete with companies, including major pharmaceutical and biotechnology firms that are pursuing other forms of treatment or prevention for diseases that we target. We also may experience competition from companies that have acquired or may acquire technologies from universities and other research institutions. As these companies develop their technologies, they may develop proprietary positions which may prevent us from successfully commercializing products.

Some of our competitors are established companies with greater financial and other resources than we have. Other companies may succeed in developing products and obtaining regulatory approval from the FDA or comparable foreign agencies faster than we do, or in developing products that are more effective than ours. Research and development by others may seek to render our technologies or products obsolete or noncompetitive or result in treatments or cures superior to any therapeutics developed by us.

## If we lose our key personnel or are unable to attract and retain additional personnel, we may not be able to achieve our business objectives.

We are highly dependent on our principal scientific, manufacturing, clinical, regulatory and management personnel, including Vijay B. Samant, our President and Chief Executive Officer. The loss of the services of these individuals might significantly delay or prevent the achievement of our objectives. We do not maintain "key person" life insurance on any of

our personnel. We depend on our continued ability to attract, retain and motivate highly qualified management and scientific personnel. We face competition for qualified individuals from other companies, academic institutions, government entities and other organizations in attracting and retaining personnel. To pursue our product development plans, we may need to hire additional management personnel and additional scientific personnel to perform research and development, as well as additional personnel with expertise in clinical trials, government regulation and manufacturing. However, due to the reasons noted above, we may not be successful in hiring or retaining qualified personnel and therefore we may not be able to achieve our business objectives.

(\*) We have limited experience in manufacturing our product candidates in commercial quantities. We may not be able to comply with applicable manufacturing regulations or produce sufficient product for contract or commercial purposes.

The commercial manufacturing of vaccines and other biological products is a time-consuming and complex process, which must be performed in compliance with the FDA's current Good Manufacturing Practices, or cGMP, regulations. We may not be able to comply with the cGMP regulations, and our manufacturing process may be subject to delays, disruptions or quality control problems. In addition, we may need to complete the installation and validation of additional large-scale fermentation and related purification equipment to produce the quantities of product expected to be required for commercial purposes. We have limited experience in manufacturing at this scale. Noncompliance with the cGMP regulations, the inability to complete the installation or validation of additional large-scale equipment, or other problems with our manufacturing process may limit or delay the development or commercialization of our product candidates, and cause us to breach our contract manufacturing service arrangements or our obligations under our agreements with collaborators, including our obligations under our supply and services agreement with Astellas.

We currently depend on third parties to conduct our clinical trials and may initially depend on third parties to manufacture our product candidates commercially.

We currently rely on third parties, including clinical research organizations, to perform critical services for us in connection with our clinical trials. Clinical research organizations are responsible for many aspects of the trials, including finding and enrolling subjects for testing and administering the trials. Although we rely on these third parties to conduct our clinical trials, we are responsible for ensuring that each of our clinical trials is conducted in accordance with its protocol and applicable regulations, including good clinical practices. Our reliance on third parties does not relieve us of these responsibilities and requirements. These third parties may not comply with all regulatory and contractual requirements or may not otherwise perform their services in a timely or acceptable manner, and we may need to enter into new arrangements with alternative third parties and our clinical trials may be extended, delayed or terminated. In addition, if such third parties fail to perform their obligations in compliance with our clinical trial protocols or applicable regulations, our clinical trials may not meet regulatory requirements or may need to be repeated. These risks also apply to the development activities of our collaborators and licensees, and we do not control our collaborators' and licensees' research and development, clinical trials or regulatory activities.

We may also initially depend on collaborators, licensees or other third parties to manufacture our product candidates in commercial quantities. There are a limited number of third parties that could manufacture our product candidates. We may be unable to enter into any arrangement for the commercial manufacture of our product candidates, and any arrangement we secure may not meet our requirements for manufacturing quality or quantity. Our dependence on third parties for the commercial manufacture of our product candidates may also reduce our profit margins and our ability to develop and deliver products in a timely manner.

We have no marketing or sales experience, and if we are unable to develop our own sales and marketing capability, we may not be successful in commercializing our products.

Our current strategy is to market our proprietary products directly in the United States, but we currently do not possess pharmaceutical marketing or sales capabilities. To market and sell our proprietary products, we will need to develop a sales force and a marketing group with relevant pharmaceutical industry experience, or make appropriate arrangements with strategic partners to market and sell these products. Developing a marketing and sales force is expensive and time-consuming and could delay any product launch. If we are unable to successfully employ qualified marketing and sales personnel or develop other sales and marketing capabilities, we may not be able to generate sufficient product revenue to become profitable.

#### Healthcare reform and restrictions on reimbursement may limit our returns on potential products.

Our ability to earn sufficient returns on our products will depend in part on how much, if any, reimbursement for our products and related treatments will be available from:

- · Government health administration authorities;
- · Government agencies procuring biodefense products for military or public use, including some for which we may become a sole-source vendor;
- Private health coverage insurers;
- Managed care organizations; and
- · Other organizations.

If we fail to obtain appropriate reimbursement, we could be prevented from successfully commercializing our potential products. There are ongoing efforts by governmental and third-party payers to contain or reduce the costs of healthcare through various reform measures. In the United States, the Federal government passed comprehensive healthcare reform legislation in 2010. Many of the details regarding the implementation of this legislation are yet to be determined and we currently cannot predict whether or to what extent such implementation or adoption of reforms may impair our business.

Additionally, third-party payers are increasingly challenging the price of medical products and services. If purchasers or users of our products are not able to obtain adequate reimbursement for the cost of using our products, they may forego or reduce their use. Significant uncertainty exists as to the reimbursement status of newly approved healthcare products, and whether adequate third-party coverage will be available.

## We use hazardous materials in our business. Any claims relating to improper handling, storage or disposal of these materials could be time consuming and costly.

Our research and development processes involve the controlled storage, use and disposal of hazardous materials and biological materials. Our hazardous materials include certain compressed gases, flammable liquids, acids and bases, and other toxic compounds. We are subject to federal, state and local regulations governing the use, manufacture, storage, handling and disposal of materials and waste products. Although we believe that our safety procedures for handling and disposing of these hazardous materials comply with the standards prescribed by law and regulation, the risk of accidental contamination or injury from hazardous materials cannot be completely eliminated. In the event of an accident, we could be held liable for any damages that result. We have insurance that covers our use of hazardous materials with the following coverage limits: up to \$250,000 per occurrence for losses related to the release of bio-contaminants, \$250,000 per occurrence for losses from refrigerant contamination and \$250,000 per occurrence for losses from radioactive contamination. Any liability could exceed the limits or fall outside the coverage of our insurance. We could incur significant costs to comply with current or future environmental laws and regulations.

#### We may have significant product liability exposure.

We face an inherent business risk of exposure to product liability and other claims in the event that our technologies or products are alleged to have caused harm. We also have potential liability for products manufactured by us on a contract basis for third parties. Although we currently maintain product liability insurance in the amount of \$10 million in the aggregate plus additional coverage specific to the foreign countries where our clinical trials are being conducted, this insurance coverage may not be sufficient, and we may not be able to obtain sufficient coverage in the future at a reasonable cost. Our inability to obtain product liability insurance at an acceptable cost or to otherwise protect against potential product liability claims could prevent or inhibit the commercialization of any products developed by us or our collaborators, or our ability to manufacture products for third parties. If we are sued for any injury caused by our technologies or products, or by third-party products that we manufacture, our liability could exceed our insurance coverage and total assets.

#### (\*)Negative conditions in the global credit markets may impair the liquidity of a portion of our investment portfolio.

Our investment securities consist of high-grade auction rate securities, corporate debt securities and government agency securities. As of September 30, 2011, our long-term investments included (at par value) \$6.5 million of auction rate securities secured by municipal bonds and student loans. At September 30, 2011, the auction rate securities we held had Standard and Poor's credit ratings of BBB or AAA. Our auction rate securities are debt instruments with a long-term maturity

and with an interest rate that is reset in short intervals through auctions. Ongoing conditions in the global credit markets have prevented some investors from liquidating their holdings of auction rate securities because the amount of securities submitted for sale has exceeded the amount of purchase orders for such securities. If there is insufficient demand for the securities at the time of an auction, the auction may not be completed and the interest rates may be reset to predetermined rates. When auctions for these securities fail, the investments may not be readily convertible to cash until a future auction of these investments is successful or they are redeemed or mature.

Since February 2008, there has been insufficient demand at auction for all of our auction rate securities held at September 30, 2011. As a result, these affected securities are currently not liquid, and we could be required to hold them until they are redeemed by the issuer or to maturity. As of September 30, 2011, we had recognized \$1.5 million of losses related to those auction rate securities by adjusting their carrying value. The market value of these securities has partially recovered from the lows that created the loss. As of September 30, 2011, we had recorded cumulative unrealized gains of \$1.0 million. Any future decline in market value may result in additional losses being recognized.

In the event we need to access the funds that are in an illiquid state, we will not be able to do so without the possible loss of principal, until a future auction for these investments is successful or they are redeemed by the issuer or they mature. If we are unable to sell these securities in the market or they are not redeemed, then we may be required to hold them to maturity.

#### (\*)Our stock price could continue to be highly volatile and you may not be able to resell your shares at or above the price you pay for them.

The market price of our common stock, like that of many other life sciences companies, has been and is likely to continue to be highly volatile. From January 1, 2008, to September 30, 2011, our stock price has ranged from \$1.04 to \$5.51. The following factors, among others, could have a significant impact on the market price of our common stock:

- The results of our preclinical studies and clinical trials or announcements regarding our plans for future studies or trials, or those of our collaborators, licensees or competitors;
- Evidence or lack of evidence of the safety or efficacy of our potential products or those of our collaborators, licensees or competitors;
- The success of our collaborators and licensees, including Astellas, in the development or commercialization of our product candidates;
- The announcement by us or our collaborators, licensees or competitors of technological innovations or new products;
- Developments concerning our patent or other proprietary rights or those of our collaborators, licensees or competitors, including litigation and challenges to our proprietary rights;
- Other developments with our collaborators or licensees, including our entry into new collaborative or licensing arrangements;
- · Geopolitical developments, natural or man-made disease threats, or other events beyond our control;
- U.S. and foreign governmental regulatory actions;
- Changes or announcements in reimbursement policies;
- Period-to-period fluctuations in our operating results;
- Market conditions for life science stocks in general;
- Changes in the collective short interest in our stock;
- Changes in estimates of our performance by securities analysts; and
- · Our cash balances, need for additional capital, and access to capital.

#### We are at risk of securities class action litigation due to our expected stock price volatility.

In the past, stockholders have brought securities class action litigation against a company following a decline in the market price of its securities. This risk is especially acute for us because life science companies have experienced greater than

average stock price volatility in recent years and, as a result, have been subject to, on average, a greater number of securities class action claims than companies in other industries. To date, we have not been subject to class action litigation. However, we may in the future be the target of this litigation. Securities litigation could result in substantial costs and divert our management's attention and resources, and could seriously harm our business.

Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Our certificate of incorporation and bylaws include anti-takeover provisions, such as a classified board of directors, a prohibition on stockholder actions by written consent, the authority of our board of directors to issue preferred stock without stockholder approval, and supermajority voting requirements for specified actions. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which generally prohibits stockholders owning in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years. These provisions may delay or prevent an acquisition of us, even if the acquisition may be considered beneficial by some stockholders. In addition, they may discourage or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management.

#### The issuance of preferred stock could adversely affect our common stockholders.

We have on file two effective shelf registration statements that collectively allow us to raise up to an additional \$105.6 million from the sale of common stock, preferred stock, debt securities and/or warrants and our restated certificate of incorporation authorizes us to issue up to 5,000,000 shares of preferred stock. The issuance of preferred stock could adversely affect the voting power of holders of our common stock, and reduce the likelihood that our common stockholders will receive dividend payments and payments upon liquidation. The issuance of preferred stock could also decrease the market price of our common stock, or have terms and conditions that could discourage a takeover or other transaction that might involve a premium price for our shares or that our stockholders might believe to be in their best interests.

## <u>ITEM 6.</u> <u>EXHIBITS</u>

Exhibit Number	Description of Document
3.1(i)(1)	Restated Certificate of Incorporation.
3.2(ii)(2)	Amended and Restated Bylaws.
3.3(i)(2)	Certificate of Amendment to Restated Certificate of Incorporation.
4.1(1)	Specimen Common Stock Certificate.
10.1 a	U.S. License Agreement dated July 12, 2011, between the Company and Astellas Pharma Inc.
10.2 a	Ex-U.S. License Agreement dated July 12, 2011, between the Company and Astellas Pharma Inc.
10.3 a	Supply and Services Agreement dated July 12, 2011, between the Company and Astellas Pharma Inc.
10.4 a	Exclusive License Agreement dated February 3, 2003, between the Company and City of Hope.
31.1	Certification of Vijay B. Samant, Chief Executive Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Jill M. Broadfoot, Chief Financial Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Vijay B. Samant, Chief Executive Officer, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Jill M. Broadfoot, Chief Financial Officer, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS*	XBRL Instance Document.
101.SCH*	XBRL Taxonomy Extension Schema Document.
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document.
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document.

<sup>(1)</sup> Incorporated by reference to the exhibit of the same number filed with the Company's Registration Statement on Form S-3 (No. 33-95812) filed on August 15, 1995.

<sup>(2)</sup> Incorporated by reference to the exhibit of the same number filed with the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2010.

<sup>&</sup>lt;sup>a</sup> Confidential treatment of certain portions of this agreement has been requested and such portions have been omitted and filed separately with the SEC pursuant to Rule 24b-2 under the Securities Exchange Act of 1934, as amended.

<sup>\*</sup> Furnished herewith and not "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

## SIGNATURE

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.

Vical Incorporated

Date: November 4, 2011

By: /s/ JILL M. BROADFOOT

Jill M. Broadfoot
Senior Vice President, Chief Financial Officer and
Secretary (on behalf of the registrant and as the registrant's Principal Financial and Accounting Officer)

\*\*\* Text Omitted and Filed Separately Pursuant to a Confidential Treatment Request under 17 C.F.R. §§ 200.80(b)(4) and 240.24b-2(b)(1)

#### U.S. LICENSE AGREEMENT

THIS U.S. LICENSE AGREEMENT (the "Agreement") is entered into as of the Effective Date (as defined below) by and between VICAL INCORPORATED, a Delaware corporation ("Vical"), having an address of 10390 Pacific Center Court, San Diego, California, 92121, USA, and ASTELLAS PHARMA INC., a company organized under the laws of Japan ("Astellas"), having an address of 3-11, Nihonbashi-Honcho 2-chome, Chuo-Ku, Tokyo 103-8411, Japan.

#### RECITALS

WHEREAS, Vical has developed expertise and owns proprietary rights related to Compounds and Products in the Field (each as defined below), as more fully described below;

WHEREAS, Astellas is engaged in the research, development and commercialization of pharmaceutical products; and

WHEREAS, Astellas wishes to obtain, and Vical is willing to grant to Astellas, an exclusive license under Vical Technology (as defined below) to develop and commercialize Products in the Field in the Territory (as defined below), subject to the terms and conditions set forth herein.

#### AGREEMENT

Now, THEREFORE, in consideration of the foregoing premises and the mutual covenants contained herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties agree as follows:

#### 1. DEFINITIONS

- 1.1 "Affiliate" shall mean, with respect to a particular party, a person, corporation, partnership, or other entity that controls, is controlled by or is under common control with such party. For the purposes of this definition, 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 or cause the direction of the management and policies of such entity, whether by the ownership of more than fifty percent (50%) of the voting stock of such entity, or by contract or otherwise.
  - 1.2 "Astellas Indemnitee" shall have the meaning provided in Section 11.1.
  - 1.3 "Astellas Reserved Product" shall have the meaning provided in Section 3.5(b).
- **1.4** "BLA" shall mean a Biologics License Application as described in Title 21 of the U.S. Code of Federal Regulations, Part 601, et seq., that is filed with the FDA in order to gain the FDA's approval to commercialize a biologic pharmaceutical product in the Territory.
  - 1.5 "Calendar Quarter" shall mean each respective period of three consecutive months ending on March 31, June 30, September 30 and December 31.

- 1.6 "Calendar Year" shall mean each respective period of twelve (12) consecutive months beginning on January 1.
- 1.7 "City of Hope" shall mean City of Hope, a California nonprofit public benefit corporation located at 1500 East Duarte Road, Duarte, California 91010, USA.
- 1.8 "City of Hope Agreement" shall mean that certain Exclusive License Agreement, dated February 3, 2003, by and between Vical and City of Hope concerning [...\*\*\*...], and any amendments made in accordance with its terms. A copy of the City of Hope Agreement has been provided to Astellas under separate cover.
  - 1.9 "CMC" shall mean chemistry, manufacturing and controls.
  - 1.10 "CMV" shall mean cytomegalovirus.
- 1.11 "Combination Product" shall mean any pharmaceutical product that contains one or more Compound(s) in combination with one or more other therapeutically and/or prophylactically active ingredient(s), whether packaged together or included in a prime-boost regimen or in the same therapeutic formulation, including, in each case, all formulations, line extensions and modes of administration, but excluding, in each case, any formulation with the Vaxfectin Adjuvant. For clarification, poloxamers, other delivery systems and adjuvants shall not be considered therapeutically and/or prophylactically active ingredients.
  - **1.12 "Commercialization Plan"** shall have the meaning provided in Section 4.2.
- 1.13 "Commercially Reasonable Efforts" shall mean that level of efforts and resources consistent with commercially reasonable practices of a company in the pharmaceutical industry with respect to the research, development or commercialization of a pharmaceutical product at a similar stage of research, development or commercialization, taking into account relevant factors including, without limitation, measures of patent coverage, relative safety and efficacy, product profile, the competitiveness of the marketplace, the proprietary position of such product, the regulatory structure involved, the market potential of such product and other relevant factors, including comparative technical, legal, scientific and/or medical factors, all as measured by the facts and circumstances in effect at the time when the carrying out of such obligations is due.
  - 1.14 "Committees" shall mean the JDC and JSC, collectively, and "Committee" shall mean the JDC or JSC, as applicable.
  - 1.15 "Competitive Product" shall have the meaning provided in Section 3.5(c).
  - 1.16 "Compound" shall mean [...\*\*\*...] plasmid that encodes [...\*\*\*...] of glycoprotein B and/or phosphoprotein 65 [...\*\*\*...]
- 1.17 "Confidential Information" shall mean all Information and other proprietary scientific, marketing, financial or commercial information or data, which one party or any of its Affiliates has furnished or otherwise made available to the other party or its Affiliates, whether

made available orally, in writing, or in electronic form. Confidential Information shall include all such information provided or made available pursuant to the Confidentiality Agreement. All Vical Technology shall be Confidential Information of Vical. All Confidential Information shall be subject to the Article 9.

- **1.18 "Confidentiality Agreement"** shall mean that certain Confidentiality Agreement [...\*\*\*...].
- 1.19 "Control" shall mean, with respect to any Information, Patent or other intellectual property right, possession by a party of the ability (whether by ownership, license or otherwise, but without taking into account any rights granted by one party to the other party under the terms of this Agreement) to grant access, a right to use, a license, or a sublicense (as applicable) to such Information, Patent or other intellectual property right without violating the terms of any agreement or other arrangement with any Third Party.
  - 1.20 "CytRx" shall mean CytRx Corporation, a Delaware corporation located at 154 Technology Parkway, Technology Park/Atlanta, Norcross, GA 30092, USA.
- 1.21 "CytRx Agreement" shall mean that certain License Agreement, dated December 7, 2001, by and between Vical and CytRx, and any amendments made in accordance with its terms. A copy of the CytRx Agreement has been provided to Astellas under separate cover.
- 1.22 "Development Plan" shall mean the annual plan for preclinical and clinical development of Products in the Field, including the budget for such activities to be performed by Vical, and any amendment or modification to such plan, which plan (other than such plan agreed as of the Effective Date) is drafted by the JDC and approved by the JSC.
  - 1.23 "Effective Date" shall have the meaning provided in Section 12.15.
  - 1.24 "Excluded Claim" shall have the meaning provided in Section 12.3(c)(vi).
  - 1.25 "Excluded Product" shall have the meaning provided in Section 3.5(a).
  - **1.26** "Executives" shall have the meaning provided in Section 2.1(d).
- 1.27 "Existing IND" shall mean the existing Investigational New Drug Application (including any amendments thereto) for Product in the Field in the Territory, as filed by Vical with the FDA pursuant to 21 C.F.R. §312 and Controlled by Vical on the Effective Date.
- 1.28 "Ex-U.S. Agreement" shall mean that certain Ex-U.S. License Agreement of even date herewith by and between Vical and Astellas, as amended in accordance with its terms.
- 1.29 "FDA" shall mean the United States Food and Drug Administration, or any successor agency thereto having the administrative authority to regulate the marketing of human pharmaceutical products or biological therapeutic products in the Territory.

- 1.30 "Field" shall mean all therapeutic and prophylactic use to control or prevent CMV infection in (a) Immunocompromised Patients, including HSCT Recipients and SOT Recipients, and (b) human transplant donors, but excluding, in each case, any therapeutic or prophylactic use to control or prevent CMV infection other than as expressly described in clauses (a) and (b).
- 1.31 "First Commercial Sale" shall mean, with respect to a Product, the first sale for end use to a Third Party in the Territory after the Regulatory Authority has granted Regulatory Approval in the Territory.
- 1.32 "FTE" shall mean the equivalent of the work time of a full-time employee or contractor of Vical or its Affiliate for a twelve (12) month period ([..\*\*\*...]) based on [...\*\*\*...] ([...\*\*\*...]) hours worked per 12-month period.
- 1.33 "Generic Product" shall mean a product that is introduced in the Territory by an entity other than Astellas or a Sublicensee or their respective Affiliates, which contains the same or equivalent (by FDA standards) therapeutically and/or prophylactically active ingredient(s) and is approved in reliance, in whole or in part, on a prior Regulatory Approval of a Product by the FDA.
  - 1.34 "HSCT" shall mean transplantation of hematopoietic stem cells, including peripheral blood stem cells, cord blood stem cells and bone marrow.
  - 1.35 "HSCT Recipient" shall mean a human recipient in a HSCT.
  - 1.36 "HSCT Study" shall have the meaning set forth in Section 5.1.
  - 1.37 "HSR Act" shall have the meaning provided in Section 12.15.
  - 1.38 "HSR Filing Date" shall have the meaning provided in Section 12.15.
  - 1.39 "ICC" shall have the meaning set forth in Section 12.3(c)(i).
  - 1.40 "ICC Rules" shall have the meaning set forth in Section 12.3(c)(i).
  - 1.41 "IFRS" shall mean the International Financial Reporting Standards.
- 1.42 "Immunocompromised Patients" shall mean human patients whose immune system is not functioning normally because of an immunodeficiency disorder or other disease, or as the result of the administration of immunosuppressive drugs or other drugs that may indirectly cause a reduction of the immune system function. For the avoidance of doubt, elderly patients and pregnant women shall not be deemed Immunocompromised Patients solely because such patients are elderly or pregnant, respectively.
- 1.43 "Information" shall mean all tangible and intangible (a) techniques, technology, practices, trade secrets, inventions (whether patentable or not), methods, protocols, processes, knowledge, know-how, skill, experience, information, data and results (including

pharmacological, toxicological, clinical, analytical and quality control data and results), regulatory filings, marketing reports, software and algorithms and (b) compositions of matter, cells, cell lines, assays, animal models and physical, biological or chemical material.

- **1.44** "[...\*\*\*...]" shall have the meaning set forth in Section [...\*\*\*...].
- 1.45 "JDC" shall have the meaning set forth in Section 2.2.
- 1.46 "JSC" shall have the meaning set forth in Section 2.1.
- 1.47 "Losses" shall have the meaning provided in Section 11.1.
- 1.48 "[...\*\*\*...]" shall have the meaning set forth in Section [...\*\*\*...].
- 1.49 "Manufacturing Coordinators" shall have the meaning set forth in Section 2.7.
- 1.50 "Manufacturing Plan" shall mean (a) the annual plan for (i) CMC activities (including, without limitation, formulation, analytical and process development, and scale-up, stability, packaging and shipping studies) with respect to Compound and Products in the Field and (ii) the manufacture of Compound and Products in the Field and (b) any amendment or modification to such plan, which plan (other than such plan agreed as of the Effective Date) is drafted by the Manufacturing Coordinators and approved by the JSC during the term of the Services Agreement.
- 1.51 "Net Sales" shall mean the gross amounts invoiced by Astellas and/or its Sublicensees for sales or other dispositions of Products to Third Parties in the Territory, less the following items, as allocable to such Products (if not previously deducted from the amount invoiced): (a) trade, quantity and cash discounts, credits or allowances; (b) credits or allowances additionally granted upon returns, rejections or recalls or for retroactive price reductions and billing errors; (c) rebates, discounts and chargeback payments in any form granted to managed health care organizations, pharmacy benefit managers (or equivalents thereof), national, state/provincial, local, and other governments, their agencies and purchasers and reimbursers, or to trade customers; (d) freight, shipping and insurance charges directly related to the distribution of Products; and (e) taxes, duties or other governmental tariffs (other than income taxes).

Upon any sale or other disposition of any Product for any consideration other than exclusively monetary consideration on bona fide arm's-length terms, for purposes of calculating Net Sales under this Agreement, such Product shall be deemed to be sold exclusively for money at the average sales price during the applicable reporting period generally achieved for such Product when such Product is sold alone and not as part of a Combination Product.

In no event will any particular amount, identified above, be deducted more than once in calculating Net Sales. Sales of a Product between Astellas and its Sublicensees for resale shall be excluded from the computation of Net Sales, but the subsequent resale of such Product to a Third Party shall be included within the computation of Net Sales. Any free-of-charge disposal or use of a Product for development, regulatory or marketing purposes, such as clinical trials,

compassionate use or indigent patient programs, shall not be deemed a sale or disposition for purposes of calculating Net Sales.

In the case of a Combination Product, Net Sales for such Combination Product shall be calculated by multiplying actual Net Sales of such Combination Product by the fraction A/(A+B) where A is the invoice price of the Product that contains one or more Compound(s) as the sole active ingredient(s), if sold separately, and B is the total invoice price of the other active ingredient(s) in the Combination Product is not sold separately in the Territory, Net Sales for the purpose of determining royalties of the Combination Product shall be calculated by multiplying actual Net Sales of such Combination Product by the fraction A/D, where A is the average invoice price of the Product that contains one or more Compound(s) as the sole active ingredient(s), if sold separately in such country, and D is the average invoice price of the Combination Product in such country. If the Product that contains one or more Compound(s) as the sole active ingredient(s) is not sold separately in the Territory, the parties shall determine Net Sales for such Combination Product by mutual agreement based on the relative contribution of the Product that contains one or more Compound(s) as the sole active ingredient(s) in the Combination Product.

Net Sales will be calculated in accordance with this definition and Astellas' accounting policies generally consistent with IFRS on an accrual basis, as consistently applied. To the extent any accrued amounts used in the calculation of Net Sales are estimates, such estimates shall be trued-up in accordance with Astellas' accounting policies generally consistent with IFRS, as consistently applied, and Net Sales and related payments under this Agreement shall be reconciled as appropriate.

- 1.52 "Option" shall have the meaning provided in Section 4.3.
- 1.53 "Patent Term Extension" shall have the meaning provided in Section 7.3.
- 1.54 "Patents" shall mean (a) all patents, including design patents, certificates of invention, applications for certificates of invention, priority patent filings and patent applications, including provisional patent applications and design patent applications, and (b) any renewal, divisional, continuation, continuation-in-part, or request for continued examination of any of such patents, certificates of invention and patent applications, and any and all patents or certificates of invention issuing thereon, and any and all reissues, reexaminations, extensions, certificates of correction, divisions, renewals, substitutions, confirmations, registrations, revalidations, revisions, and additions of or to any of the foregoing.
- 1.55 "Phase 3 Clinical Trial" shall mean a pivotal clinical trial of a Product conducted in human patients in any country designed to ascertain efficacy and safety of such Product for the purpose of submitting an application for Regulatory Approval to the competent Regulatory Authority in the Territory, including any human clinical trial that would satisfy the requirements for a Phase 3 study as defined in 21 C.F.R. 312.21(c) or its successor regulation.

**1.56** "[...\*\*\*...]" shall have the meaning set forth in Section [...\*\*\*...].

- 1.57 "Product" shall mean any pharmaceutical product that contains one or more Compound(s), alone or as a Combination Product, including, in each case, all formulations, line extensions and modes of administration, including any pharmaceutical product containing any formulation of one or more Compound(s) with poloxamer CRL1005, but excluding, in each case, any formulation with the Vaxfectin Adjuvant.
- 1.58 "Regulatory Approval" shall mean any and all approvals (including individual and national price and reimbursement approvals, as applicable), licenses, registrations, or authorizations of any country, federal, supranational, state or local regulatory agency, department, bureau or other governmental entity that are necessary to market and sell a Product in the Field in the Territory.
- 1.59 "Regulatory Authority" shall mean any national, federal, supra-national, regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity whose review and/or approval is necessary for the manufacture, packaging, use, storage, import, export, distribution, promotion, marketing, offer for sale and sale of a Product in the Field in the Territory.
  - 1.60 "Representatives" shall have the meaning provided in Section 12.1.
  - 1.61 "Reserved Product" shall have the meaning provided in Section 3.5(b).
  - 1.62 "Restricted Period" shall have the meaning provided in Section 3.5(c).
  - 1.63 "Royalty Term" shall have the meaning provided in Section 5.3(b).
  - 1.64 "Sale" shall have the meaning provided in Section 12.7(a).
- 1.65 "Services Agreement" shall mean that certain Supply and Services Agreement of even date herewith by and between Vical and Astellas, as amended in accordance with its terms.
  - 1.66 "SOT" shall mean solid organ transplantation.
  - 1.67 "SOT Recipient" shall mean a human recipient in a SOT.
  - 1.68 "SPA" shall have the meaning set forth in Section 5.1.
  - **1.69 "Standstill Period"** shall have the meaning provided in Section 12.1.
  - **1.70** "[...\*\*\*...]" shall have the meaning set forth in Section [...\*\*\*...].
  - 1.71 "Sublicense Agreement" shall have the meaning provided in Section 3.2.
- 1.72 "Sublicensee" shall mean a Third Party or Affiliate to whom Astellas has granted a sublicense of the right to research, develop, make, have made, use, sell, offer for sale, have sold or import a Product in the Field in the Territory, beyond the mere right to purchase such Product.
  - 1.73 "Term" shall have the meaning provided in Section 10.1.

- 1.74 "Territory" shall mean the United States of America and its territories and possessions, including Puerto Rico and the District of Columbia.
- 1.75 "Third Party" shall mean any entity other than Vical or Astellas or an Affiliate of Vical or Astellas.
- 1.76 "Valid Claim" shall mean a claim of an issued patent or pending patent application within the Vical Primary Patents that has not been revoked or held unenforceable or invalid by a decision of a court or governmental agency of competent jurisdiction from which no appeal can be taken, or with respect to which an appeal is not taken within the time allowed for appeal, and that has not been abandoned, disclaimed or admitted to be invalid or unenforceable through reissue, disclaimer, or otherwise.
- 1.77 "Vaxfectin Adjuvant" shall mean Vical's proprietary cationic lipid-based system known as Vaxfectin® comprising (±)-N-(3-aminopropyl)-N,N-dimethyl-2,3-bis(syn-9-tetradeceneyloxy)-1-propanaminium bromide (GAP-DMORIE) or derivatives thereof and one or more co-lipid(s), including 1,2-diphytanoyl-sn-glycero-3-phosphoethanolamine (DPyPE), which is claimed or disclosed in a Patent Controlled by Vical.
  - 1.78 "Vical Indemnitee" shall have the meaning provided in Section 11.2.
- 1.79 "Vical Know-How" shall mean Information not included in the Vical Patents that Vical Controls on the Effective Date or during the Term, which Information is necessary or useful for the development, registration, manufacture, use, promotion, distribution, offer for sale, sale, import or export of Compounds or Products in the Field in the Territory, including any Information Controlled by Vical regarding poloxamer CRL1005 under which Vical has an exclusive license pursuant to the CytRx Agreement, and any replication or any part of any of the foregoing. For clarification, in the case of a Combination Product, Vical Know-How does not include any Information Controlled by Vical relating to any therapeutically and/or prophylactically active ingredient in such Combination Product other than a Compound.
- 1.80 "Vical Patents" shall mean all Patents that Vical Controls as of the Effective Date or during the Term, which Patents claim the composition of matter of, or any method of making or using, Compounds or Products in the Field in the Territory, including the Vical Primary Patents, but excluding [...\*\*\*...]. For clarification, in the case of a Combination Product, Vical Patents do not include any Patents Controlled by Vical, which Patents relate to any therapeutically and/or prophylactically active ingredient in such Combination Product other than a Compound. The Vical Patents as of the Effective Date are listed on EXHIBIT A.
- 1.81 "Vical Primary Patents" shall mean (a) [...\*\*\*...], and such other Vical Patents as the parties agree to include in this subsection (a) pursuant to the last sentence of this Section 1.81, and (b) any renewal, divisional, continuation, continuation-in-part, or request for continued examination of any of such patents, including provisional patent applications, and any and all patents or certificates of invention issuing thereon, and any and all reissues, reexaminations, extensions, certificates of correction, divisions, renewals, substitutions, confirmations, registrations, revalidations, revisions, and additions of or

to any of the foregoing. Without limiting the foregoing, if at any time during the Term the parties mutually agree in writing that any Vical Patent other than the Patents set forth above can maintain market exclusivity of a Product in the Field in the Territory, such Vical Patent shall thereafter be regarded as a Vical Primary Patent and shall automatically be included in Section 1.81(a) above. For clarity, if the parties cannot mutually agree regarding whether any other Vical Patent shall be included as a Vical Primary Patent, such disagreement shall not be subject to arbitration as set forth in Section 12.3(c) and such Vical Patent shall not be a Vical Primary Patent.

- 1.82 "Vical Reserved Product" shall have the meaning provided in Section 3.5(b).
- **1.83** "Vical Retained Product" shall have the meaning provided in Section 3.5(a).
- 1.84 "Vical Technology" shall mean the Vical Patents and Vical Know-How.
- 1.85 "Withdrawal Notice" shall have the meaning provided in Section 2.6.

#### 2. GOVERNANCE

- **2.1 Joint Steering Committee.** For purposes of this Agreement and the Ex-U.S. Agreement, the parties will establish one joint steering committee (the 'JSC') to oversee the activities of the parties with respect to development, regulatory, manufacturing and commercialization matters relating to Products in the Field.
- (a) Composition. The JSC will be comprised of three (3) members appointed by Astellas and three (3) members appointed by Vical, or such other equal number of members of each party agreed by Astellas and Vical. Each party will notify the other party of its initial JSC members within thirty (30) days after the Effective Date. Each party may change its JSC members at any time by written notice to the other party, which may be delivered at a scheduled meeting of the JSC. Any member of the JSC may designate a substitute to attend and perform the functions of that member at any meeting of the JSC. The JSC shall appoint for each meeting a Vical member or an Astellas member, on an alternating basis, as chairman for such meeting, whose role shall be to (i) provide written notice to the JSC members of agenda items proposed for discussion or decision at such meeting at least ten (10) days prior to such JSC meeting, together with appropriate information related thereto, and (ii) convene and preside at such meeting of the JSC; provided, however, that the chairman shall not be entitled to prevent items from being discussed or to cast any tie-breaking vote. Each party may, with the consent of the other party, such consent not to be unreasonably withheld or delayed, invite non-member, non-voting representatives of such party to attend meetings of the JSC.
- (b) Responsibilities. The JSC shall be responsible for monitoring and providing strategic oversight of the parties' activities with respect to development, regulatory, manufacturing and commercialization matters relating to Products in the Field. Without limiting the foregoing, the JSC shall:

(i) review and approve the Development Plan and the Manufacturing Plan (including any amendments thereto);

- (ii) review (but not approve) the Commercialization Plan (including any amendments thereto);
- (iii) provide a forum in which Astellas updates Vical, and Vical provides input, with regard to development, regulatory, manufacturing and commercialization matters relating to Products in the Field;
- (iv) facilitate the exchange of data and other Information between the parties with regard to development, regulatory, manufacturing and commercialization matters relating to Products in the Field; and
  - (v) perform such other duties as are specifically assigned by the parties to the JSC in this Agreement or any other written agreement between the parties.
- (c) Meetings. The JSC will hold meetings at such frequency as determined by the JSC members, but no less than once every six (6) months. Such meetings may be in person, via videoconference, or via teleconference. The location of in-person JSC meetings will alternate between Vical's offices in San Diego, California and Astellas' offices in Deerfield, Illinois unless the parties otherwise agree.
- (d) Decision-Making. The JSC may make decisions with respect to any subject matter that is within the JSC's decision-making authority. Subject to this Section 2.1(d), all decisions of the JSC shall be made by unanimous vote, with the representatives of Vical on the JSC collectively having one vote and the representatives of Astellas on the JSC collectively having one vote in all such decisions. If the JSC cannot make a decision with regard to any matter to be decided by the JSC within fifteen (15) days after such matter has been brought to the JSC's attention, then such matter shall be referred to the Chief Executive Officer of Vical and a senior executive of Astellas who reports directly to the Chief Executive Officer of Astellas (the Chief Executive Officer of Vical and such senior executive of Astellas, collectively, the "Executives") for resolution. If the Executives cannot resolve the issue within thirty (30) days after the matter has been brought to their attention then, subject to good faith consideration of the views of Vical, and subject to Section 2.4, Astellas' Executive shall have the tie-breaking vote on such matter.
- 2.2 Joint Development Committee. For purposes of this Agreement and the Ex-U.S. Agreement, the parties will establish one joint development committee (the "JDC") with respect to development of Products in the Field.
- (a) Composition. The JDC will be comprised of three (3) members appointed by Astellas and three (3) members appointed by Vical, or such other equal number of members of each party agreed by Astellas and Vical. Each party will notify the other party of its initial JDC members within thirty (30) days after the Effective Date. Each party may change its JDC members at any time by written notice to the other party, which may be delivered at a scheduled meeting of the JDC. Any member of the JDC may designate a substitute to attend and perform the functions of that member at any meeting of the JDC. The JDC shall appoint for each meeting a Vical member or an Astellas member, on an alternating basis, as chairman for such meeting, whose role shall be to (i) provide written notice to the JDC members of agenda items

proposed for discussion or decision at such meeting at least ten (10) days prior to such JDC meeting, together with appropriate information related thereto, and (ii) convene and preside at such meeting of the JDC; provided, however, that the chairman shall not be entitled to prevent items from being discussed or to cast any tie-breaking vote. Each party may, with the consent of the other party, such consent not to be unreasonably withheld or delayed, invite non-member, non-voting representatives of such party to attend meetings of the JDC.

- **(b) Responsibilities.** The JDC shall be responsible for oversight of the progress of the parties' activities with respect to development of Compounds and Products in the Field. Without limiting the foregoing, the JDC shall:
- (i) draft the Development Plan (including any amendments thereto) for approval by the JSC, and provide a forum for review and discussion of the Development Plan;
  - (ii) provide a forum for review and discussion of the results of the development of Compounds and Products in the Field;
  - (iii) facilitate the exchange of Information between the parties regarding the development of Compounds and Products in the Field; and
  - (iv) perform such other duties as are specifically assigned by the JSC to the JDC.
- (c) Meetings. The JDC will hold meetings at such frequency as determined by the JDC members, but no less than once each Calendar Quarter. Such meetings may be in person, via videoconference, or via teleconference. The location of in-person JDC meetings will alternate between Vical's offices in San Diego, California and Astellas' offices in Deerfield, Illinois unless the parties otherwise agree.
- (d) Decision-Making. The JDC may make decisions with respect to any subject matter that is within the JDC's decision-making authority. Subject to this Section 2.2(d), all decisions of the JDC shall be made by unanimous vote, with the representatives of Vical on the JDC collectively having one vote and the representatives of Astellas on the JDC collectively having one vote in all such decisions. If the JDC cannot make a decision with regard to any matter to be decided by the JDC within fifteen (15) days after such matter has been brought to the JDC's attention, then such matter shall be referred to the JSC for resolution in accordance with Section 2.1(d).
- 2.3 Minutes. Reasonably detailed written minutes will be kept of all Committee meetings and will reflect material decisions made at such meetings. Minutes for each meeting of each Committee will be prepared by the chairman of such meeting and such minutes shall be sent to each member of the respective Committee for review and approval within ten (10) days after the meeting. Minutes will be deemed approved unless a member of the respective Committee objects to the accuracy of such minutes within fifteen (15) days of receipt.
- 2.4 Scope of Decision-Making. Neither Committee nor any Executive in the course of resolving any dispute of the JSC shall have any right or power to amend this Agreement, to

decide any matter in contravention of any terms of this Agreement or to change any rights or obligations of either party under this Agreement. Without limiting the foregoing, neither Committee nor any Executive in the course of resolving any dispute of the JSC shall have the right or power to (a) require Vical to perform studies or other development work that is not expressly agreed in writing by Vical and Astellas, or (b) require Vical to incur expenses other than as set forth in this Agreement or otherwise expressly agreed in writing by Vical and Astellas.

- 2.5 Expenses. Each party shall bear all its own costs in connection with its participation in the Committees, including expenses incurred by the members that it appoints to the Committees in connection with their activities as members of the Committees.
- 2.6 Withdrawal. At any time during the Term and for any reason, Vical shall have the right to withdraw from participation in either Committee or both Committees upon written notice to Astellas, which notice shall be effective immediately upon receipt ("Withdrawal Notice"). Following the issuance of a Withdrawal Notice and subject to this Section 2.6, Vical's representatives on the applicable Committee(s) shall not participate in any meetings of the applicable Committee(s), nor shall Vical have any right to vote on decisions within the authority of the applicable Committee(s). If, at any time, following the issuance of a Withdrawal Notice, Vical wishes to resume participation in the applicable Committee(s), Vical shall notify Astellas in writing and, thereafter, Vical's representatives on the applicable Committee(s) shall be entitled to attend any subsequent meeting of the applicable Committee(s) as if a Withdrawal Notice had not been issued by Vical. Following Vical's issuance of a Withdrawal Notice, unless and until Vical resumes participation in the applicable Committee(s) in accordance with this Section 2.6: (a) all meetings of the Committee(s) shall be held at Astellas' facilities; (b) Astellas shall have the right to make the final decision on all matters within the scope of authority of the Committee(s); and (c) Vical shall have the right to continue to receive the minutes of the Committee(s) meetings, but shall not have the right to approve the minutes for any meeting of the applicable Committee(s) held after Vical's issuance of a Withdrawal Notice. For clarity, if Vical withdraws and then resumes participation in a Committee, it shall not have any right to retroactively review or modify any decision made by the Committee during Vical's withdrawal period.
- 2.7 Manufacturing Coordinators. Promptly after the Effective Date, each party shall appoint an individual to act as the manufacturing coordinator for such party (the "Manufacturing Coordinator"). The Manufacturing Coordinators shall be the primary contacts of the parties regarding the manufacture of Compounds and Products in the Field (including CMC activities such as formulation, analytical and process development, and scale-up, stability, packaging and shipping studies), draft the Manufacturing Plan (including any amendments thereto) for approval by the JSC and otherwise facilitate the exchange of Information between the parties regarding the manufacture of Compounds and Products in the Field. The Manufacturing Coordinators will meet at such frequency as determined by the Manufacturing Coordinators, but no less than once every six (6) months. Each Manufacturing Coordinator shall be permitted to attend meetings of the JSC as non-voting participants. Each party may replace its Manufacturing Coordinator with an alternative representative at any time with prior written notice to the other party.

### 3. LICENSES AND OTHER RIGHTS

- 3.1 License and Sublicense Grant. Subject to the terms and conditions of this Agreement, Vical hereby grants to Astellas an exclusive (even as to Vical and its Affiliates, but subject to the Option, to Vical's performance of such development, regulatory and manufacturing activities as agreed in writing by the parties), royalty-bearing license and sublicense, with the right to sublicense in accordance with Section 3.2, under the Vical Technology, to research, develop, register, make, have made, use, promote, distribute, sell, offer for sale, have sold, import and export Products in the Field in the Territory; provided that the sublicense with respect to any Vical Patents licensed to Vical under the City of Hope Agreement shall be non-exclusive.
- 3.2 Sublicensing. Astellas shall have the right to grant sublicenses under the license granted in Section 3.1 to one or more Third Parties or Affiliates subject to the provisions of this Section 3.2. Each agreement under which Astellas grants a sublicense under the license granted in Section 3.1 (each, a "Sublicense Agreement") shall (a) be in writing and (b) be consistent with, and subject to the terms and conditions of, this Agreement (including the terms relating to sublicenses of Vical Technology licensed or conveyed to Vical under the City of Hope Agreement and CytRx Agreement, as applicable). Astellas acknowledges and agrees that the right to grant sublicenses under the rights granted to Vical with respect to Vical Technology licensed or otherwise conveyed to Vical under the City of Hope Agreement is limited to sublicenses granted to Astellas' Affiliate(s) (for so long as each Affiliate sublicensee remains an Affiliate) and such Affiliate sublicensees shall not have the right to grant further sublicenses to any Third Party. Astellas shall be responsible for compliance of any Sublicensee with this Agreement. Any breach of this Agreement by the acts or omissions of a Sublicensee shall be a breach of this Agreement by Astellas. Astellas shall provide Vical with a full and complete copy of each Sublicense Agreement with a Third Party (and if required by the CytRx Agreement and/or the City of Hope Agreement, each Sublicense Agreement with an Affiliate) within [...\*\*\*...] ([...\*\*\*...]) days after execution thereof; provided, that Astellas may redact any confidential information contained therein that is not necessary to disclose to ensure compliance with this Agreement.
- 3.3 In-License Agreements. Astellas acknowledges that the Vical Technology licensed or otherwise conveyed to Vical under the City of Hope Agreement or the CytRx Agreement is subject to the applicable terms and conditions of the City of Hope Agreement or the CytRx Agreement. In the event that City of Hope or CytRx notifies Vical of a default or breach under the City of Hope Agreement or the CytRx Agreement, respectively, related to any failure by Astellas or any Sublicensee to perform any obligation or covenant under this Agreement, the parties will discuss how to resolve the matter and, if the parties agree to a proposed resolution of the matter, they will cooperate in responding to City of Hope or CytRx, as applicable. If Astellas does not resolve such matter as agreed by the parties, or if the parties do not agree to a resolution of the matter, then Vical shall have the right, but not the obligation, to take such actions as reasonably necessary or appropriate to cure such default or breach and shall keep Astellas reasonably informed regarding such actions, and Astellas shall promptly reimburse Vical for all reasonable costs and expenses actually incurred by Vical solely as a result of such default or breach by Astellas or any Sublicensee. In the event Vical receives from CytRx or City of Hope notice of termination of the CytRx Agreement or the City of Hope Agreement,

respectively, Vical shall notify Astellas thereof within [...\*\*\*...] ([...\*\*\*...]) days after receipt by Vical of such notice. Vical shall have no liability to Astellas for any termination or modification of the City of Hope Agreement or the CytRx Agreement arising out of or resulting from the failure of Astellas or any Sublicensee to abide by, comply with or perform under the terms, conditions or obligations of this Agreement. In addition, in the event the rights to the Vical Technology licensed to Vical under the CytRx Agreement cease to be licensed to Vical under the CytRx Agreement and Astellas obtains a license with respect to such Vical Technology directly from CytRx, then Astellas may deduct from the applicable payments owed to Vical hereunder the amount actually paid by Astellas to CytRx for such license with respect to such Vical Technology up to the amount that Vical would have been obligated to pay to CytRx under the CytRx Agreement with respect to such payment.

3.4 Disclosure of Vical Know-How. Upon Astellas' request, Vical shall make available to Astellas Vical Know-How in Vical's possession that has not previously been provided to Astellas, including any raw data and/or original data relating to Compounds and Products in the Field; provided that any Vical Know-How relating to the manufacture of Compounds and Products in the Field shall be made available through a technology transfer arrangement as provided in the Services Agreement. Vical shall not destroy, discard or otherwise dispose of or shall have not destroyed, discarded or otherwise disposed of any Vical Know-How without prior written approval of Astellas, which approval shall not be unreasonably withheld.

# 3.5 Agreements.

(a) By Vical. During the Term, Vical shall not, directly or indirectly through any Affiliate or Third Party, market, promote, distribute, offer for sale or sell, or grant any license or sublicense under the Vical Technology to market, promote, distribute, offer for sale or sell, (i) any Product that contains any formulation of one or more Compound(s) with poloxamer CRL1005 (an "Excluded Product") outside the Field in the Territory or (ii) any pharmaceutical product that contains any formulation of one or more Compound(s) with the Vaxfectin Adjuvant, alone or in combination with one or more other therapeutically and/or prophylactically active ingredients, in any dosage form or mode of administration (a "Vical Retained Product") in the Field in the Territory; provided, however, that nothing shall prevent Vical from, directly or indirectly through any Affiliate or Third Party, marketing, promoting, distributing, offering for sale or selling, or granting any license or sublicense under the Vical Technology to market, promote, distribute, offer for sale or sell, any Vical Retained Product so long as Vical or such Affiliate or Third Party does not market or promote the Vical Retained Product for use in the Field in the Territory.

(b) Reserved Products. The provisions of this Section 3.5(b) shall apply with respect to any Product other than an Excluded Product (a"Reserved Product") outside the Field in the Territory. Vical retains all rights, directly or indirectly through any Affiliate or Third Party, to research, develop, market, promote, distribute, offer for sale or sell, or grant any license or sublicense under the Vical Technology to research, develop, market, promote, distribute, offer for sale or sell, any Reserved Product outside the Field in the Territory, subject to this Section 3.5(b) (any such Reserved Product with respect to which Vical has retained rights, a "Vical Reserved Product"). Astellas may notify Vical in writing that it proposes to designate

any Reserved Product as an "Astellas Reserved Product," specifying whether such Reserved Product would contain a Compound alone, a Compound formulated with an adjuvant (identifying the adjuvant) or a Compound administered through a delivery system (identifying the delivery system). Astellas may provide such written request at any time after it or its Sublicensee has initiated good laboratory practices preclinical studies of such Reserved Product. The Reserved Product specified in such written notice from Astellas shall be deemed an Astellas Reserved Product unless Vical provides written notice to Astellas within thirty (30) days after Vical's receipt of such written notice from Astellas that Vical has granted a license or similar rights with respect to such Product to a Third Party or has initiated good laboratory practices preclinical studies of such Reserved Product, in which case such Reserved Product shall not be an Astellas Reserved Product and shall remain a Vical Reserved Product. During the Term for so long as Astellas uses Commercially Reasonable Efforts to develop, manufacture and commercialize an Astellas Reserved Product, Vical shall not, directly or indirectly through any Affiliate or Third Party, market, promote, distribute, offer for sale or sell, or grant any license or sublicense under the Vical Technology to market, promote, distribute, offer for sale or sell, such Astellas Reserved Product outside the Field in the Territory.

(c) By Astellas. During the Term, Astellas shall not, directly or indirectly through any Affiliate or Third Party, market, promote, distribute, offer for sale or sell, or grant any license or sublicense to market, promote, distribute, offer for sale or sell, any DNA vaccine product for use in the Field in the Territory, other than Products in the Field in the Territory (a "Competitive Product"). Further, Astellas agrees not to practice any Vical Technology except to develop, register, make, have made, use, promote, distribute, sell, offer for sale, have sold, import and export Products in the Field in the Territory during the Term in accordance with the terms of this Agreement and any other written agreement between the parties. If Astellas or any of its respective Affiliates signs a definitive agreement whereby it would acquire a license to or ownership of a Competitive Product, acquire ownership or control of or otherwise merge with an entity that owns or has a license to (or is commercializing for its own account) a Competitive Product or be acquired by or otherwise merged with an entity that owns or has a license to (or is commercializing for its own account) a Competitive Product, in all such cases that would result in a violation of this Section 3.5(c), then Astellas or its Affiliate shall promptly notify Vical in writing and, as promptly as reasonably possible but in no event later than [...\*\*\*...] ([...\*\*\*...]) months after the signing date of such definitive agreement ("Restricted Period"), either (i) divest itself of such Competitive Product and notify Vical in writing of such divesture, or (ii) notify Vical in writing that such Competitive Product shall be incorporated into this Agreement and thereafter such Competitive Product shall be a Product subject to the terms and conditions of this Agreement. If Astellas or its Affiliate elects to divest itself of such Competitive Product, such divesture shall occur by an outright sale to a Third Party of all of Astellas' and its Affiliate's rights to such Co

3.6 Retained Rights; No Implied Licenses. Except for the rights and licenses expressly granted in this Agreement, Vical retains all rights under the Vical Technology, and no rights shall be deemed granted by Vical to Astellas by implication, estoppel or otherwise.

### 4. DEVELOPMENT AND COMMERCIALIZATION OF PRODUCTS

4.1 Development of Products in the Field in the Territory. Subject to the terms and conditions of this Agreement, during the Term, Astellas shall be solely responsible for the development of and obtaining Regulatory Approvals for Products in the Field in the Territory, including all costs associated with such activities, subject to the terms of any written agreement between the parties providing for Vical to perform any such activities. Without limiting the foregoing, Astellas shall have sole responsibility, at Astellas' cost and expense, for conducting clinical and non-clinical studies of Products in the Field in the Territory and for preparing, filing, obtaining and maintaining the appropriate applications with Regulatory Authorities, and for all contacts with Regulatory Authorities, regarding Products in the Field in the Territory. Vical will transfer the Existing IND to Astellas, the timing of such transfer to be discussed in good faith by Vical and Astellas, provided, that such transfer shall be completed by the date of commencement of the first Phase 3 Clinical Trial of a Product in the Field in the Territory. Astellas shall use Commercially Reasonable Efforts to develop, and to file for, obtain and maintain Regulatory Approvals for, at least one Product [...\*\*\*...] and at least one Product [...\*\*\*...] in the Field in the Territory. Astellas shall perform all development and regulatory activities with respect to Products in the Field in the Territory in compliance with the Development Plan and all applicable laws, rules and regulations. Furthermore, Astellas shall be solely responsible for the timely reporting of all relevant adverse drug reactions/experiences, Product quality, Product complaints and safety data relating to Compounds and Products, in each case in the Field, to the appropriate Regulatory Authorities in accordance with the applicable laws, rules and regulations of the Regulatory Authorities in the Territory. Prior to commencement of the first Phase 3 Clinical Trial, Vical shall complete tra

4.2 Commercialization of Products in the Field in the Territory. Subject to the terms and conditions of this Agreement (including the Option), during the Term, Astellas shall be solely responsible for the commercialization of Products in the Field in the Territory, including any post-marketing studies of Products in the Field in the Territory, including all costs associated with such activities. Astellas shall use Commercially Reasonable Efforts to commercialize at least one Product [...\*\*\*...] and at least one Product [...\*\*\*...] in the Field in the Territory. Within a reasonable time prior to anticipated commercial launch of a Product, Astellas shall prepare a plan for the marketing, promotion and commercialization of such Product in the Field in the Territory, which plan shall be in reasonable scope and detail and may be amended by Astellas (the "Commercialization Plan"). Astellas shall provide, or cause to be provided, any material amendments to the Commercialization Plan to the JSC for review on an annual basis and shall provide, or cause to be provided, any material amendments to the Commercialization Plan to the JSC for review. Astellas shall perform all commercialization activities with respect to Products in the Field in the Territory in compliance with the Commercialization Plan and all applicable laws, rules and regulations. Without limiting the foregoing, Astellas shall have the sole right and responsibility for all commercial and medical affairs matters with respect to Products in the Field in the Territory.

- 4.3 Commercialization Option. Astellas hereby grants to Vical an exclusive option to co-promote and/or collaborate in medical affairs activities with respect to Products in the Field in the Territory (the "Option"). Vical may exercise the Option by providing written notice to Astellas no later than [..\*\*\*...] ([...\*\*\*...]) days after Astellas provides written notice to Vical of [...\*\*\*...]. For clarification, Vical shall in no event be obligated to make any payment to Astellas in connection with exercising the Option. Upon timely exercise by Vical of the Option, the parties shall engage in good faith negotiations to conclude a separate written agreement within [...\*\*\*...] ([...\*\*\*...]) days after exercise of the Option (or such longer period as agreed by the parties), which agreement would provide for mutually agreeable terms pursuant to which Vical would copromote and/or collaborate in medical affairs activities with respect to Products in the Field in the Territory in accordance with the Commercialization Plan and would provide for Astellas [...\*\*\*...], provided, however, that Vical's activities thereunder shall not exceed [...\*\*\*...] percent ([...\*\*\*...]%) of the total activities of the parties in each of the co-promotion and the medical affairs. Notwithstanding the exercise of the Option or the execution of an agreement as set forth in the immediately preceding sentence, Astellas shall at all times remain obligated to pay the applicable amounts specified under Article 5 with respect to Products.
- **4.4 Manufacture and Supply of Products.** Subject to the terms and conditions of this Agreement and the Services Agreement, during the Term, Astellas shall be solely responsible for the manufacture and supply of Products in the Field in the Territory, including CMC-related work necessary for obtaining Regulatory Approval for Products in the Field in the Territory, including all costs associated with such activities. Astellas shall perform all manufacturing activities with respect to Products in the Field in the Territory in compliance with the Manufacturing Plan and all applicable laws, rules and regulations.
- 4.5 Disclosure Regarding Astellas' Efforts. Astellas shall keep Vical regularly and fully informed regarding development, regulatory, manufacturing and commercialization activities of Astellas and its Sublicensees with respect to Products in the Field in the Territory. Without limiting the foregoing, Astellas shall keep Vical reasonably informed of the progress of such activities, through the JSC, the JDC and directly, and shall, within [...\*\*\*...] ([...\*\*\*...])[...\*\*\*...] after the end of each Calendar Year during the Term, provide Vical a report setting forth a reasonably detailed description of the progress and status of development, manufacture and commercialization of, and regulatory strategy and filings made and Regulatory Approvals obtained for, Products in the Field in the Territory, and a reasonably detailed description of the development, manufacture, commercialization and regulatory activities that Astellas plans to undertake during the subsequent Calendar Year.
- **4.6 Subcontractors.** Astellas may perform some or all of its obligations under this Article 4 through one or more subcontractors (which may include Vical). Astellas shall remain responsible for the performance by any Third Party subcontractors and the compliance of such Third Party subcontractors with the provisions of this Agreement in connection with such performance.

### 5. FEES AND PAYMENTS

- **5.1 Upfront Fee.** Astellas shall make a non-refundable, non-creditable payment to Vical of US\$[...\*\*\*...], payable as follows: (a) US\$[...\*\*\*...] shall be paid to Vical within thirty (30) days after the Effective Date; and (b) US\$[...\*\*\*...] shall be paid to Vical within thirty (30) days after the earliest of (i) agreement by the FDA in a special protocol assessment ("SPA") on a protocol with the primary endpoint of [...\*\*\*...] for a Phase 3 Clinical Trial of a Product for use in HSCT Recipients in the Field (aft'HSCT Study"), (ii) agreement by Astellas and Vical to go forward with an HSCT Study without a SPA or (iii) initiation (enrollment of first patient) of an HSCT Study.
- **5.2 Milestone Payments.** Within thirty (30) days after the occurrence of each of the following milestone events, Astellas shall pay to Vical the corresponding non-refundable, non-creditable milestone payment set forth below (whether such milestone event is achieved by Astellas or any Sublicensee):

Milestone Event	Milestone Payment
[***]	US\$ [***]
[***]	
[***]	US\$ [***]

[...\*\*\*...]
[...\*\*\*...]
US\$[...\*\*\*...]

[...\*\*\*...]

[...\*\*\*...]

[...\*\*\*...]

Each of the milestone payments described in this Section 5.2 shall be payable one time for the first achievement of such milestone event by any applicable Product, regardless of the number of

other Products that subsequently achieve such milestone event. For clarification, in the event two or more milestone events are achieved at the same time, the milestone payments for both milestone events shall be due.

### 5.3 Royalties.

- (a) Royalty Rate. Astellas shall pay Vical royalties equal to [...\*\*\*...] percent ([...\*\*\*...]%) of Net Sales of Products in the Field in the Territory.
- **(b) Royalty Term.** Royalties under this Section 5.3 shall be payable on a Product-by-Product basis during the period of time commencing on the First Commercial Sale of such Product in the Territory and ending upon the latest to occur of (i) expiration of the last to expire Valid Claim with respect to such Product (or any Compound therein), (ii) expiration of any data or other regulatory exclusivity period for such Product in the Territory or (iii) ten (10) years after the earliest date of First Commercial Sale of such Product for any indication in the Field in the Territory (the "Royalty Term").
- (c) Royalty Reduction. During any portion of the Royalty Term for a Product in which (i) there is no Valid Claim with respect to such Product (or any Compound therein), (ii) a Generic Product(s) is marketed in the Territory, and (iii) unit share of the Generic Product(s) in the Territory are equal to or greater than [...\*\*\*...] percent ([...\*\*\*...]%) of total unit number of such Product and the Generic Product(s) sold in the Territory for at least [...\*\*\*...] ([...\*\*\*...])[...\*\*\*...] Calendar Quarters, the royalty rate payable under Section 5.3(a) on Net Sales of such Product in the Territory during such portion of the Royalty Term shall be reduced by [...\*\*\*...] percent ([...\*\*\*...]%) (i.e., from [...\*\*\*...]% to [...\*\*\*...]%); provided, however, that during any such portion of the Royalty Term for such Product that Vical owes royalties on Net Sales of such Product in the Territory under both of the City of Hope Agreement and the CytRx Agreement, the royalty rate payable under Section 5.3(a) on Net Sales of such Product in the Territory during such portion of the Royalty Term shall instead be reduced to [...\*\*\*...] percent ([...\*\*\*...]%).
- **5.4 Payments to Third Parties.** Vical shall be responsible for any fees, milestone and royalty payments owed to City of Hope and CytRx under the City of Hope Agreement and CytRx Agreement, respectively. Except as provided in the preceding sentence, Astellas (or its Sublicensee) shall be responsible for any and all payments owed to any Third Party for any Patents, Information or other intellectual property rights licensed or acquired by Astellas (or its Sublicensee) after the Effective Date in order to develop, make, have made, use, promote, distribute, sell, offer for sale, have sold or import any Product in the Field in the Territory (it being understood that the decision to license or acquire any such Patents, Information or other intellectual property rights shall be at Astellas' (or its Sublicensee's) discretion).

### 6. PAYMENT; RECORDS; AUDITS

**6.1 Payment; Reports.** All payments due under this Agreement shall be paid within [...\*\*\*...] ([...\*\*\*...]) days of the end of each Calendar Quarter, unless otherwise specifically provided herein. Royalty payments shall be calculated and reported for each Calendar Quarter. Each royalty payment due to Vical shall be accompanied by a report of Net Sales by Astellas and its Sublicensees, each in sufficient detail to permit confirmation of the accuracy of the payment

made, including, without limitation and on a country-by-country basis, the number of Products sold, the gross sales with reconciliation to Net Sales of such Products, the royalties payable, the method used to calculate the royalties, and the exchange rates used.

- **6.2 Exchange Rate; Manner and Place of Payment.** All payments hereunder shall be payable in U.S. dollars. When conversion of payments from any foreign currency is required, such conversion shall be at an exchange rate equal to the weighted average of the rates of exchange (i.e. the average of TTS rate and TTB rate) for the currency of the country from which the royalties are payable as published by the Bank of Tokyo Mitsubishi UFJ, Ltd. in Japan (or such other bank or source agreed in writing by the parties), during the Calendar Quarter for which a payment is due. All payments owed under this Agreement shall be made by wire transfer in immediately available funds to a bank account designated in writing by Vical, unless otherwise specified in writing by Vical.
- **6.3 Income Tax Withholding.** Each party will pay any and all taxes levied on account of any payments made to it under this Agreement. If any taxes are required to be withheld by the paying party, the paying party will (a) deduct such taxes from the payment made to the other party, (b) timely pay the taxes to the proper taxing authority, and (c) send proof of payment to the other party and certify its receipt by the taxing authority within thirty (30) days following such payment. For purposes of this Section, each party agrees to provide the other with reasonable assistance to enable the due deduction by the paying party and appropriate recovery by the other party, which assistance includes, but is not limited to, provision of any tax forms and other information that may be reasonably necessary in order for the paying party not to withhold tax or to withhold tax at a reduced rate under an applicable bilateral income tax treaty.
- **6.4 Records; Audits.** Astellas shall keep, and require its Sublicensees to keep, complete, fair and true books of accounts and records for the purpose of determining the amounts payable to Vical pursuant to this Agreement, as well as the expenses of any [...\*\*\*...]. Such books and records shall be kept for such period of time required by law, but no less than [...\*\*\*...] ([...\*\*\*...]) years following the end of the Calendar Quarter to which they pertain. Vical (or City of Hope or CytRx, as applicable) shall have the right to cause an independent, certified public accountant, reasonably acceptable to Astellas, to audit such records to confirm Net Sales, royalties and other payments for a period covering not more than the preceding [...\*\*\*...] ([...\*\*\*...]) years. Except for any audits of the expenses of any [...\*\*\*...], for-cause audits or as otherwise permitted under the City of Hope Agreement or CytRx Agreement, as applicable, audits may be exercised not more often than [...\*\*\*...] each year, [...\*\*\*...] for each relevant record, and during normal business hours upon reasonable prior written notice to Astellas. Any such auditor shall not disclose Astellas' Confidential Information to Vical, except to the extent such disclosure is necessary to verify the accuracy of such records. Prompt adjustments shall be made by the parties to reflect the results of such audit. Vical (or City of Hope or CytRx, as applicable) shall bear the full cost of such audit unless such audit discloses an underpayment by Astellas of more than [...\*\*\*...] percent ([...\*\*\*...]%) of the amount of royalties or other payment due under this Agreement or an overstatement by more than [...\*\*\*...] percent ([...\*\*\*...]%) of the expenses of any [...\*\*\*...], in which case, Astellas shall bear the full cost of such audit and shall promptly remit to Vical the amount of any underpayment.

6.5 Late Payments. In the event that any payment due under this Agreement is not made when due, the payment shall accrue interest from the date due at the rate of [... \*\*\*...] percent ([...\*\*\*...]%) above the U.S. Prime Rate (as set forth by Bloomberg (Ticker symbol PRIME index)); provided, however, that in no event shall such rate exceed the maximum legal annual interest rate. The payment of such interest shall not limit Vical from exercising any other rights it may have as a consequence of the lateness of any payment.

### 7. INTELLECTUAL PROPERTY

7.1 Ownership. Vical has, and shall retain, all right, title and interest in and to, the Vical Patents and Vical Know-How. [...\*\*\*...].

7.2 Patent Prosecution and Maintenance. As between the parties, Vical (or its licensor, as applicable) shall have the sole right, but not the obligation, to prepare, file, prosecute (including any interferences, extensions, reissue proceedings and reexaminations) and maintain the Vical Patents, at its sole cost (subject to Section 7.3) and by counsel of its own choice. Vical shall provide Astellas with reasonable opportunity to review and comment on any material document that Vical intends to file or cause to be filed with the relevant intellectual property or patent office with respect to the Vical Patents in the Territory, and Vical shall give due consideration to such comments provided by Astellas agrees to reasonably cooperate in the preparation, filing, and prosecution of any Vical Patents and in the obtaining and maintenance of any supplementary protection certificates and the like with respect to any Vical Patent claiming a Product being developed or commercialized by Astellas or Sublicensees in the Territory. Such cooperation includes, but is not limited to, promptly informing Vical of any matters coming to Astellas' attention that may affect the preparation, filing, prosecution or maintenance of any Vical Patents. In the event that Vical determines to abandon or cease prosecution or maintenance of any Vical Patent in the Territory, Vical shall provide reasonable prior written notice to Astellas of such intention to abandon or cease prosecution or maintenance. In such case, subject to the rights of Vical's licensor with respect to any Vical Patent licensed to Vical by a Third Party, Astellas may elect, upon written notice by Astellas to Vical, to cause Vical to continue prosecution and/or maintenance of such Vical Patent that is not a Vical Primary Patent. Astellas' sole cost and expenses and in accordance with Astellas' instructions for any such Vical Patent that is not a Vical Primary Patent within thirty (30) days from the date of invoice for such costs and expenses by Vical. In the event that Astell

- 7.3 Additional Patent Term Extension Obligations. Astellas shall keep Vical fully informed of the progress of Astellas (and, as applicable, its Sublicensee(s)) toward Regulatory Approval of the first Product in the Territory. Astellas shall assist Vical in determining with respect to such Product if the Vical Patents would be eligible for patent term extension pursuant to 35 U.S.C. §§154–56 ("Patent Term Extension"). Astellas acknowledges that time is of the essence with respect to submission of any application for Patent Term Extension. Astellas shall give Vical notification in writing of its (or, as applicable, its Sublicensee's) first obtaining Regulatory Approval of a Product in the Territory within [...\*\*\*...] ([...\*\*\*...]) days of receipt of written notice of such Regulatory Approval from the applicable Regulatory Authority. Vical shall apply for Patent Term Extension for any Vical Primary Patent as requested by Astellas, at Vical's expense. At Vical's request, Astellas shall, in a timely manner, reasonably assist Vical in preparing an application for Patent Term Extension. Astellas agrees to join in such applications at Vical's request. Astellas shall reasonably support such applications and shall provide such information as may be requested by Vical or any Regulatory Authority in support of such applications.
- **7.4 Patent Enforcement.** Each party shall promptly notify the other in writing of any alleged or threatened infringement of any Vical Patent in the Territory of which such party becomes aware. The following provisions shall apply with respect any action or proceeding with respect to infringement by a Third Party of any Vical Patent in the Territory, subject to the terms of the City of Hope Agreement and CytRx Agreement with respect to Vical Patents licensed from City of Hope and CytRx, respectively.

## (a) Enforcement.

(i) Astellas First Right. As between the parties, excepting Patents licensed to Vical under the CytRx Agreement and the City of Hope Agreement, Astellas shall have the first right to bring and control any action or proceeding with respect to infringement by a Third Party of any Vical Patent in the Field in the Territory, at its own expense and by counsel of its own choice, except as provided in this Section 7.4(a)(i) and except that Section 7.4(a)(ii) shall instead apply with respect to infringement by a Third Party of any Vical Patent both in the Field and outside the Field in the Territory. Vical shall have the right, at its own expense, to be represented in any such action with respect to infringement of any Vical Patents in the Field in the Territory by counsel of its own choice, and Astellas and its counsel shall reasonably cooperate with, and take into account the view of, Vical and its counsel in strategizing, preparing and presenting any such action or proceeding. If Astellas fails to bring an action or proceeding with respect to infringement of any Vical Patent in the Field in the Territory within (A) [...\*\*\*...] ([...\*\*\*...]) days following the notice of alleged infringement or (B) [...\*\*\*...] ([...\*\*\*...]) days before the time limit, if any, set forth in the appropriate laws and regulations for the filing of such actions, whichever comes first, Vical shall have the right (but not the obligation) to bring and control any such action at its own expense and by counsel of its own choice, and Astellas shall have the right, at its own expense, to be represented in any such action by counsel of its own choice.

(ii) Vical First Right. As between the parties, Vical shall have the first right to bring and control any action or proceeding with respect to infringement by a Third Party of any Vical Patent (including any Patents licensed to Vical under the CytRx Agreement

and the City of Hope Agreement) in the Territory other than as set forth in Section 7.4(a)(i) at its own expense and by counsel of its own choice, except as provided in this Section 7.4(a)(ii). Astellas shall have the right, at its own expense, to be represented in any such action with respect to any such infringement of any Vical Patents in the Territory by counsel of its own choice, and Vical and its counsel shall reasonably cooperate with, and take into account the view of, Astellas and its counsel in strategizing, preparing and presenting any such action or proceeding. If Vical fails to bring an action or proceeding with respect to such infringement of any Vical Patent in the Territory within (A) [...\*\*\*...] ([...\*\*\*...]) days following the notice of alleged infringement or (B) [...\*\*\*...] ([...\*\*\*...]) days before the time limit, if any, set forth in the appropriate laws and regulations for the filing of such actions, whichever comes first, and such infringement of such Vical Patent would have a material adverse effect on Astellas' rights with respect to any Product in the Field in the Territory, then Astellas shall have the right (but not the obligation) to bring and control any such action at its own expense and by counsel of its own choice, and Vical shall have the right, at its own expense, to be represented in any such action by counsel of its own choice.

- (b) Cooperation; Awards. In the event a party brings an infringement action in accordance with this Section 7.4, the other party shall reasonably cooperate, including if required to bring such action, joining such action as a necessary party or the furnishing of a power of attorney. Neither party shall have the right to settle any patent infringement litigation with respect to any Vical Patent under this Section 7.4 in a manner that diminishes the rights or interests of the other party without the consent of such other party (which shall not be unreasonably withheld). Except as otherwise agreed to by the parties as part of a cost-sharing arrangement, any recovery or damages realized as a result of such action or proceeding shall be used first to reimburse the parties' documented out-of-pocket legal expenses relating to the action or proceeding, and any remaining damages relating to the Products (including lost sales or lost profits with respect to Products) shall be retained by the party that brought and controlled the action and, if Astellas brought and controlled such action, shall be deemed Net Sales subject to the royalty provisions of Section 5.3.
- 7.5 Third Party Infringement Claims. Each party shall promptly notify the other party in writing of any allegation by a Third Party that the activity of either party with respect to the development, manufacture or commercialization of any Product in the Field in the Territory infringes or may infringe the intellectual property rights of such Third Party. Vical shall have the sole right to control any defense of any such claim involving alleged infringement of Third Party rights by Vical's activities, at Vical's sole cost and expense and by counsel of its own choice, and Astellas shall have the right, at its own expense, to be represented in any such action by counsel of its own choice. Astellas' sole cost and expense and by counsel of its own choice, and Vical shall have the right, at its own expense, to be represented in any such action by counsel of its own choice. Neither party shall enter into any settlement or compromise of any action under this Section 7.5 which would in any manner diminish the rights or interests of the other party without the consent of such other party (which shall not be unreasonably withheld).

7.6 Orange Book Listing. Astellas shall have the sole right to make any filing with respect to any Vical Primary Patents in connection with the FDA's Orange Book. Upon request

of Astellas, Vical shall cooperate with Astellas to file appropriate information with the FDA listing any Vical Primary Patents in the Orange Book.

- 7.7 Patent Marking. Astellas shall mark all Products made, used or sold in the Territory, or their containers, if required under applicable laws, rules and regulations relating to patent marking.
- **7.8 Certification.** Astellas and Vical each will immediately (and no later than five (5) days following the date when Astellas or Vical becomes aware the certification described in this Section), give notice to the other of any certification of which they become aware filed under the U.S. Drug Price Competition and Patent Term Restoration Act of 1984, as amended, arising from the filing of an application for the regulatory approval of a Generic Product claiming that Patents covering any Product are invalid or non-enforceable or that infringement will not arise from the manufacture, use or sale of any Product in the Field in the Territory by a Third Party. Any action based on such a certification shall be brought and controlled as provided in Section 7.4.
- 7.9 Trademarks. Astellas shall be responsible for selection, registration and maintenance of the trademark(s) for Products in the Field in the Territory, at its own cost, and all such trademark(s) shall be filed and exclusively owned by Astellas. At Astellas' election, Vical shall grant to Astellas during the Term a royalty-free exclusive license with the right to sublicense under Vical's interest in Vical's common law trademark TransVax<sup>TM</sup> for use solely in connection with the sale and offer for sale of Products in the Field in the Territory. Such license shall become perpetual in the event Astellas obtains a perpetual and fully paid-up license and sublicense under the Vical Technology pursuant to Section 10.1. For clarity, Vical is and shall remain the owner of all right, title and interest in and to Vical's common law trademark TransVax<sup>TM</sup> and the goodwill now and hereafter associated therewith shall at all times inure to the benefit of Vical.

### 8. REPRESENTATIONS AND WARRANTIES

- 8.1 Mutual Representations and Warranties. Each party represents and warrants to the other party as of the Effective Date that:
- (a) Organization. It is duly organized and validly existing under the laws of its jurisdiction of incorporation or formation, and has full corporate or other power and authority to enter into this Agreement and to carry out the provisions hereof.
- (b) Authorization. It is duly authorized to execute and deliver this Agreement and to perform its obligations hereunder, and the person or persons executing this Agreement on its behalf has been duly authorized to do so by all requisite corporate or partnership action.
- (c) Binding Agreement. This Agreement is legally binding upon it, enforceable in accordance with its terms, and does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound, nor violate any material law or regulation of any court, governmental body or administrative or other agency having jurisdiction over it.

- (d) Agreements with Employees and Contractors. All of such party's employees or contractors acting on its behalf pursuant to this Agreement or any other written agreement between the parties are and will be obligated under a binding written agreement to comply with obligations of confidentiality and non-use consistent with those set forth in Article 9.
- (e) No Debarment. Such party is not debarred under the United States Federal Food, Drug and Cosmetic Act or comparable laws in any other country or jurisdiction, and it does not, and will not during the Term, employ or use the services of any person or entity who is debarred, in connection with the development, manufacture or commercialization of the Products. In the event that either party becomes aware of the debarment or threatened debarment of any person or entity providing services to such party, including the party itself and its Affiliates or Sublicensees, which directly or indirectly relate to activities under this Agreement, the other party shall be immediately notified in writing.
  - 8.2 Vical Representations and Warranties. Vical represents, warrants and covenants to Astellas as of the Effective Date that:
- (a) Control. Except for those rights in-licensed by Vical under the City of Hope Agreement and CytRx Agreement, Vical is the sole owner of all of the Vical Technology existing as of the Effective Date, free and clear of all liens.
  - (b) Right to Grant License. Vical has the right to grant the license and sublicenses it grants to Astellas under Section 3.1 of this Agreement.
- (c) No Conflicting Grant of Rights. Vical and its Affiliates have not, and will not during the Term, grant any right to any Third Party that would conflict with the rights granted to Astellas hereunder or, except with Astellas' prior written consent, allow a Third Party to create and maintain any security interest in (i) Vical Patents (excepting Patents licensed to Vical under the CytRx Agreement and the City of Hope Agreement) or (ii) any rights granted to Astellas hereunder, to secure third-party financing; provided that Vical may allow a Third Party to create and maintain such a security interest without Astellas' prior written consent if such security interest is subject to the rights granted to Astellas under such Vical Patents or other rights as set forth in this Agreement.
- (d) No Infringement. Vical has not received any notice alleging, and is not otherwise actually aware, that the practice of the Vical Patents infringes or may infringe any Patent(s) of any Third Party.
- (e) No Legal Actions. As of the Effective Date, there are no pending legal actions, nor has Vical received any written notice regarding any pending legal actions, with respect to the Vical Technology, and no Vical Patent is the subject of any interference, opposition, cancellation or other protest proceeding.
- (f) Disclosure. Up to and including the Effective Date, Vical has made available to Astellas (i) all material information (including without limitation pre-clinical and clinical data and the Existing IND) in its possession or Control relating to the Compound, the Product(s) and Vical Patents in the Field in the Territory, including material information in its

possession or Control that is material to the utility or safety of the Compound and/or the Product(s) in the Field in the Territory, and (ii) all safety data in its possession or Control relating to the Compound and Product(s).

- (g) Existing IND. Vical has sufficient legal and/or beneficial title and ownership in the Existing IND sufficient to transfer such Existing IND to Astellas in accordance with Section 4.1; no Regulatory Authority has, to Vical's knowledge, commenced or threatened to initiate any action or proceeding to refuse to file, reject, not approve, or withdraw the Existing IND, nor has Vical received any notice to such effect; and to Vical's knowledge, Vical is not in violation of any applicable laws that could reasonably be expected to form the basis for such an action.
- **8.3 Disclaimer.** Except as expressly set forth herein, THE VICAL TECHNOLOGY IS PROVIDED "AS IS," AND EACH PARTY EXPRESSLY DISCLAIMS ANY AND ALL WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION THE WARRANTIES OF DESIGN, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NONINFRINGEMENT OF THE INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES, OR ARISING FROM A COURSE OF DEALING, USAGE OR TRADE PRACTICES.
- **8.4 Limitation of Liability.** NEITHER PARTY SHALL BE ENTITLED TO RECOVER FROM THE OTHER PARTY ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES IN CONNECTION WITH THIS AGREEMENT OR ANY LICENSE GRANTED HEREUNDER; *provided, however*, that this Section 8.4 shall not be construed to limit either party's indemnification obligations under Article 11 or its right to obtain recover damages for breach of Article 9. For clarification, payments under Article 5 shall not be considered special, incidental, consequential or punitive damages.

### 9. CONFIDENTIALITY

9.1 Confidential Information. Except to the extent expressly authorized by this Agreement or otherwise agreed in writing by the parties, the parties agree that, during the Term and until the [...\*\*\*...] ([...\*\*\*...]) anniversary of the date of expiration or termination of the later to expire or terminate of this Agreement or the Ex-U.S. Agreement, each party (in such capacity, the "receiving party") shall keep confidential and shall not publish or otherwise disclose and shall not use for any purpose other than as expressly provided for in this Agreement or the Confidentiality Agreement any Confidential Information of the other party (in such capacity, the "disclosing party"). The receiving party may use Confidential Information of the extent required to accomplish the purposes of this Agreement. The receiving party will use at least the same standard of care as it uses to protect proprietary or confidential information of its own (but not less than reasonable care) to ensure that its employees, agents, consultants and other representatives do not disclose or make any unauthorized use of the Confidential Information of the disclosing party. The receiving party will promptly notify the disclosing party upon discovery of any unauthorized use or disclosure of the Confidential Information of the disclosing party. Without limiting the foregoing, the parties acknowledge that Vical Know-How includes valuable trade secrets and that it is in the interests of both parties to

protect the confidentiality of the Vical Know-How; provided, that nothing will limit or prevent Vical from using or disclosing the Vical Know-How in connection with its discussions and activities outside the scope of the exclusive license granted to Astellas hereunder with respect to Compounds and Products in the Field in the Territory.

- 9.2 Exceptions. Confidential Information shall not include any information which the receiving party can demonstrate by competent evidence: (a) is now, or hereafter becomes, through no act or failure to act on the part of the receiving party, generally known or available; (b) is known by the receiving party at the time of receiving such information, as evidenced by its records; (c) is hereafter furnished to the receiving party by a Third Party, as a matter of right and without restriction on disclosure; or (d) is independently discovered or developed by the receiving party without the use of Confidential Information of the disclosing party.
- **9.3 Authorized Disclosure.** The receiving party may disclose Confidential Information of the disclosing party as expressly permitted by this Agreement or if and to the extent such disclosure is reasonably necessary in the following instances:
  - (a) prosecuting or defending litigation as permitted by this Agreement;
  - **(b)** complying with applicable court orders or governmental regulations;
- (c) in the case of Astellas, conducting development, manufacturing and/or commercialization activities in accordance with the license granted in Section 3.1, including making regulatory filings with respect to Products;
  - (d) in the case of Vical, as reasonably necessary to fulfill its obligations under the City of Hope Agreement and CytRx Agreement; and
- (e) disclosure to Affiliates, sublicensees, subcontractors, employees, consultants, agents or other Third Parties who need to know such information for the development, manufacture and commercialization of Products in accordance with this Agreement or in connection with due diligence or similar investigations by such Third Parties, and disclosure to potential Third Party investors in confidential financing documents, provided, in each case, that any such Affiliate, sublicensee, subcontractor, employee, consultant, agent or Third Party agrees to be bound by similar terms of confidentiality and non-use at least equivalent in scope to those set forth in this Article 9.

Notwithstanding the foregoing, in the event the receiving party is required to make a disclosure of the disclosing party's Confidential Information pursuant to Section 9.3(a) or (b), it will, except where impracticable, give reasonable advance notice to the disclosing party of such disclosure and use efforts to secure confidential treatment of such information at least as diligent as the receiving party would use to protect its own confidential information, but in no event less than reasonable efforts. In any event, the receiving party agrees to take all reasonable action to avoid disclosure of Confidential Information of the disclosing party.

**9.4 Confidentiality of this Agreement and its Terms.** Except as otherwise provided in this Article 9, each party agrees not to disclose to any Third Party the existence of this Agreement or the terms of this Agreement without the prior written consent of the other party

hereto, except that each party may disclose the terms of this Agreement that are not otherwise made public as contemplated by Section 9.5 as permitted under Section 9.3.

#### 9.5 Public Announcements.

(a) Press Releases. As soon as practicable following the date hereof, the parties shall each issue a mutually agreed press release announcing the existence of this Agreement. Except as required by applicable laws and regulations (including disclosure requirements of the U.S. Securities and Exchange Commission ("SEC") or any stock exchange on which securities issued by a party or its Affiliates are traded), neither party shall make any other public announcement concerning this Agreement or the subject matter hereof without the prior written consent of the other, which shall not be unreasonably withheld or delayed; provided that each party may make any public statement, including statements in response to questions by the press, analysts, investors or those attending industry conferences or financial analyst calls, or issue press releases, so long as any such public statement or press release is not inconsistent with prior public disclosures or public statements approved by the other party pursuant to this Section 9.5 and which do not reveal non-public information about the other party. For avoidance of doubt, Vical shall have the right, without the prior written consent of Astellas, to announce events such as achievement of milestones under this Agreement, and other events deemed material by its General Counsel; provided, however, that Vical shall consult with Astellas with regard thereto and provide reasonable opportunity for Astellas to review such announcement in advance. In the event of a required public announcement, to the extent practicable under the circumstances, the party making such announcement shall provide the other party with a copy of the proposed text of such announcement sufficiently in advance of the scheduled release to afford such other party a reasonable opportunity to review and comment upon the proposed text.

**(b) Filing of Agreement.** The parties will coordinate in advance with each other in connection with the filing of this Agreement (including redaction of certain provisions of this Agreement) with the SEC or any stock exchange or governmental agency on which securities issued by a party or its Affiliate are traded, and each party will use reasonable efforts to seek confidential treatment for the terms proposed to be redacted; provided that each party will ultimately retain control over what information to disclose to the SEC or any stock exchange or other governmental agency, as the case may be, and provided further that the parties will use their reasonable efforts to file redacted versions with any governing bodies which are consistent with redacted versions previously filed with any other governing bodies. Other than such obligation, neither party (or its Affiliates) will be obligated to consult with or obtain approval from the other party with respect to any filings to the SEC or any stock exchange or other governmental agency.

#### (c) Publications.

(i) Except as otherwise set forth in Section 9.5(c)(ii) below, at least [...\*\*\*...] ([...\*\*\*...]) days prior to publishing, publicly presenting, and/or submitting for written or oral publication a manuscript, abstract or the like that includes Information relating to any Product in the Field that has not been previously published, each party shall provide to the other party a draft copy thereof for its review (unless such party is required by law to publish such Information sooner, in which case such party shall provide such draft copy to the other party as much in

advance of such publication as possible). The publishing party shall consider in good faith any comments provided by the other party during such [...\*\*\*...] ([...\*\*\*...]) day period. In addition, the publishing party shall, at the other party's reasonable request, remove therefrom any Confidential Information of such other party, except each party shall have the right to publicly disclose any information, including Confidential Information, pertaining to safety or efficacy of the Product that such party believes in good faith it is obligated by applicable law or appropriate to conform to applicable regulatory requirements to disclose; provided that it shall delay publication for a period not to exceed [... \*\*\*...] ([...\*\*\*...]) days in order to allow the other party to file for patent protection as permitted by this Agreement in relation to its Confidential Information. The contribution of each party shall be noted in all publications or presentations by acknowledgment or co-authorship, as appropriate.

- (ii) In the event Astellas desires to publish, publicly present, and/or submit for written or oral publication a manuscript, abstract or the like that includes Information relating to any Product in the Field but that does not include any Confidential Information of Vical, Astellas shall provide to Vical a draft copy thereof for its review prior to the date of such publication, presentation or submission, and Astellas shall consider in good faith any comments provided by Vical with respect thereto.
- (iii) Astellas shall, within a reasonable amount of time after the Effective Date and from time to time thereafter, provide to Vical a copy of its plan for publication regarding Compounds and Products in the Field, including all material updates and changes thereto.
- 9.6 Equitable Relief. Given the nature of the Confidential Information and the competitive damage that would result to the disclosing party upon unauthorized disclosure, use or transfer of its Confidential Information to any Third Party, the parties agree that monetary damages may not be a sufficient remedy for any breach of this Article 9. In addition to all other remedies, the disclosing party shall be entitled to seek specific performance and injunctive and other equitable relief as a remedy for any breach or threatened breach of this Article 9.

### 10. TERM AND TERMINATION

10.1 Term. The term of this Agreement shall commence on the Effective Date and continue until the expiration of the last Royalty Term, subject, in each case, to earlier termination pursuant to Section 10.2 (the "Term"). Upon expiration (but not early termination) of this Agreement [...\*\*\*...] under this Agreement, the license and sublicense granted by Vical to Astellas under Section 3.1 shall remain in effect on a perpetual, fully paid-up and royalty-free basis, subject to the limits set forth in Article 3.

# 10.2 Early Termination.

### (a) Termination for Cause.

(i) A party shall have the right to terminate this Agreement upon written notice to the other party if such other party is in material breach of this Agreement and has not cured such breach within sixty (60) days (thirty (30) days with respect to any payment breach) after written notice from the terminating party requesting cure of such breach. Any such

termination shall become effective at the end of such sixty (60) day (thirty (30) day with respect to any payment breach) period unless the breaching party has cured any such breach prior to the end of such period. Furthermore, each party shall have the right to terminate this Agreement upon written notice to the other party if the Services Agreement is terminated by such party due to material breach by the other party.

- (ii) A party shall have the right to terminate this Agreement upon written notice to the other party upon the bankruptcy, dissolution or winding up of such other party, or the making or seeking to make or arrange an assignment for the benefit of creditors of such other party, or the initiation of proceedings in voluntary or involuntary bankruptcy, or the appointment of a receiver or trustee of such other party's property that is not discharged within ninety (90) days.
- (b) Other Astellas Termination Right. Astellas shall have the right to terminate this Agreement if Astellas reasonably determines that further development and/or commercialization of Products in the Field in the Territory will not be beneficial for Astellas for scientific, regulatory, commercial, financial, ethical or other fair reasons specified in reasonable detail in writing to Vical: (i) prior to completion of the technology transfer of Vical Know-How relating to the manufacture of Compounds and Products in the Field to Astellas or its designee, upon one hundred eighty (180) days' prior written notice to Vical, and (ii) thereafter, upon ninety (90) days' prior written notice to Vical.
- (c) Other Vical Termination Rights. Vical shall have the right to terminate this Agreement immediately upon written notice to Astellas if Astellas or any of its Affiliates or Sublicensees, directly or indirectly through any Third Party, commences any interference or opposition proceeding with respect to, challenges the validity or enforceability of, or opposes any extension of or the grant of a supplementary protection certificate with respect to, any Vical Patent.

## 10.3 Effect of Termination or Expiration; Surviving Obligations.

- (a) Effect of Any Termination. Upon any termination of this Agreement by either party:
  - (i) all rights and obligations of the parties under this Agreement shall terminate, except as provided in Sections 10.3, 10.4, 10.5 and, as applicable, 10.6;
- (ii) Astellas shall perform its outstanding non-cancellable obligations with respect to Products in the Territory that existed or accrued prior to the notice date of termination; and
- (iii) Astellas shall cooperate with and provide reasonable assistance to Vical with respect to any applications for Patent Term Extension, including providing such information as may be requested by Vical or any Regulatory Authority in support of such applications.

- **(b)** Effect of Any Termination Other than Termination by Astellas for Cause. Upon any termination of this Agreement by Astellas under Section 10.2(b) or by Vical under Section 10.2(a) or (c):
- (i) if, at the time of such termination, there are any ongoing clinical trials with respect to Products in the Field in the Territory, the parties shall, at Vical's option, negotiate in good faith and adopt a plan to wind-down the development activities in an orderly fashion or, at Vical's election, promptly transition such development activities to Vical or its designee, with due regard for patient safety and the rights of any subjects that are participants in any clinical trials of the Product and take any actions Vical deems reasonably necessary or appropriate to avoid any human health or safety problems and in compliance with all applicable laws, rules and regulations; and
  - (ii) Astellas shall, and hereby does, grant to Vical:
- (1) the unrestricted right to use and refer to all Information, including all data and regulatory documents, relating to any Compound or Product, in the Territory and also in any country or countries outside the Territory upon any termination of the Ex-U.S. Agreement in such country or countries;
- (2) an exclusive, royalty-free, perpetual, irrevocable license, with the right to sublicense and further sublicense, under all Patents Controlled by Astellas or its Affiliates that claim or cover a Compound or Product specifically or its manufacture or use in the Territory, solely to research, develop, register, use, make, have made, promote, sell, offer for sale, distribute, import and export Compounds and Products in the Field in the Territory;
- (3) a non-exclusive, royalty-free, perpetual, irrevocable license, with the right to sublicense and further sublicense, under all Patents Controlled by Astellas or its Affiliates other than those referenced in subsection (2) above, which Patents would, but for the license granted in this subsection (3), be infringed by the development, use, manufacture, promotion, sale, offer for sale, distribution, import or export of a Compound or Product in the Field in the Territory, solely to develop, use, make, have made, promote, sell, offer for sale, distribute, import and export Compounds and Products in the Field in the Territory; and
- (4) take such other actions and execute such other instruments, assignments and documents as may be necessary to effect the transfers of rights as set forth in subsections (1), (2) and (3) above.
- (c) Surviving Terms. Expiration or termination of this Agreement shall not relieve the parties of any obligation accruing prior to such expiration or termination. Without limiting the foregoing, the obligations and rights of the parties under Sections 6.4 (for the period described therein), 7.1, 8.3, 8.4, 10.3, 10.4 and 10.5 and Articles 1, 9, 11 and 12 shall survive expiration or termination of this Agreement.
- (d) Return of Confidential Information. Within [...\*\*\*...] days following the expiration or termination of this Agreement, each party shall deliver to the other party or destroy any and all Confidential Information of the other party in its possession, as per

instruction by the party which owns such Confidential Information. Notwithstanding the foregoing, in case that Astellas grants to Vical right and license pursuant to Section 10.3(b), the party, which is entitled to develop, manufacture and commercialize the Product after expiration or termination of this Agreement, shall not be required to make delivery or destruction pursuant to this Section 10.3(d).

- 10.4 Exercise of Right to Terminate. The use by either party hereto of a termination right provided for under this Agreement shall not give rise to the payment of damages or any other form of compensation or relief to the other party with respect thereto.
- 10.5 Damages; Relief. Subject to Section 10.4 above, termination of this Agreement shall not preclude either party from claiming any other damages, compensation or relief that it may be entitled to upon such termination.

10.6 Rights in Bankruptcy. All rights and licenses granted under or pursuant to this Agreement by a party are, and will otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code, licenses of right to "intellectual property" as defined under Section 101 of the U.S. Bankruptcy Code. The parties agree that a party, as licensee of such rights under this Agreement, will 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 the commencement of a bankruptcy proceeding by or against the licensing party under the U.S. Bankruptcy Code, the licensee will be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property, and same, if not already in its possession, will be promptly delivered to it (a) upon any such commencement of a bankruptcy proceeding upon its written request therefor, unless the licensing party elects to continue to perform all of its obligations under this Agreement, or (b) if not delivered under subsection (a) above, following the rejection of this Agreement by or on behalf of the licensing party upon written request therefor by the licensee.

### 11. INDEMNIFICATION

11.1 Indemnification by Vical. Vical hereby agrees to save, defend and hold Astellas, its Affiliates and its and their respective directors, officers, employees and agents and, with respect to the indemnification set forth in Section 11.1(c) only, also Astellas' Sublicensees, subcontractors and distributors (each, a "Astellas Indemnitee") harmless from and against any and all claims, suits, actions, demands, liabilities, expenses and/or loss, including reasonable legal expense and attorneys' fees (collectively, "Losses"), to which any Astellas Indemnitee may become subject as a result of any claim, demand, action or other proceeding by any Third Party to the extent such Losses arise directly or indirectly out of (a) the gross negligence or willful misconduct of any Vical Indemnitee with respect to any obligations or activities contemplated by this Agreement, (b) the breach by Vical of any warranty, representation, covenant or agreement made by Vical in this Agreement, or (c) infringement or alleged infringement of any Patents co-owned by Vical and the Wisconsin Alumni Research Foundation as a result of the development, manufacture, use, handling, storage, sale or other disposition of any Product in the Territory by Astellas or any of its Sublicensees; except, in each case, to the extent such Losses result from the gross negligence or willful misconduct of any Astellas Indemnitee or the breach by Astellas of any warranty, representation, covenant or agreement made by Astellas in this Agreement.

- 11.2 Indemnification by Astellas. Astellas hereby agrees to save, defend and hold Vical and its Affiliates and its and their respective directors, officers, employees and agents (each, a "Vical Indemnitee") harmless from and against any and all Losses to which any Vical Indemnitee may become subject as a result of any claim, demand, action or other proceeding by any Third Party to the extent such Losses arise directly or indirectly out of: (a) the development, manufacture, use, handling, storage, sale or other disposition of any Product in the Territory by Astellas or any of its Sublicensees, (b) the gross negligence or willful misconduct of any Astellas Indemnitee with respect to any obligations or activities contemplated by this Agreement, or (c) the breach by Astellas of any warranty, representation, covenant or agreement made by Astellas in this Agreement; except, in each case, to the extent such Losses result from the gross negligence or willful misconduct of any Vical Indemnitee or the breach by Vical of any warranty, representation, covenant or agreement made by Vical in this Agreement.
- 11.3 Control of Defense. Any person entitled to indemnification under this Article 11 shall give notice to the indemnifying party of any Losses that may be subject to indemnification, promptly after learning of such Losses, and the indemnifying party shall assume the defense of such Losses with counsel reasonably satisfactory to the indemnified party. If such defense is assumed by the indemnifying party with counsel so selected, the indemnifying party will not be subject to any liability for any settlement of such Losses made by the indemnified party without its consent (but such consent will not be unreasonably withheld or delayed), and will not be obligated to pay the fees and expenses of any separate counsel retained by the indemnified party with respect to such Losses.
- 11.4 Insurance. Each party shall, at its own expense, procure and maintain during the Term and for a period of three (3) years thereafter, insurance policy/policies, including product liability insurance, adequate to cover its obligations hereunder and which are consistent with normal business practices of prudent companies similarly situated. Such insurance shall not be construed to create a limit of a party's liability with respect to its obligations hereunder including the indemnification obligations under this Article 11. Each party shall provide the other party with written evidence of such insurance or self-insurance upon request. Each party shall provide the other party with written notice at least thirty (30) days prior to the cancellation, non-renewal or material change in such insurance self-insurance which could materially adversely affect the rights of such other party hereunder.

### 12. GENERAL PROVISIONS

- **12.1 Standstill Agreement.** For a period of [...\*\*\*...] ([...\*\*\*...]) years following the Effective Date (the "Standstill Period"), neither Astellas nor any of Astellas' Representatives (as defined below) will, in any manner, directly or indirectly:
- (a) make, effect, initiate, directly participate in or cause (i) any acquisition of beneficial ownership of any securities of Vical or any securities of any subsidiary or other Affiliate of Vical, if, after such acquisition, Astellas would beneficially own more than [...\*\*\*...] percent ([...\*\*\*...]%) of the outstanding common stock of Vical, (ii) any acquisition of any assets of Vical or any assets of any subsidiary or other Affiliate of Vical, (iii) any tender offer, exchange offer, merger, business combination, recapitalization, restructuring, liquidation, dissolution or extraordinary transaction involving Vical or any subsidiary or other Affiliate of Vical, or

involving any securities or assets of Vical or any securities or assets of any subsidiary or other affiliate of Vical, or (iv) any "solicitation" of "proxies" (as those terms are used in the proxy rules of the Securities and Exchange Commission) or consents with respect to any securities of Vical provided that nothing in this Section 12.1 shall preclude any activities of Astellas or its Representatives with respect to the grant by Vical or any Affiliate of Vical of any license, or the supply by Vical or any subsidiary or other Affiliate of Vical of any products, in each case to Astellas or any of its Affiliates as contemplated by this Agreement;

- (b) form, join or participate in a group (within the meaning of Section 13(d)(3) of the Securities Exchange Act of 1934, as amended) with respect to the beneficial ownership of any securities of Vical;
  - (c) act, alone or in concert with others, to seek to control the management, board of directors or policies of Vical;
  - (d) take any action that might require Vical to make a public announcement regarding any of the types of matters set forth in Section 12.1(a);
  - (e) agree or offer to take, or encourage or propose (publicly or otherwise) the taking of, any action referred to in Section 12.1(a), (b), (c) or (d);
  - (f) assist, induce or encourage any Third Party to take any action of the type referred to in Section 12.1(a), (b), (c), (d) or (e);
  - (g) enter into any discussions, negotiations, arrangement or agreement with any Third Party relating to any of the foregoing; or
- (h) request or propose that Vical or any of Vical's Representatives amend, waive or consider the amendment or waiver of any provision set forth in this Section 12.1.

For purposes of this Agreement, a party's "Representatives" will be deemed to include each person or entity that is or becomes (i) an Affiliate of such party, or (ii) an officer, director, employee, partner, attorney, advisor, accountant, agent or representative of such party or of any of such party's Affiliates, providing such person is acting on behalf of such party.

Notwithstanding the foregoing, Section 12.1 shall no longer apply (i) during a period commencing with Vical's announcement in a filing with the Securities and Exchange Commission or a press release that (a) it is seeking purchaser for itself or (b) is otherwise exploring strategic options in this regard, and ending with Vical's announcement in a filing with the Securities and Exchange Commission or a press release that is terminating such search or exploration; (ii) during the period beginning with the commencement by a Third Party of a publicly-announced tender or exchange offer for more than [...\*\*\*...] percent ([...\*\*\*...]%) of voting power of the outstanding voting securities of Vical, and ending with the termination by such Third Party of such tender or exchange offer; or (iii) if Vical announces in a filing with the Securities and Exchange Commission or a press release a transaction, or an intention to effect any transaction, which would result in (a) the sale by Vical or one or more Affiliate(s) of assets representing [...\*\*\*...] percent ([...\*\*\*...]%) or more of the consolidated assets of Vical; or (b) the common shareholders of Vical immediately prior to such transaction owning less than [[...\*\*\*...]

percent ([...\*\*\*...]%) of the outstanding common stock of the acquiring entity or, in case of a merger transaction, the surviving corporation (or, if the surviving corporation is an Affiliate of a parent company); provide that, in the case of clause (ii) Astellas has not directly or indirectly taken any action prohibited under this Section 12.1.

The expiration of the Standstill Period will not terminate or otherwise affect any of the other provisions of this Agreement.

12.2 Governing Law. This Agreement shall be governed by, and construed and enforced in accordance with, the laws of the State of New York, excluding its conflicts of laws principles with the exception of sections 5-1401 and 5-1402 of New York General Obligations Law.

### 12.3 Dispute Resolution.

- (a) Objective. The parties recognize that disputes as to matters arising under or relating to this Agreement or either party's rights and/or obligations hereunder may arise from time to time. It is the objective of the parties to establish procedures to facilitate the resolution of such disputes in an expedient manner by mutual cooperation and without resort to litigation. To accomplish this objective, the parties agree to follow the procedures set forth in this Section 12.3 to resolve any such dispute if and when it arises.
- (b) Resolution by Executives. Except as otherwise provided in Section 2.1, if an unresolved dispute as to matters arising under or relating to this Agreement or either party's rights and/or obligations hereunder arises, either party may refer such dispute to the Executives, who shall meet in person or by telephone within ten (10) days after such referral to attempt in good faith to resolve such dispute. If such matter cannot be resolved by discussion of the Executives within ten (10) days following such meeting (as may be extended by mutual written agreement), such dispute shall be resolved in accordance with Section 12.3(c). For avoidance of doubt, any disputes, controversies or differences arising from the JSC pursuant to Article 2 shall be resolved solely in accordance with Section 2.1.

#### (c) Arbitration.

- (i) If the parties do not resolve a dispute as provided in Section 12.3(b), and a party wishes to pursue the matter, each such dispute that is not an "Excluded Claim" shall be resolved by binding arbitration in accordance with the Rules of Arbitration of the International Chamber of Commerce ("ICC") as then in effect (the "ICC Rules"), and judgment on the arbitration award may be entered in any court having jurisdiction thereof. The decision rendered in any such arbitration will be final and not appealable. If either party intends to commence binding arbitration of such dispute, such party will provide written notice to the other party informing the other party of such intention and the issues to be resolved. Within thirty (30) days after the receipt of such notice, the other party may by written notice to the party initiating binding arbitration, add additional issues to be resolved.
  - (ii) The arbitration shall be conducted by a panel of three (3) arbitrators experienced in the pharmaceutical business, none of whom shall be a current or

former employee or director, or a then-current stockholder, of either party, their respective Affiliates or any Sublicensee. Within thirty (30) days after receipt of the original notice of binding arbitration, each party shall select one person to act as arbitrator and the two party-selected arbitrators shall select a third arbitrator within ten (10) days of their appointment. If the arbitrators selected by the parties are unable or fail to agree upon the third arbitrator, the third arbitrator shall be appointed by the ICC in accordance with the ICC Rules. The place of arbitration shall be New York, New York and all proceedings and communications shall be in English.

- (iii) It is the intention of the parties that discovery, although permitted as described herein, will be limited except in exceptional circumstances. The arbitrators will permit such limited discovery necessary for an understanding of any legitimate issue raised in the arbitration, including the production of documents. No later than thirty (30) days after selection of the arbitrators, the parties and their representatives shall hold a preliminary meeting with the arbitrators, to mutually agree upon and thereafter follow procedures seeking to assure that the arbitration will be concluded within six (6) months from such meeting. Failing any such mutual agreement, the arbitrators will design and the parties shall follow procedures to such effect.
- (iv) Either party may apply to the arbitrators for interim injunctive relief until the arbitration award is rendered or the controversy is otherwise resolved. Either party also may, without waiving any remedy under this Agreement, seek from any court having jurisdiction any injunctive or provisional relief necessary to protect the rights or property of that party pending the arbitration award. The arbitrators shall have no authority to award punitive or any other non-compensatory damages. The arbitrators shall have the power to order that all or part of the legal or other costs incurred by a party in connection with the arbitration be paid by the other party. Subject to the preceding sentence, each party shall bear an equal share of the arbitrators' and any administrative fees of arbitration.
- (v) Except to the extent necessary to confirm or enforce an award or as may be required by applicable law, neither a party nor an arbitrator may disclose the existence, content, or results of an arbitration without the prior written consent of both parties. In no event shall an arbitration be initiated after the date when commencement of a legal or equitable proceeding based on the dispute, controversy or claim would be barred by the applicable New York statute of limitations.
- (vi) As used in this Section, the term "Excluded Claim" shall mean a dispute, controversy or claim that concerns (A) the validity, enforceability or infringement of a patent, trademark, copyright or regulatory data exclusivity; or (B) any antitrust, anti-monopoly or competition law or regulation, whether or not statutory.
- 12.4 Entire Agreement; Modification. This Agreement, including the Exhibits hereto, is both a final expression of the parties' agreement and a complete and exclusive statement with respect to all of its terms. Except for the Ex-U.S. Agreement, the Services Agreement and the separate letter agreement between the parties, this Agreement supersedes all prior and contemporaneous agreements and communications, whether oral, written or otherwise, concerning any and all matters contained herein and therein, including the Confidentiality

Agreement. This Agreement may only be modified or supplemented in a writing expressly stated for such purpose and signed by the parties to this Agreement.

- 12.5 Relationship Between the Parties. The parties' relationship, as established by this Agreement, is solely that of independent contractors. This Agreement does not create any partnership, joint venture or similar business relationship between the parties. Neither party is a legal representative of the other party, and neither party can assume or create any obligation, representation, warranty or guarantee, express or implied, on behalf of the other party for any purpose whatsoever.
- 12.6 Non-Waiver. The failure of a party to insist upon strict performance of any provision of this Agreement or to exercise any right arising out of this Agreement shall neither impair that provision or right nor constitute a waiver of that provision or right, in whole or in part, in that instance or in any other instance. Any waiver by a party of a particular provision or right shall be in writing, shall be as to a particular matter and, if applicable, for a particular period of time and shall be signed by such party.
- 12.7 Assignment. Except as expressly provided hereunder, neither this Agreement nor any rights or obligations hereunder may be assigned or otherwise transferred by either party without the prior written consent of the other party (which consent shall not be unreasonably withheld); provided, however, that either party may assign or otherwise transfer this Agreement and its rights and obligations hereunder without the other party's consent:
- (a) in connection with the transfer or sale of all or substantially all of the business or assets of such party relating to products for control or prevention of CMV infection to a Third Party, whether by merger, sale of stock, sale of assets or otherwise (a "Sale"), provided that in the event of a Sale (whether this Agreement is actually assigned or is assumed by the acquiring party by operation of law (e.g., in the context of a reverse triangular merger)), intellectual property rights of the acquiring party to such transaction (if other than one of the parties to this Agreement) shall not be included in the technology licensed hereunder; or
- (b) to an Affiliate, provided that the assigning party shall remain liable and responsible to the non-assigning party hereto for the performance and observance of all such duties and obligations by such Affiliate.

The rights and obligations of the parties under this Agreement shall be binding upon and inure to the benefit of the successors and permitted assigns of the parties. Any assignment not in accordance with this Agreement shall be void.

- 12.8 No Third Party Beneficiaries. This Agreement is neither expressly nor impliedly made for the benefit of any party other than those executing it, except for City of Hope with respect to City of Hope's rights under the City of Hope Agreement and except as otherwise provided in this Agreement with respect to Astellas Indemnitees under Section 11.1 and Vical Indemnitees under Section 11.2.
- 12.9 Severability. If, for any reason, any part of this Agreement is adjudicated invalid, unenforceable or illegal by a court of competent jurisdiction, such adjudication shall not affect or impair, in whole or in part, the validity, enforceability or legality of any remaining

portions of this Agreement. All remaining portions shall remain in full force and effect as if the original Agreement had been executed without the invalidated, unenforceable or illegal part.

- 12.10 Cumulative Remedies. No remedy referred to in this Agreement is intended to be exclusive, but each shall be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under law.
- 12.11 Notices. Any notice to be given under this Agreement must be in writing and delivered either in person, by any method of mail (postage prepaid) requiring return receipt, or by overnight courier or facsimile or electronic mail (email) transmission confirmed thereafter by any of the foregoing, to the party to be notified at its address(es) given below, or at any address such party has previously designated by prior written notice to the other. Notice shall be deemed sufficiently given for all purposes upon the earliest of: (a) the date of actual receipt; (b) if mailed, five (5) days after the date of postmark; or (c) if delivered by overnight courier, the next business day the overnight courier regularly makes deliveries.

If to Astellas, notices must be addressed to:

Astellas Pharma Inc. 3-11, Nihonbashi-Honcho 2-chome Chuo-Ku, Tokyo 103-8411 Japan Attention: Vice President, Legal Facsimile: [...\*\*\*...]

With a copy to:

Astellas Pharma Inc.
3-11, Nihonbashi-Honcho 2-chome
Chuo-Ku, Tokyo 103-8411
Japan
Attention: Vice President, Licensing and Alliances
Facsimile: [...\*\*\*...]

If to Vical, notices must be addressed to:

Vical Incorporated 10390 Pacific Center Court San Diego, California 92121 USA

Attention: Business Development Facsimile: (858) 646-1150 Email: licensing@vical.com

With a copy to:

Cooley LLP 4401 Eastgate Mall San Diego, California 92121 USA Attention: [...\*\*\*...] Telephone: (858) 550-6000

Facsimile: (858) 550-6420 Email: [...\*\*\*...]

12.12 Force Majeure. Except for the obligation to make payment when due, each party shall be excused from liability for the failure or delay in performance of any obligation under this Agreement by reason of any event beyond such party's reasonable control including but not limited to Acts of God, fire, flood, explosion, earthquake, or other natural forces, war, civil unrest, accident, destruction or other casualty, any lack or failure of transportation facilities, any lack or failure of supply of raw materials, any strike or labor disturbance, or any other event similar to those enumerated above. Such excuse from liability shall be effective only to the extent and duration of the event(s) causing the failure or delay in performance and provided that the party has not caused such event(s) to occur. Notice of a party's failure or delay in performance due to force majeure must be given to the other party within ten (10) days after its occurrence. All delivery dates under this Agreement that have been affected by force majeure shall be tolled for the duration of such force majeure. In no event shall any party be required to prevent or settle any labor disturbance or dispute.

## 12.13 Interpretation.

- (a) Captions & Headings. The captions and headings of clauses contained in this Agreement preceding the text of the articles, sections, subsections and paragraphs hereof are inserted solely for convenience and ease of reference only and shall not constitute any part of this Agreement, or have any effect on its interpretation or construction.
- **(b) Interpretation.** All references in this Agreement to the word "including" shall be deemed to be followed by the phrase "without limitation" or like expression. All references in this Agreement to the singular shall include the plural where applicable, and all references to gender shall include both genders and the neuter.
- (c) Articles, Sections & Subsections. Unless otherwise specified, references in this Agreement to any article shall include all sections, subsections, and paragraphs in such article; references in this Agreement to any section shall include all subsections and paragraphs in such sections; and references in this Agreement to any subsection shall include all paragraphs in such subsection.
  - (d) Days. All references to days in this Agreement shall mean calendar days, unless otherwise specified.

- (e) Ambiguities. Ambiguities and uncertainties in this Agreement, if any, shall not be interpreted against either party, irrespective of which party may be deemed to have caused the ambiguity or uncertainty to exist.
- (f) English Language. This Agreement has been prepared in the English language and the English language shall control its interpretation. In addition, all notices required or permitted to be given hereunder, and all written, electronic, oral or other communications between the parties regarding this Agreement shall be in the English language.
- 12.14 Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original document, and all of which, together with this writing, shall be deemed one instrument. Signatures provided by facsimile transmission or in Adobe<sup>TM</sup> Portable Document Format (PDF) sent by electronic mail shall be deemed to be original signatures.
- 12.15 HSR Filing. Each of Vical and Astellas agrees to prepare and make appropriate filings under the Hart-Scott-Rodino Anti-Trust Improvements Act of 1976, as amended (the "HSR Act") and any analogous foreign laws and regulations, relating to this Agreement and the transactions contemplated hereby as soon as reasonably practicable, but in any event within ten (10) days after the date of execution of this Agreement (the "HSR Filing Date"). The parties agree to cooperate in the antitrust clearance process and to furnish promptly to the Federal Trade Commission, the Antitrust Division of the Department of Justice and any other agency or authority, any information reasonably requested by them in connection with such filings. Other than the provisions of this Section 12.15, the rights and obligations of the parties under this Agreement shall not become effective until the waiting period provided by the HSR Act shall have terminated or expired without any action by any governmental agency or challenge to the transaction (the date of such termination or expiration shall be the "Effective Date" of this Agreement). Upon the occurrence of the Effective Date, all provisions of this Agreement shall become effective automatically without the need for further action by the parties. In the event that antitrust clearance from the Federal Trade Commission and Antitrust Division of the Department of Justice is not obtained within ninety (90) days after the date of execution of this Agreement (or such later date as agreed in writing by the parties), this Agreement may be terminated by either party.

[Remainder of this page intentionally left blank.]

IN WITNESS WHEREOF, the parties hereto have duly executed this	s U.S. LICENSE AGREEMENT as of the date set forth below.	
VICAL INCORPORATED	ASTELLAS PHARMA INC.	
By:	By:	
Name: Vijay B. Samant	Name: Yoshihiko Hatanaka	
Title: President and CEO	Title: President and CEO	
Date: July , 2011	Date: July , 2011	

SIGNATURE PAGE TO U.S. LICENSE AGREEMENT

# EXHIBIT A

# Vical Patents in the Territory

# **Vical Primary Patents**

- 1. [...\*\*\*...]
- a. [...\*\*\*...]
- 2. [...\*\*\*...]
- a. [...\*\*\*...]
- b. [...\*\*\*...]
- c. [...\*\*\*...]

# **Vical Patents**

- 1. [...\*\*\*...]
- a. [...\*\*\*...]
- 2. [...\*\*\*...]
- a. [...\*\*\*...]
- b. [...\*\*\*...]
- c. [...\*\*\*...]
- d. [...\*\*\*...]
- 3. [...\*\*\*...]
- J. [... ...
- 4. [...\*\*\*...]
- 5. [...\*\*\*...]
- 6. [...\*\*\*...]
- 7. [...\*\*\*...]

- 8. [...\*\*\*...]
- 9. [...\*\*\*...]
- 10. [...\*\*\*...]

\*\*\* Text Omitted and Filed Separately Pursuant to a Confidential Treatment Request under 17 C.F.R. §§ 200.80(b)(4) and 240.24b-2(b)(1)

### EX-U.S. LICENSE AGREEMENT

THIS EX-U.S. LICENSE AGREEMENT (the "Agreement") is entered into as of the Effective Date (as defined below) by and between VICAL INCORPORATED, a Delaware corporation ("Vical"), having an address of 10390 Pacific Center Court, San Diego, California, 92121, USA, and ASTELLAS PHARMA INC., a company organized under the laws of Japan ("Astellas"), having an address of 3-11, Nihonbashi-Honcho 2-chome, Chuo-Ku, Tokyo 103-8411, Japan.

#### RECITALS

WHEREAS, Vical has developed expertise and owns proprietary rights related to Compounds and Products in the Field (each as defined below), as more fully described below:

WHEREAS, Astellas is engaged in the research, development and commercialization of pharmaceutical products; and

WHEREAS, Astellas wishes to obtain, and Vical is willing to grant to Astellas, an exclusive license under Vical Technology (as defined below) to develop and commercialize Products in the Field in the Territory (as defined below), subject to the terms and conditions set forth herein.

### AGREEMENT

**Now, THEREFORE,** in consideration of the foregoing premises and the mutual covenants contained herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties agree as follows:

## 1. DEFINITIONS

- 1.1 "Affiliate" shall mean, with respect to a particular party, a person, corporation, partnership, or other entity that controls, is controlled by or is under common control with such party. For the purposes of this definition, 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 or cause the direction of the management and policies of such entity, whether by the ownership of more than fifty percent (50%) of the voting stock of such entity, or by contract or otherwise.
  - 1.2 "Astellas Indemnitee" shall have the meaning provided in Section 11.1.
  - 1.3 "Astellas Reserved Product" shall have the meaning provided in Section 3.5(b).
  - 1.4 "Calendar Quarter" shall mean each respective period of three consecutive months ending on March 31, June 30, September 30 and December 31.

- 1.5 "Calendar Year" shall mean each respective period of twelve (12) consecutive months beginning on January 1.
- 1.6 "CMC" shall mean chemistry, manufacturing and controls.
- 1.7 "CMV" shall mean cytomegalovirus.
- 1.8 "Combination Product" shall mean any pharmaceutical product that contains one or more Compound(s) in combination with one or more other therapeutically and/or prophylactically active ingredient(s), whether packaged together or included in a prime-boost regimen or in the same therapeutic formulation, including, in each case, all formulations, line extensions and modes of administration, but excluding, in each case, any formulation with the Vaxfectin Adjuvant. For clarification, poloxamers, other delivery systems and adjuvants shall not be considered therapeutically and/or prophylactically active ingredients.
  - **1.9 "Commercialization Plan"** shall have the meaning provided in Section 4.2.
- 1.10 "Commercially Reasonable Efforts" shall mean that level of efforts and resources consistent with commercially reasonable practices of a company in the pharmaceutical industry with respect to the research, development or commercialization of a pharmaceutical product at a similar stage of research, development or commercialization, taking into account relevant factors including, without limitation, measures of patent coverage, relative safety and efficacy, product profile, the competitiveness of the marketplace, the proprietary position of such product, the regulatory structure involved, the market potential of such product and other relevant factors, including comparative technical, legal, scientific and/or medical factors, all as measured by the facts and circumstances in effect at the time when the carrying out of such obligations is due.
  - 1.11 "Committees" shall mean the JDC and JSC, collectively, and "Committee" shall mean the JDC or JSC, as applicable.
  - 1.12 "Competitive Product" shall have the meaning provided in Section 3.4.
  - 1.13 "Compound" shall mean [...\*\*\*...] plasmid that encodes [...\*\*\*...] of glycoprotein B and/or phosphoprotein 65 [...\*\*\*...]
- 1.14 "Confidential Information" shall mean all Information and other proprietary scientific, marketing, financial or commercial information or data, which one party or any of its Affiliates has furnished or otherwise made available to the other party or its Affiliates, whether made available orally, in writing, or in electronic form. Confidential Information shall include all such information provided or made available pursuant to the Confidentiality Agreement. All Vical Technology shall be Confidential Information of Vical. All Confidential Information shall be subject to the Article 9.
  - $\textbf{1.15 ``Confidentiality Agreement''} \text{ shall mean that certain Confidentiality Agreement } [\dots ****\dots].$

- 1.16 "Control" shall mean, with respect to any Information, Patent or other intellectual property right, possession by a party of the ability (whether by ownership, license or otherwise, but without taking into account any rights granted by one party to the other party under the terms of this Agreement) to grant access, a right to use, a license or a sublicense (as applicable) to such Information, Patent or other intellectual property right without violating the terms of any agreement or other arrangement with any Third Party.
  - 1.17 "CytRx" shall mean CytRx Corporation, a Delaware corporation located at 154 Technology Parkway, Technology Park/Atlanta, Norcross, GA 30092, USA.
- 1.18 "CytRx Agreement" shall mean that certain License Agreement, dated December 7, 2001, by and between Vical and CytRx, and any amendments made in accordance with its terms. A copy of the CytRx Agreement has been provided to Astellas under separate cover.
- 1.19 "Development Plan" shall mean the annual plan for preclinical and clinical development of Products in the Field, including the budget for such activities to be performed by Vical, and any amendment or modification to such plan, which plan (other than such plan agreed as of the Effective Date) is drafted by the JDC and approved by the JSC.
  - **1.20** "Effective Date" shall have the meaning provided in Section 12.15.
- 1.21 "EMA" shall mean the European Medicines Agency or any successor agency thereto having the administrative authority to regulate the marketing of human pharmaceutical products or biological therapeutic products in the European Union.
  - 1.22 "Excluded Claim" shall have the meaning provided in Section 12.3(c)(vi).
  - 1.23 "Excluded Product" shall have the meaning provided in Section 3.5(a).
  - 1.24 "Executives" shall have the meaning provided in Section 2.1(d).
- 1.25 "Field" shall mean all therapeutic and prophylactic use to control or prevent CMV infection in (a) Immunocompromised Patients, including HSCT Recipients and SOT Recipients, and (b) human transplant donors, but excluding, in each case, any therapeutic or prophylactic use to control or prevent CMV infection other than as expressly described in clauses (a) and (b).
- 1.26 "First Commercial Sale" shall mean, with respect to a Product, the first sale for end use to a Third Party in a country in the Territory after the applicable Regulatory Authority has granted Regulatory Approval in such country.
- 1.27 "Generic Product" shall mean, on a country-by-country basis, a product that is introduced in the applicable country in the Territory by an entity other than Astellas or a Sublicensee or their respective Affiliates, which (i) contains the same or equivalent (by EMA or other applicable Regulatory Authority standards, on a country-by-country basis) therapeutically and/or prophylactically active ingredient(s) in the same dosage form, route of administration, and

strength or concentration as a Product sold by Astellas or a Sublicensee or their respective Affiliates in such country, (ii) has been granted Regulatory Approval by an abridged procedure pursuant to and in accordance with Article 10 of Directive 2001/83/EC (or equivalent legislation in the Territory) in reliance in whole or in part on the prior Regulatory Approval of a Product or the safety and efficacy data generated for the prior Regulatory Approval for such Product, or (iii) has been granted regulatory approval by a procedure pursuant to and in accordance with Article 10a of Directive 2001/83/EC (or equivalent legislation in the Territory).

- 1.28 "HSCT" shall mean transplantation of hematopoietic stem cells, including peripheral blood stem cells, cord blood stem cells and bone marrow.
- 1.29 "HSCT Recipient" shall mean a human recipient in a HSCT.
- 1.30 "HSR Act" shall have the meaning provided in Section 12.15.
- 1.31 "HSR Filing Date" shall have the meaning provided in Section 12.15.
- 1.32 "ICC" shall have the meaning set forth in Section 12.3(c)(i).
- 1.33 "ICC Rules" shall have the meaning set forth in Section 12.3(c)(i).
- 1.34 "IFRS" shall mean the International Financial Reporting Standards.
- 1.35 "Immunocompromised Patients" shall mean human patients whose immune system is not functioning normally because of an immunodeficiency disorder or other disease, or as the result of the administration of immunosuppressive drugs or other drugs that may indirectly cause a reduction of the immune system function. For the avoidance of doubt, elderly patients and pregnant women shall not be deemed Immunocompromised Patients solely because such patients are elderly or pregnant, respectively.
- 1.36 "Information" shall mean all tangible and intangible (a) techniques, technology, practices, trade secrets, inventions (whether patentable or not), methods, protocols, processes, knowledge, know-how, skill, experience, information, data and results (including pharmacological, toxicological, clinical, analytical and quality control data and results), regulatory filings, marketing reports, software and algorithms and (b) compositions of matter, cells, cell lines, assays, animal models and physical, biological or chemical material.
  - 1.37 "[...\*\*\*...]" shall have the meaning set forth in Section [...\*\*\*...].
  - 1.38 "JDC" shall have the meaning set forth in Section 2.2.
  - 1.39 "JSC" shall have the meaning set forth in Section 2.1.
  - 1.40 "Losses" shall have the meaning provided in Section 11.1.
- 1.41 "MAA" shall mean a marketing authorization application or equivalent application, and all amendments and supplements thereto, filed with the applicable Regulatory

Authority in a country or jurisdiction in the Territory (including any supra-national agency such as the EMA in the European Union).

- 1.42 "Major Markets" shall mean [...\*\*\*...], and "Major Market" shall mean any of the foregoing.
- 1.43 "[...\*\*\*...]" shall have the meaning set forth in Section [...\*\*\*...].
- **1.44 "Manufacturing Coordinators"** shall have the meaning set forth in Section 2.7.
- 1.45 "Manufacturing Plan" shall mean (a) the annual plan for (i) CMC activities (including, without limitation, formulation, analytical and process development, and scale-up, stability, packaging and shipping studies) with respect to Compound and Products in the Field and (ii) the manufacture of Compound and Products in the Field and (b) any amendment or modification to such plan, which plan (other than such plan agreed as of the Effective Date) is drafted by the Manufacturing Coordinators and approved by the JSC during the term of the Services Agreement.
- 1.46 "Net Sales" shall mean the gross amounts invoiced by Astellas and/or its Sublicensees for sales or other dispositions of Products to Third Parties in the Territory, less the following items, as allocable to such Products (if not previously deducted from the amount invoiced): (a) trade, quantity and cash discounts, credits or allowances; (b) credits or allowances additionally granted upon returns, rejections or recalls or for retroactive price reductions and billing errors; (c) rebates, discounts and chargeback payments in any form granted to managed health care organizations, pharmacy benefit managers (or equivalents thereof), national, state/provincial, local, and other governments, their agencies and purchasers and payers/reimbursers, or to trade customers; (d) freight, shipping and insurance charges directly related to the distribution of Products; and (e) taxes, duties or other governmental tariffs (other than income taxes). Net Sales (including Net Sales for the Combination Product) will be calculated on a country-by-country basis.

Upon any sale or other disposition of any Product for any consideration other than exclusively monetary consideration on bona fide arm's-length terms, for purposes of calculating Net Sales under this Agreement, such Product shall be deemed to be sold exclusively for money at the average sales price during the applicable reporting period generally achieved for such Product in the country in which such sale or other disposition occurred when such Product is sold alone and not as part of a Combination Product.

In no event will any particular amount, identified above, be deducted more than once in calculating Net Sales. Sales of a Product between Astellas or its Sublicensees and their Subdistributors exclusively for monetary consideration on bona fide arm's length terms at fair market value shall be included in the computation of Net Sales, and for clarity the subsequent resale by a Subdistributor of such Product to a Third Party shall be excluded from the computation of Net Sales. Sales of a Product between Astellas and its Sublicensees (which are not Subdistributors) for resale shall be excluded from the computation of Net Sales, but the subsequent resale of such Product to a Third Party shall be included within the computation of

Net Sales. Any free-of-charge disposal or use of a Product for development, regulatory or marketing purposes, such as clinical trials, compassionate use or indigent patient programs, shall not be deemed a sale or disposition for purposes of calculating Net Sales.

In the case of a Combination Product, Net Sales for such Combination Product shall be calculated by multiplying actual Net Sales of such Combination Product by the fraction A/(A+B) where A is the invoice price of the Product that contains one or more Compound(s) as the sole active ingredient(s), if sold separately, and B is the total invoice price of the other active ingredient(s) in the Combination Product, if sold separately. If, on a country-by-country basis, the other active ingredient(s) in the Combination Product is not sold separately in such country, Net Sales for the purpose of determining royalties of the Combination Product shall be calculated by multiplying actual Net Sales of such Combination Product by the fraction A/D, where A is the average invoice price of the Product that contains one or more Compound(s) as the sole active ingredient(s) is not sold separately in a given country, the parties shall determine Net Sales for such Combination Product by mutual agreement based on the relative contribution of the Product that contains one or more Compound(s) as the sole active ingredient(s) in the Combination Product.

Net Sales will be calculated in accordance with this definition and Astellas' accounting policies generally consistent with IFRS on an accrual basis, as consistently applied. To the extent any accrued amounts used in the calculation of Net Sales are estimates, such estimates shall be trued-up in accordance with Astellas' accounting policies generally consistent with IFRS, as consistently applied, and Net Sales and related payments under this Agreement shall be reconciled as appropriate.

- 1.47 "Patent Term Extension" shall have the meaning provided in Section 7.3.
- 1.48 "Patents" shall mean (a) all patents, including design patents, certificates of invention, applications for certificates of invention, priority patent filings and patent applications, including provisional patent applications and design patent applications, and (b) any renewal, divisional, continuation, continuation-in-part, or request for continued examination of any of such patents, certificates of invention and patent applications, and any and all patents or certificates of invention issuing thereon, and any and all reissues, reexaminations, extensions, certificates of correction, divisions, renewals, substitutions, confirmations, registrations, revalidations, revisions, and additions of or to any of the foregoing.
- 1.49 "Phase 3 Clinical Trial" shall mean a pivotal clinical trial of a Product conducted in human patients in any country designed to ascertain efficacy and safety of such Product for the purpose of submitting an application for Regulatory Approval to the competent Regulatory Authority in the Territory.
  - **1.50** "[...\*\*\*...]" shall have the meaning set forth in Section [...\*\*\*...].
- 1.51 "Product" shall mean any pharmaceutical product that contains one or more Compound(s), alone or as a Combination Product, including, in each case, all formulations, line

extensions and modes of administration, including any pharmaceutical product containing any formulation of one or more Compound(s) with poloxamer CRL1005, but excluding, in each case, any formulation with the Vaxfectin Adjuvant.

- 1.52 "Regulatory Approval" shall mean any and all approvals (including individual and national price and reimbursement approvals, as applicable), licenses, registrations, or authorizations of any country, federal, supranational, state or local regulatory agency, department, bureau or other governmental entity that are necessary to market and sell a Product in the Field in any country or regulatory jurisdiction in the Territory.
- 1.53 "Regulatory Authority" shall mean any national, federal, supra-national, regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity whose review and/or approval is necessary for the manufacture, packaging, use, storage, import, export, distribution, promotion, marketing, offer for sale and sale of a Product in the Field in a country or regulatory jurisdiction in the Territory.
  - 1.54 "Representatives" shall have the meaning provided in Section 12.1.
  - 1.55 "Reserved Product" shall have the meaning provided in Section 3.5(b).
  - 1.56 "Restricted Period" shall have the meaning provided in Section 3.5(c).
  - 1.57 "Royalty Term" shall have the meaning provided in Section 5.3(b).
  - 1.58 "Sale" shall have the meaning provided in Section 12.7(a).
- 1.59 "Services Agreement" shall mean that certain Supply and Services Agreement of even date herewith by and between Vical and Astellas, as amended in accordance with its terms.
  - 1.60 "SOT" shall mean solid organ transplantation.
  - 1.61 "SOT Recipient" shall mean a human recipient in a SOT.
  - 1.62 "Standstill Period" shall have the meaning provided in Section 12.1.
  - **1.63** "[...\*\*\*...]" shall have the meaning set forth in Section [...\*\*\*...].
- **1.64** "Subdistributor" shall mean a Third Party appointed by Astellas or one of its Sublicensees as a distributor of Product which Third Party purchases Product in the Territory from Astellas or its Sublicensee and resells and distributes (including registration, promotion and marketing) the Product in its respective territory.
  - **1.65** "Sublicense Agreement' shall have the meaning provided in Section 3.2.
- 1.66 "Sublicensee" shall mean a Third Party or Affiliate to whom Astellas has granted a sublicense of the right to research, develop, make, have made, use, sell, offer for sale, have sold or import a Product in the Field in the Territory, beyond the mere right to purchase such Product.

- **1.67** "Term" shall have the meaning provided in Section 10.1.
- 1.68 "Territory" shall mean the world, excluding the United States of America and its territories and possessions, including Puerto Rico and the District of Columbia.
- 1.69 "Third Party" shall mean any entity other than Vical or Astellas or an Affiliate of Vical or Astellas.
- 1.70 "U.S. Agreement" shall mean that certain U.S. License Agreement of even date herewith by and between Vical and Astellas, as amended in accordance with its terms
- 1.71 "Valid Claim" shall mean a claim of an issued patent or pending patent application within the Vical Primary Patents that has not been revoked or held unenforceable or invalid by a decision of a court or governmental agency of competent jurisdiction from which no appeal can be taken, or with respect to which an appeal is not taken within the time allowed for appeal, and that has not been abandoned, disclaimed or admitted to be invalid or unenforceable through reissue, disclaimer, or otherwise.
- 1.72 "Vaxfectin Adjuvant" shall mean Vical's proprietary cationic lipid-based system known as Vaxfectin® comprising (±)-N-(3-aminopropyl)-N,N-dimethyl-2,3-bis(syn-9-tetradeceneyloxy)-1-propanaminium bromide (GAP-DMORIE) or derivatives thereof and one or more co-lipid(s), including 1,2-diphytanoyl-sn-glycero-3-phosphoethanolamine (DPyPE), which is claimed or disclosed in a Patent Controlled by Vical.
  - 1.73 "Vical Indemnitee" shall have the meaning provided in Section 11.2.
- 1.74 "Vical Know-How" shall mean Information not included in the Vical Patents that Vical Controls on the Effective Date or during the Term, which Information is necessary or useful for the development, registration, manufacture, use, promotion, distribution, offer for sale, sale import or export of Compounds or Products in the Field in the Territory, including any Information Controlled by Vical regarding poloxamer CRL1005 under which Vical has an exclusive license pursuant to the CytRx Agreement, and any replication or any part of any of the foregoing. For clarification, in the case of a Combination Product, Vical Know-How does not include any Information Controlled by Vical relating to any therapeutically and/or prophylactically active ingredient in such Combination Product other than a Compound.
- 1.75 "Vical Patents" shall mean all Patents that Vical Controls as of the Effective Date or during the Term, which Patents claim the composition of matter of, or any method of making or using, Compounds or Products in the Field in the Territory, including the Vical Primary Patents. For clarification, in the case of a Combination Product, Vical Patents do not include any Patents Controlled by Vical, which Patents relate to any therapeutically and/or prophylactically active ingredient in such Combination Product other than a Compound. The Vical Patents as of the Effective Date are listed on EXHIBIT A.
- 1.76 "Vical Primary Patents" shall mean (a) [...\*\*\*...], and such other Vical Patents as the parties agree to include in this subsection (a) pursuant to the last sentence of this Section 1.76, (b) corresponding foreign

Patents in the Territory, whether now existing or hereafter filed and (c) any renewal, divisional, continuation, continuation-in-part, or request for continued examination of any of such patents, including provisional patent applications, and any and all patents or certificates of invention issuing thereon, and any and all reissues, reexaminations, extensions, certificates of correction, divisions, renewals, substitutions, confirmations, registrations, revisions, and additions of or to any of the foregoing. Without limiting the foregoing, if at any time during the Term the parties mutually agree in writing that any Vical Patent other than the Patents set forth above can maintain market exclusivity of a Product in the Field in such country or countries in the Territory, such Vical Patent shall thereafter be regarded as a Vical Primary Patent and shall automatically be included in Section 1.76(a) above with respect to such country or countries. For clarity, if the parties cannot mutually agree regarding whether any other Vical Patent shall be included as a Vical Primary Patent, such disagreement shall not be subject to arbitration as set forth in Section 12.3(c) and such Vical Patent shall not be a Vical Primary Patent.

- 1.77 "Vical Reserved Product" shall have the meaning provided in Section 3.5(b).
- 1.78 "Vical Retained Product" shall have the meaning provided in Section 3.5(a).
- 1.79 "Vical Technology" shall mean the Vical Patents and Vical Know-How.
- **1.80 "Withdrawal Notice"** shall have the meaning provided in Section 2.6.

### 2. GOVERNANCE

- **2.1 Joint Steering Committee.** For purposes of this Agreement and the U.S. Agreement, the parties will establish one joint steering committee (the "JSC") to oversee the activities of the parties with respect to development, regulatory, manufacturing and commercialization matters relating to Products in the Field.
- (a) Composition. The JSC will be comprised of three (3) members appointed by Astellas and three (3) members appointed by Vical, or such other equal number of members of each party agreed by Astellas and Vical. Each party will notify the other party of its initial JSC members within thirty (30) days after the Effective Date. Each party may change its JSC members at any time by written notice to the other party, which may be delivered at a scheduled meeting of the JSC. Any member of the JSC may designate a substitute to attend and perform the functions of that member at any meeting of the JSC. The JSC shall appoint for each meeting a Vical member or an Astellas member, on an alternating basis, as chairman for such meeting, whose role shall be to (i) provide written notice to the JSC members of agenda items proposed for discussion or decision at such meeting at least ten (10) days prior to such JSC meeting, together with appropriate information related thereto, and (ii) convene and preside at such meeting of the JSC; provided, however, that the chairman shall not be entitled to prevent items from being discussed or to cast any tie-breaking vote. Each party may, with the consent of the other party, such consent not to be unreasonably withheld or delayed, invite non-member, non-voting representatives of such party to attend meetings of the JSC.
- (b) Responsibilities. The JSC shall be responsible for monitoring and providing strategic oversight of the parties' activities with respect to development, regulatory,

manufacturing and commercialization matters relating to Products in the Field. Without limiting the foregoing, the JSC shall:

- (i) review and approve the Development Plan and the Manufacturing Plan (including any amendments thereto);
- (ii) review (but not approve) the Commercialization Plan (including any amendments thereto);
- (iii) provide a forum in which Astellas updates Vical, and Vical provides input, with regard to development, regulatory, manufacturing and commercialization matters relating to Products in the Field;
- (iv) facilitate the exchange of data and other Information between the parties with regard to development, regulatory, manufacturing and commercialization matters relating to Products in the Field; and
  - (v) perform such other duties as are specifically assigned by the parties to the JSC in this Agreement or any other written agreement between the parties.
- (c) Meetings. The JSC will hold meetings at such frequency as determined by the JSC members, but no less than once every six (6) months. Such meetings may be in person, via videoconference, or via teleconference. The location of in-person JSC meetings will alternate between Vical's offices in San Diego, California and Astellas' offices in Deerfield, Illinois unless the parties otherwise agree.
- (d) Decision-Making. The JSC may make decisions with respect to any subject matter that is within the JSC's decision-making authority. Subject to this Section 2.1(d), all decisions of the JSC shall be made by unanimous vote, with the representatives of Vical on the JSC collectively having one vote and the representatives of Astellas on the JSC collectively having one vote in all such decisions. If the JSC cannot make a decision with regard to any matter to be decided by the JSC within fifteen (15) days after such matter has been brought to the JSC's attention, then such matter shall be referred to the Chief Executive Officer of Vical and a senior executive of Astellas who reports directly to the Chief Executive Officer of Astellas (the Chief Executive Officer of Vical and such senior executive of Astellas, collectively, the "Executives") for resolution. If the Executives cannot resolve the issue within thirty (30) days after the matter has been brought to their attention then, subject to good faith consideration of the views of Vical, and subject to Section 2.4, Astellas' Executive shall have the tie-breaking vote on such matter.
- **2.2 Joint Development Committee.** For purposes of this Agreement and the U.S. Agreement, the parties will establish one joint development committee (the "JDC") with respect to development of Products in the Field.
- (a) Composition. The JDC will be comprised of three (3) members appointed by Astellas and three (3) members appointed by Vical, or such other equal number of members of each party agreed by Astellas and Vical. Each party will notify the other party of its

initial JDC members within thirty (30) days after the Effective Date. Each party may change its JDC members at any time by written notice to the other party, which may be delivered at a scheduled meeting of the JDC. Any member of the JDC may designate a substitute to attend and perform the functions of that member at any meeting of the JDC. The JDC shall appoint for each meeting a Vical member or an Astellas member, on an alternating basis, as chairman for such meeting, whose role shall be to (i) provide written notice to the JDC members of agenda items proposed for discussion or decision at such meeting at least ten (10) days prior to such JDC meeting, together with appropriate information related thereto, and (ii) convene and preside at such meeting of the JDC; provided, however, that the chairman shall not be entitled to prevent items from being discussed or to cast any tie-breaking vote. Each party may, with the consent of the other party, such consent not to be unreasonably withheld or delayed, invite non-member, non-voting representatives of such party to attend meetings of the JDC.

- **(b) Responsibilities.** The JDC shall be responsible for oversight of the progress of the parties' activities with respect to development of Compounds and Products in the Field. Without limiting the foregoing, the JDC shall:
- (i) draft the Development Plan (including any amendments thereto) for approval by the JSC, and provide a forum for review and discussion of the Development Plan;
  - (ii) provide a forum for review and discussion of the results of the development of Compounds and Products in the Field;
  - (iii) facilitate the exchange of Information between the parties regarding the development of Compounds and Products in the Field; and
  - (iv) perform such other duties as are specifically assigned by the JSC to the JDC.
- (c) Meetings. The JDC will hold meetings at such frequency as determined by the JDC members, but no less than once each Calendar Quarter. Such meetings may be in person, via videoconference, or via teleconference. The location of in-person JDC meetings will alternate between Vical's offices in San Diego, California and Astellas' offices in Deerfield, Illinois unless the parties otherwise agree.
- (d) Decision-Making. The JDC may make decisions with respect to any subject matter that is within the JDC's decision-making authority. Subject to this Section 2.2(d), all decisions of the JDC shall be made by unanimous vote, with the representatives of Vical on the JDC collectively having one vote and the representatives of Astellas on the JDC collectively having one vote in all such decisions. If the JDC cannot make a decision with regard to any matter to be decided by the JDC within fifteen (15) days after such matter has been brought to the JDC's attention, then such matter shall be referred to the JSC for resolution in accordance with Section 2.1(d).
- 2.3 Minutes. Reasonably detailed written minutes will be kept of all Committee meetings and will reflect material decisions made at such meetings. Minutes for each meeting of

each Committee will be prepared by the chairman of such meeting and such minutes shall be sent to each member of the respective Committee for review and approval within ten (10) days after the meeting. Minutes will be deemed approved unless a member of the respective Committee objects to the accuracy of such minutes within fifteen (15) days of receipt.

- 2.4 Scope of Decision-Making. Neither Committee nor any Executive in the course of resolving any dispute of the JSC shall have any right or power to amend this Agreement, to decide any matter in contravention of any terms of this Agreement or to change any rights or obligations of either party under this Agreement. Without limiting the foregoing, neither Committee nor any Executive in the course of resolving any dispute of the JSC shall have the right or power to (a) require Vical to perform studies or other development work that is not expressly agreed in writing by Vical and Astellas, or (b) require Vical to incur expenses other than as set forth in this Agreement or otherwise expressly agreed in writing by Vical and Astellas.
- 2.5 Expenses. Each party shall bear all its own costs in connection with its participation in the Committees, including expenses incurred by the members that it appoints to the Committees in connection with their activities as members of the Committees.
- 2.6 Withdrawal. At any time during the Term and for any reason, Vical shall have the right to withdraw from participation in either Committee or both Committees upon written notice to Astellas, which notice shall be effective immediately upon receipt ("Withdrawal Notice"). Following the issuance of a Withdrawal Notice and subject to this Section 2.6, Vical's representatives on the applicable Committee(s) shall not participate in any meetings of the applicable Committee(s), nor shall Vical have any right to vote on decisions within the authority of the applicable Committee(s). If, at any time, following the issuance of a Withdrawal Notice, Vical wishes to resume participation in the applicable Committee(s), vical shall notify Astellas in writing and, thereafter, Vical's representatives on the applicable Committee(s) shall be entitled to attend any subsequent meeting of the applicable Committee(s) as if a Withdrawal Notice had not been issued by Vical. Following Vical's issuance of a Withdrawal Notice, unless and until Vical resumes participation in the applicable Committee(s) in accordance with this Section 2.6: (a) all meetings of the Committee(s) shall be held at Astellas' facilities; (b) Astellas shall have the right to make the final decision on all matters within the scope of authority of the Committee(s); and (c) Vical shall have the right to continue to receive the minutes of the Committee(s) meetings, but shall not have the right to approve the minutes for any meeting of the applicable Committee(s) held after Vical's issuance of a Withdrawal Notice. For clarity, if Vical withdraws and then resumes participation in a Committee, it shall not have any right to retroactively review or modify any decision made by the Committee during Vical's withdrawal period.
- 2.7 Manufacturing Coordinators. Promptly after the Effective Date, each party shall appoint an individual to act as the manufacturing coordinator for such party (the "Manufacturing Coordinator"). The Manufacturing Coordinators shall be the primary contacts of the parties regarding the manufacture of Compounds and Products in the Field (including CMC activities such as formulation, analytical and process development, and scale-up, stability, packaging and shipping studies), draft the Manufacturing Plan (including any amendments thereto) for approval by the JSC and otherwise facilitate the exchange of Information between

the parties regarding the manufacture of Compounds and Products in the Field. The Manufacturing Coordinators will meet at such frequency as determined by the Manufacturing Coordinators, but no less than once every six (6) months. Each Manufacturing Coordinator shall be permitted to attend meetings of the JSC as non-voting participants. Each party may replace its Manufacturing Coordinator with an alternative representative at any time with prior written notice to the other party.

### 3. LICENSES AND OTHER RIGHTS

- 3.1 License and Sublicense Grant. Subject to the terms and conditions of this Agreement, Vical hereby grants to Astellas an exclusive (even as to Vical and its Affiliates, but subject to Vical's performance of such development, regulatory and manufacturing activities as agreed in writing by the parties), royalty-bearing license and sublicense, with the right to sublicense in accordance with Section 3.2, under the Vical Technology, to research, develop, register, make, have made, use, promote, distribute, sell, offer for sale, have sold, import and export Products in the Field in the Territory.
- 3.2 Sublicensing. Astellas shall have the right to grant sublicenses under the license granted in Section 3.1 to one or more Third Parties or Affiliates subject to the provisions of this Section 3.2. Each agreement under which Astellas grants a sublicense under the license granted in Section 3.1 (each, a "Sublicense Agreement") shall (a) be in writing and (b) be consistent with, and subject to the terms and conditions of, this Agreement (including the terms relating to sublicenses of Vical Technology licensed or conveyed to Vical under the CytRx Agreement, as applicable). Astellas shall be responsible for compliance of any Sublicensee with this Agreement. Any breach of this Agreement by the acts or omissions of a Sublicensee shall be a breach of this Agreement by Astellas. Astellas shall provide Vical with a full and complete copy of each Sublicense Agreement with a Third Party (and if required by the CytRx Agreement, each Sublicense Agreement with an Affiliate) within [...\*\*\*...] ([...\*\*\*...]) days after execution thereof; provided, that Astellas may redact any confidential information contained therein that is not necessary to disclose to ensure compliance with this Agreement.
- 3.3 In-License Agreements. Astellas acknowledges that the Vical Technology licensed or otherwise conveyed to Vical under the CytRx Agreement is subject to the applicable terms and conditions of the CytRx Agreement. In the event that CytRx notifies Vical of a default or breach under the CytRx Agreement related to any failure by Astellas or any Sublicensee to perform any obligation or covenant under this Agreement, the parties will discuss how to resolve the matter and, if the parties agree to a proposed resolution of the matter, they will cooperate in responding to CytRx. If Astellas does not resolve such matter as agreed by the parties, or if the parties do not agree to a resolution of the matter, then Vical shall have the right, but not the obligation, to take such actions as reasonably necessary or appropriate to cure such default or breach and shall keep Astellas reasonably informed regarding such actions, and Astellas shall promptly reimburse Vical for all reasonable costs and expenses actually incurred by Vical solely as a result of such default or breach by Astellas or any Sublicensee. In the event Vical receives from CytRx notice of termination of the CytRx Agreement, Vical shall notify Astellas thereof within [...\*\*\*...] (l...\*\*\*...] days after receipt by Vical of such notice. Vical shall have no liability to Astellas for any termination or modification of the CytRx Agreement arising out of or resulting from the failure of Astellas or any Sublicensee to abide by, comply with or perform under the

terms, conditions or obligations of this Agreement. In addition, in the event the rights to the Vical Technology licensed to Vical under the CytRx Agreement cease to be licensed to Vical under the CytRx Agreement and Astellas obtains a license with respect to such Vical Technology directly from CytRx, then Astellas may deduct from the applicable payments owed to Vical hereunder the amount actually paid by Astellas to CytRx for such license with respect to such Vical Technology up to the amount that Vical would have been obligated to pay to CytRx under the CytRx Agreement with respect to such payment.

3.4 Disclosure of Vical Know-How. Upon Astellas' request, Vical shall make available to Astellas Vical Know-How in Vical's possession that has not previously been provided to Astellas, including any raw data and/or original data relating to Compounds and Products in the Field; provided that any Vical Know-How relating to the manufacture of Compounds and Products in the Field shall be made available through a technology transfer arrangement as provided in the Services Agreement. Vical shall not destroy, discard or otherwise dispose of or shall have not destroyed, discarded or otherwise disposed of any Vical Know-How without prior written approval of Astellas, which approval shall not be unreasonably withheld.

## 3.5 Agreements.

(a) By Vical. During the Term, Vical shall not, directly or indirectly through any Affiliate or Third Party, market, promote, distribute, offer for sale or sell, or grant any license or sublicense under the Vical Technology to market, promote, distribute, offer for sale or sell, (i) any Product that contains any formulation of one or more Compound(s) with poloxamer CRL1005 (an "Excluded Product") outside the Field in the Territory or (ii) any pharmaceutical product that contains any formulation of one or more Compound(s) with the Vaxfectin Adjuvant, alone or in combination with one or more other therapeutically antd/or prophylactically active ingredients, in any dosage form or mode of administration (a "Vical Retained Product") in the Field in the Territory; provided, however, that nothing shall prevent Vical from, directly or indirectly through any Affiliate or Third Party, marketing, promoting, distributing, offering for sale or selling, or granting any license or sublicense under the Vical Technology to market, promote, distribute, offer for sale or sell, any Vical Retained Product so long as Vical or such Affiliate or Third Party does not market or promote the Vical Retained Product for use in the Field in the Territory.

(b) Reserved Products. The provisions of this Section 3.5(b) shall apply with respect to any Product other than an Excluded Product (a"Reserved Product") outside the Field in the Territory. Vical retains all rights, directly or indirectly through any Affiliate or Third Party, to research, develop, market, promote, distribute, offer for sale or sell, or grant any license or sublicense under the Vical Technology to research, develop, market, promote, distribute, offer for sale or sell, any Reserved Product outside the Field in the Territory, subject to this Section 3.5(b) (any such Reserved Product with respect to which Vical has retained rights, a "Vical Reserved Product"). Astellas may notify Vical in writing that it proposes to designate any Reserved Product as an "Astellas Reserved Product," specifying whether such Reserved Product would contain a Compound alone, a Compound formulated with an adjuvant (identifying the adjuvant) or a Compound administered through a delivery system (identifying the delivery system). Astellas may provide such written request at any time after it or its

Sublicensee has initiated good laboratory practices preclinical studies of such Reserved Product. The Reserved Product specified in such written notice from Astellas shall be deemed an Astellas Reserved Product unless Vical provides written notice to Astellas within thirty (30) days after Vical's receipt of such written notice from Astellas that Vical has granted a license or similar rights with respect to such Product to a Third Party or has initiated good laboratory practices preclinical studies of such Reserved Product, in which case such Reserved Product shall not be an Astellas Reserved Product and shall remain a Vical Reserved Product. During the Term for so long as Astellas uses Commercially Reasonable Efforts to develop, manufacture and commercialize an Astellas Reserved Product, Vical shall not, directly or indirectly through any Affiliate or Third Party, market, promote, distribute, offer for sale or sell, or grant any license or sublicense under the Vical Technology to market, promote, distribute, offer for sale or sell, such Astellas Reserved Product outside the Field in the Territory.

(c) By Astellas. During the Term, Astellas shall not, directly or indirectly through any Affiliate or Third Party, market, promote, distribute, offer for sale or sell, or grant any license or sublicense to market, promote, distribute, offer for sale or sell, any DNA vaccine product for use in the Field in the Territory, other than Products in the Field in the Territory (a "Competitive Product"). Further, Astellas agrees not to practice any Vical Technology except to develop, register, make, have made, use, promote, distribute, sell, offer for sale, have sold, import and export Products in the Field in the Territory during the Term in accordance with the terms of this Agreement and any other written agreement between the parties. If Astellas or any of its respective Affiliates signs a definitive agreement whereby it would acquire a license to or ownership of a Competitive Product, acquire ownership or control of or otherwise merge with an entity that owns or has a license to (or is commercializing for its own account) a Competitive Product or be acquired by or otherwise merged with an entity that owns or has a license to (or is commercializing for its own account) a Competitive Product or be acquired by or otherwise merged with an entity that owns or has a license to (or is commercializing for its own account) a Competitive Product or be acquired by or otherwise merged with an entity that owns or has a license to (or is commercializing for its own account) a Competitive Product, in all such cases that would result in a violation of this Section 3.5(c), then Astellas or its Affiliate shall promptly notify Vical in writing and, as promptly as reasonably possible but in no event later than [...\*\*\*...] after the signing date of such definitive agreement ("Restricted Period"), either (i) divest itself of such Competitive Product and notify Vical in writing of such divesture, or (ii) notify Vical in writing that such Competitive Product shall be a Product subject to the terms and conditions of this Agreement. If Astel

3.6 Retained Rights; No Implied Licenses. Except for the rights and licenses expressly granted in this Agreement, Vical retains all rights under the Vical Technology, and no rights shall be deemed granted by Vical to Astellas by implication, estoppel or otherwise.

### 4. DEVELOPMENT AND COMMERCIALIZATION OF PRODUCTS

**4.1 Development of Products in the Field in the Territory.** Subject to the terms and conditions of this Agreement, during the Term, Astellas shall be solely responsible for the development of and obtaining Regulatory Approvals for Products in the Field in the Territory, including all costs associated with such activities, subject to the terms of any written agreement

between the parties providing for Vical to perform any such activities. Without limiting the foregoing, Astellas shall have sole responsibility, at Astellas' cost and expense, for conducting clinical and non-clinical studies of Products in the Field in the Territory and for preparing, filing, obtaining and maintaining the appropriate applications with Regulatory Authorities, and for all contacts with Regulatory Authorities, regarding Products in the Field in the Territory. Astellas shall use Commercially Reasonable Efforts to develop, and to file for, obtain and maintain Regulatory Approvals for, at least one Product [...\*\*\*...] and at least one Product [...\*\*\*...] in the Field [...\*\*\*...]. Astellas shall perform all development and regulatory activities with respect to Products in the Field in the Territory in compliance with the Development Plan and all applicable laws, rules and regulations. Furthermore, Astellas shall be solely responsible for the timely reporting of all relevant adverse drug reactions/experiences, Product quality, Product complaints and safety data relating to Compounds and Products, in each case in the Field, to the appropriate Regulatory Authorities in accordance with the applicable laws, rules and regulations of the relevant countries and Regulatory Authorities. Prior to commencement of the first Phase 3 Clinical Trial, Vical shall complete transfer from Vical to Astellas of the global safety database with respect to Compounds and Products in the Field. In addition, each party shall cooperate, and shall cause its Affiliates, licensees and Sublicensees to cooperate, in implementing and adhering to a safety data exchange arrangement with respect to Compounds and Products in the Territory that shall be set forth in a safety data exchange agreement executed by the parties.

- 4.2 Commercialization of Products in the Field in the Territory. Subject to the terms and conditions of this Agreement, during the Term, Astellas shall be solely responsible for the commercialization of Products in the Field in the Territory, including any post-marketing studies of Products in the Field in the Territory, including all costs associated with such activities. Astellas shall use Commercially Reasonable Efforts to commercialize at least one Product [...\*\*\*\*...] and at least one Product [...\*\*\*...] in the Field [...\*\*\*\*...]. Within a reasonable time prior to anticipated commercial launch of a Product, Astellas shall prepare a plan for the marketing, promotion and commercialization of such Product in the Field in the Territory, which plan shall be in reasonable scope and detail and may be amended by Astellas (the "Commercialization Plan"). Astellas shall provide, or cause to be provided, the Commercialization Plan to the JSC for review on an annual basis and shall provide, or cause to be provided, any material amendments to the Commercialization Plan to the JSC for review. Astellas shall perform all commercialization activities with respect to Products in the Field in the Territory in compliance with the Commercialization Plan and all applicable laws, rules and regulations. Without limiting the foregoing, Astellas shall have the sole right and responsibility for all commercial and medical affairs matters with respect to Products in the Field in the Territory.
- 4.3 Manufacture and Supply of Products. Subject to the terms and conditions of this Agreement and the Services Agreement, during the Term, Astellas shall be solely responsible for the manufacture and supply of Products in the Field in the Territory, including CMC-related work necessary for obtaining Regulatory Approval for Products in the Field in the Territory, including all costs associated with such activities. Astellas shall perform all

manufacturing activities with respect to Products in the Field in the Territory in compliance with the Manufacturing Plan and all applicable laws, rules and regulations.

- 4.4 Disclosure Regarding Astellas' Efforts. Astellas shall keep Vical regularly and fully informed regarding development, regulatory, manufacturing and commercialization activities of Astellas and its Sublicensees with respect to Products in the Field in the Territory. Without limiting the foregoing, Astellas shall keep Vical reasonably informed of the progress of such activities, through the JSC, the JDC and directly, and shall, within [...\*\*\*...] after the end of each Calendar Year during the Term, provide Vical a report setting forth a reasonably detailed description of the progress and status of development, manufacture and commercialization of, and regulatory strategy and filings made and Regulatory Approvals obtained for, Products in the Field in the Territory, and a reasonably detailed description of the development, manufacture, commercialization and regulatory activities that Astellas plans to undertake during the subsequent Calendar Year.
- 4.5 Subcontractors. Astellas may perform some or all of its obligations under this Article 4 through one or more subcontractors (which may include Vical). Astellas shall remain responsible for the performance by any Third Party subcontractors and the compliance of such Third Party subcontractors with the provisions of this Agreement in connection with such performance.

# 5. FEES AND PAYMENTS

- 5.1 Upfront Fee. Within thirty (30) days after the Effective Date, Astellas shall make a non-refundable, non-creditable payment to Vical of US\$[...\*\*\*...].
- **5.2 Milestone Payments.** Within thirty (30) days after the occurrence of each of the following milestone events, Astellas shall pay to Vical the corresponding non-refundable, non-creditable milestone payment set forth below (whether such milestone event is achieved by Astellas or any Sublicensee):

[***] US\$ [***]
[***]
[***] US\$ [***]

[...\*\*\*...]

[...\*\*\*...]

[***]	US\$[***]
[***]	
[***]	US\$[***]
[***]	

[...\*\*\*...]

Each of the milestone payments described in this Section 5.2 shall be payable one time for the first achievement of such milestone event by any applicable Product, regardless of the number of other Products that subsequently achieve such milestone event. For clarification, in the event two or more milestone events are achieved at the same time, the milestone payments for both milestone events shall be due.

### 5.3 Royalties.

- (a) Royalty Rate. Astellas shall pay Vical royalties equal to [...\*\*\*...] percent ([...\*\*\*...]%) of Net Sales of Products in the Field in the Territory.
- **(b) Royalty Term.** Royalties under this Section 5.3 shall be payable on a Product-by-Product and country-by-country basis during the period of time commencing on the First Commercial Sale of such Product in such a country in the Territory and ending upon the latest to occur of (i) expiration of the last to expire Valid Claim with respect to such Product (or any Compound therein) in such country, (ii) expiration of any data or other regulatory exclusivity period for such Product in such country or (iii) ten (10) years after the earliest date of First Commercial Sale of such Product for any indication in the Field in such country (the "*Royalty Term*").
- (c) Royalty Reduction. During any portion of the Royalty Term for a Product in a country in which there is no Valid Claim with respect to such Product in such country, (i) if a Generic Product is approved by the Regulatory Authority in such country and such Regulatory Authority reduces the reimbursement amount for such Product in such country by [...\*\*\*...] percent ([...\*\*\*...]%) or more of the reimbursement amount prior to approval of such Generic Product in such country, the royalty rate payable under Section 5.3(a) on Net Sales of such Product in such country during such portion of the Royalty Term shall be reduced by [...\*\*\*...] percent ([...\*\*\*...]%) (i.e., from [...\*\*\*...]% to [...\*\*\*...]%); or (ii) if a Generic Product is approved by the Regulatory Authority in such country but Section 5.3(c)(i) is not applicable, and sales of such Generic Product(s) in such country are equal to or greater than [...\*\*\*...] percent ([...\*\*\*...]%) of total unit number of such Product and the Generic Product(s) in such country for at least [...\*\*\*...] Calendar Quarters, the royalty rate payable under Section 5.3(a) on Net Sales of such Product in such country during such portion of the Royalty Term shall be reduced by [...\*\*\*...] percent ([...\*\*\*...]%) (i.e., from [...\*\*\*...]%) to [...\*\*\*...]%).
- **5.4 Payments to Third Parties.** Vical shall be responsible for any fees, milestone and royalty payments owed to CytRx under the CytRx Agreement. Except as provided in the preceding sentence, Astellas (or its Sublicensee) shall be responsible for any and all payments owed to any Third Party for any Patents, Information or other intellectual property rights licensed or acquired by Astellas (or its Sublicensee) after the Effective Date in order to develop,

make, have made, use, promote, distribute, sell, offer for sale, have sold or import any Product in the Field in the Territory (it being understood that the decision to license or acquire any such Patents, Information or other intellectual property rights shall be at Astellas' (or its Sublicensee's) discretion).

### 6. PAYMENT; RECORDS; AUDITS

- **6.1 Payment; Reports.** All payments due under this Agreement shall be paid within [...\*\*\*...] ([...\*\*\*...]) days of the end of each Calendar Quarter, unless otherwise specifically provided herein. Royalty payments shall be calculated and reported for each Calendar Quarter. Each royalty payment due to Vical shall be accompanied by a report of Net Sales by Astellas and its Sublicensees, each in sufficient detail to permit confirmation of the accuracy of the payment made, including, without limitation and on a country-by-country basis, the number of Products sold, the gross sales with reconciliation to Net Sales of such Products, the royalties payable, the method used to calculate the royalties, and the exchange rates used.
- 6.2 Exchange Rate; Manner and Place of Payment. All payments hereunder shall be payable in U.S. dollars. When conversion of payments from any foreign currency is required, such conversion shall be at an exchange rate equal to the weighted average of the rates of exchange (i.e. the average of TTS rate and TTB rate) for the currency of the country from which the royalties are payable as published by the Bank of Tokyo Mitsubishi UFJ, Ltd. in Japan (or such other bank or source agreed in writing by the parties), during the Calendar Quarter for which a payment is due. All payments owed under this Agreement shall be made by wire transfer in immediately available funds to a bank account designated in writing by Vical, unless otherwise specified in writing by Vical.
- **6.3 Income Tax Withholding.** Each party will pay any and all taxes levied on account of any payments made to it under this Agreement. If any taxes are required to be withheld by the paying party, the paying party will (a) deduct such taxes from the payment made to the other party, (b) timely pay the taxes to the proper taxing authority, and (c) send proof of payment to the other party and certify its receipt by the taxing authority within thirty (30) days following such payment. For purposes of this Section, each party agrees to provide the other with reasonable assistance to enable the due deduction by the paying party and appropriate recovery by the other party, which assistance includes, but is not limited to, provision of any tax forms and other information that may be reasonably necessary in order for the paying party not to withhold tax or to withhold tax at a reduced rate under an applicable bilateral income tax treaty.
- **6.4 Records; Audits.** Astellas shall keep, and require its Sublicensees to keep, complete, fair and true books of accounts and records for the purpose of determining the amounts payable to Vical pursuant to this Agreement, as well as the expenses of any [...\*\*\*...]. Such books and records shall be kept for such period of time required by law, but no less than [...\*\*\*...] ([...\*\*\*...]) years following the end of the Calendar Quarter to which they pertain. Vical (or CytRx, as applicable) shall have the right to cause an independent, certified public accountant, reasonably acceptable to Astellas, to audit such records to confirm Net Sales, royalties and other payments for a period covering not more than the preceding six (6) years. Except for any audits of the expenses of any [...\*\*\*...], for-cause audits or as

otherwise permitted under the CytRx Agreement, as applicable, audits may be exercised not more often than [...\*\*\*...] each year, [...\*\*\*...] for each relevant record, and during normal business hours upon reasonable prior written notice to Astellas. Any such auditor shall not disclose Astellas' Confidential Information to Vical, except to the extent such disclosure is necessary to verify the accuracy of such records. Prompt adjustments shall be made by the parties to reflect the results of such audit. Vical (or CytRx, as applicable) shall bear the full cost of such audit unless such audit discloses an underpayment by Astellas of more than [...\*\*\*...] percent ([...\*\*\*...]%) of the amount of royalties or other payment due under this Agreement or an overstatement by more than [...\*\*\*...] percent ([...\*\*\*...]%) of the expenses of any [...\*\*\*...], in which case, Astellas shall bear the full cost of such audit and shall promptly remit to Vical the amount of any underpayment.

6.5 Late Payments. In the event that any payment due under this Agreement is not made when due, the payment shall accrue interest from the date due at the rate of [... \*\*\*...] percent ([...\*\*\*...]%) above the U.S. Prime Rate (as set forth by Bloomberg (Ticker symbol PRIME index)); provided, however, that in no event shall such rate exceed the maximum legal annual interest rate. The payment of such interest shall not limit Vical from exercising any other rights it may have as a consequence of the lateness of any payment.

#### 7. INTELLECTUAL PROPERTY

- 7.1 Ownership. Vical has, and shall retain, all right, title and interest in and to, the Vical Patents and Vical Know-How. [...\*\*\*...].
- 7.2 Patent Prosecution and Maintenance. As between the parties, Vical (or its licensor, as applicable) shall have the sole right (except as otherwise provided in this Section 7.2 with respect to opposition proceedings regarding any continuation of [...\*\*\*...], but not the obligation, to prepare, file, prosecute (including any interferences, extensions, reissue proceedings and reexaminations) and maintain the Vical Patents, at its sole cost (subject to Section 7.3) and by counsel of its own choice. Vical shall provide Astellas with reasonable opportunity to review and comment on any material document that Vical intends to file or cause to be filed with the relevant intellectual property or patent office with respect to the Vical Patents in the Territory, and Vical shall give due consideration to such comments provided by Astellas. Astellas agrees to reasonably cooperate in the preparation, filing, and prosecution of any Vical Patents and in the obtaining and maintenance of any supplementary protection certificates and the like with respect to any Vical Patent claiming a Product being developed or commercialized by Astellas or Sublicensees in the Territory. Such cooperation includes, but is not limited to, promptly informing Vical of any matters coming to Astellas' attention that may affect the preparation, filing, prosecution or maintenance of any Vical Patents. In the event Vical elects not to defend any opposition proceeding for any [...\*\*\*...] in the Field in the Territory, Vical shall provide

written notice thereof to Astellas, and Astellas shall have the right, but not the obligation, to defend such opposition proceeding, at its sole cost and by counsel of its own choice, and, if Astellas elects to do so, Astellas shall keep Vical reasonably informed with respect thereto. In such case, Vical agrees to reasonably cooperate in defending the opposition proceeding. In addition, in the event that Vical determines to abandon or cease prosecution or maintenance of any Vical Patent in the Territory, Vical shall provide reasonable prior written notice to Astellas of such intention to abandon or cease prosecution or maintenance. In such case, subject to the rights of Vical's licensor with respect to any Vical Patent licensed to Vical by a Third Party, Astellas may elect, upon written notice by Astellas to Vical, to cause Vical to continue prosecution and/or maintenance of such Vical Patent in the Territory, at Vical's sole cost and expense for any Vical Primary Patent, and at Astellas' sole cost and expense and in accordance with Astellas' instructions for any such Vical Patent that is not a Vical Primary Patent within thirty (30) days from the date of invoice for such costs and expenses by Vical. In the event that Astellas desires to cease bearing the costs and expenses with respect to any such Vical Patent, Astellas shall provide reasonable prior written notice to Vical of such intention. In such case, Vical shall have the right, but not the obligation, to elect to continue prosecuting and maintaining any such Vical Patent at its own expense.

7.3 Additional Patent Term Extension Obligations Astellas shall keep Vical fully informed of the progress of Astellas (and, as applicable, its Sublicensee(s)) toward Regulatory Approval of the first Product in the Territory. Astellas shall assist Vical in determining with respect to such Product if the Vical Patents would be eligible for patent term extension pursuant to 35 U.S.C. §§154–56, supplementary protection certificate, and, as appropriate, applicable foreign patent laws ("Patent Term Extension"). Astellas acknowledges that time is of the essence with respect to submission of any application for Patent Term Extension. Astellas shall give Vical notification in writing of its (or, as applicable, its Sublicensee's) first obtaining Regulatory Approval of a Product in the Territory within [...\*\*\*...] ([...\*\*\*...]) days of receipt of written notice of such Regulatory Approval from the applicable Regulatory Authority. Vical shall apply for Patent Term Extension for any Vical Primary Patent as requested by Astellas, at Vical's expense. At Vical's request, Astellas shall, in a timely manner, reasonably assist Vical in preparing an application for Patent Term Extension. Astellas (and, as applicable, its Sublicensee(s)) shall reasonably cooperate with Vical in preparing the applications for Patent Term Extension. Astellas agrees to join in such applications at Vical's request. Astellas shall reasonably support such applications and shall provide such information as may be requested by Vical or any Regulatory Authority in support of such applications.

**7.4 Patent Enforcement.** Each party shall promptly notify the other in writing of any alleged or threatened infringement of any Vical Patent in the Territory of which such party becomes aware. The following provisions shall apply with respect any action or proceeding with respect to infringement by a Third Party of any Vical Patent in the Territory, subject to the terms of the CytRx Agreement with respect to Vical Patents licensed from CytRx.

### (a) Enforcement.

(i) Astellas First Right. As between the parties, excepting Patents licensed to Vical under the CytRx Agreement, Astellas shall have the first right to bring and control any action or proceeding with respect to infringement by a Third Party of any Vical Patent in the Field in the Territory, at its own expense and by counsel of its own choice, except as provided in this Section 7.4(a)(i) and except that Section 7.4(a)(ii) shall instead apply with respect to infringement by a Third Party of any Vical Patent both in the Field and outside the Field in the Territory. Vical shall have the right, at its own expense, to be represented in any such action with respect to infringement of any Vical Patents in the Field in the Territory by counsel of its own choice, and Astellas and its counsel shall reasonably cooperate with, and take into account the view of, Vical and its counsel in strategizing, preparing and presenting any such action or proceeding. If Astellas fails to bring an action or proceeding with respect to infringement of any Vical Patent in the Field in the Territory within (A) [...\*\*\*...] ([...\*\*\*...]) days following the notice of alleged infringement or (B) [...\*\*\*...] (i...\*\*\*...]) days before the time limit, if any, set forth in the appropriate laws and regulations for the filing of such actions, whichever comes first, Vical shall have the right (but not the obligation) to bring and control any such action at its own expense and by counsel of its own choice, and Astellas shall have the right, at its own expense, to be represented in any such action by counsel of its own choice.

(ii) Vical First Right. As between the parties, Vical shall have the first right to bring and control any action or proceeding with respect to infringement by a Third Party of any Vical Patent (including any Patents licensed to Vical under the CytRx Agreement) in the Territory other than as set forth in Section 7.4(a)(i) at its own expense and by counsel of its own choice, except as provided in this Section 7.4(a)(ii). Astellas shall have the right, at its own expense, to be represented in any such action with respect to any such infringement of any Vical Patents in the Territory by counsel of its own choice, and Vical and its counsel shall reasonably cooperate with, and take into account the view of, Astellas and its counsel in strategizing, preparing and presenting any such action or proceeding. If Vical fails to bring an action or proceeding with respect to such infringement of any Vical Patent in the Territory within (A) [...\*\*\*...] ([...\*\*\*...]) days following the notice of alleged infringement or (B) [...\*\*\*...] ([...\*\*\*...]) days before the time limit, if any, set forth in the appropriate laws and regulations for the filling of such actions, whichever comes first, and such infringement of such Vical Patent would have a material adverse effect on Astellas' rights with respect to any Product in the Field in the Territory, then Astellas shall have the right (but not the obligation) to bring and control any such action at its own expense and by counsel of its own choice, and Vical shall have the right, at its own expense, to be represented in any such action by counsel of its own choice.

(b) Cooperation; Awards. In the event a party brings an infringement action in accordance with this Section 7.4, the other party shall reasonably cooperate, including if required to bring such action, joining such action as a necessary party or the furnishing of a power of attorney. Neither party shall have the right to settle any patent infringement litigation with respect to any Vical Patent under this Section 7.4 in a manner that diminishes the rights or interests of the other party without the consent of such other party (which shall not be unreasonably withheld). Except as otherwise agreed to by the parties as part of a cost-sharing arrangement, any recovery or damages realized as a result of such action or proceeding shall be used first to reimburse the parties' documented out-of-pocket legal expenses relating to the

action or proceeding, and any remaining damages relating to the Products (including lost sales or lost profits with respect to Products) shall be retained by the party that brought and controlled the action and, if Astellas brought and controlled such action, shall be deemed Net Sales subject to the royalty provisions of Section 5.3.

- 7.5 Third Party Infringement Claims. Each party shall promptly notify the other party in writing of any allegation by a Third Party that the activity of either party with respect to the development, manufacture or commercialization of any Product in the Field in the Territory infringes or may infringe the intellectual property rights of such Third Party. Vical shall have the sole right to control any defense of any such claim involving alleged infringement of Third Party rights by Vical's activities, at Vical's sole cost and expense and by counsel of its own choice, and Astellas shall have the right, at its own expense, to be represented in any such action by counsel of its own choice. Astellas shall have the sole right to control any defense of any such claim involving alleged infringement of Third Party rights by Astellas' activities, at Astellas' sole cost and expense and by counsel of its own choice, and Vical shall have the right, at its own expense, to be represented in any such action by counsel of its own choice. Neither party shall enter into any settlement or compromise of any action under this Section 7.5 which would in any manner diminish the rights or interests of the other party without the consent of such other party (which shall not be unreasonably withheld).
- **7.6 Orange Book Listing.** Astellas shall have the sole right to make any filing with respect to any Vical Primary Patents in connection with the Patent listing source in any country in the Territory that is equivalent to the Orange Book, if any. Upon request of Astellas, with respect to countries in the Territory, Vical shall cooperate with Astellas to file appropriate information with the applicable Regulatory Authority listing any Vical Primary Patents.
- 7.7 Patent Marking. Astellas shall mark all Products made, used or sold in the Territory, or their containers, if required under applicable laws, rules and regulations relating to patent marking.
- **7.8 Registration of License.** Astellas may, at its sole discretion and at its own expense, register the license granted under this Agreement with the patent office or any other competent authorities in any country of the Territory in accordance with the relevant law in such country, and Vical shall, promptly upon Astellas' request, provide Astellas with assistance necessary for such registration, including without limitation applying for such registration for Astellas and signing all necessary documents.
- 7.9 Trademarks. Astellas shall be responsible for selection, registration and maintenance of the trademark(s) for Products in the Field in the Territory, at its own cost, and all such trademark(s) shall be filed and exclusively owned by Astellas. At Astellas' election, Vical shall grant to Astellas during the Term a royalty-free exclusive license with the right to sublicense under Vical's interest in Vical's common law trademark TransVax<sup>TM</sup> for use solely in connection with the sale and offer for sale of Products in the Field in the Territory. Such license shall become perpetual in the event Astellas obtains a perpetual and fully paid-up license and sublicense under the Vical Technology pursuant to Section 10.1. For clarity, Vical is and shall remain the owner of all right, title and interest in and to Vical's common law trademark

TransVax<sup>TM</sup> and the goodwill now and hereafter associated therewith shall at all times inure to the benefit of Vical.

#### 8. REPRESENTATIONS AND WARRANTIES

- 8.1 Mutual Representations and Warranties. Each party represents and warrants to the other party as of the Effective Date that:
- (a) Organization. It is duly organized and validly existing under the laws of its jurisdiction of incorporation or formation, and has full corporate or other power and authority to enter into this Agreement and to carry out the provisions hereof.
- **(b) Authorization.** It is duly authorized to execute and deliver this Agreement and to perform its obligations hereunder, and the person or persons executing this Agreement on its behalf has been duly authorized to do so by all requisite corporate or partnership action.
- (c) Binding Agreement. This Agreement is legally binding upon it, enforceable in accordance with its terms, and does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound, nor violate any material law or regulation of any court, governmental body or administrative or other agency having jurisdiction over it.
- (d) Agreements with Employees and Contractors. All of such party's employees or contractors acting on its behalf pursuant to this Agreement or any other written agreement between the parties are and will be obligated under a binding written agreement to comply with obligations of confidentiality and non-use consistent with those set forth in Article 9.
- (e) No Debarment. Such party is not debarred under the United States Federal Food, Drug and Cosmetic Act or comparable laws in any other country or jurisdiction, and it does not, and will not during the Term, employ or use the services of any person or entity who is debarred, in connection with the development, manufacture or commercialization of the Products. In the event that either party becomes aware of the debarment or threatened debarment of any person or entity providing services to such party, including the party itself and its Affiliates or Sublicensees, which directly or indirectly relate to activities under this Agreement, the other party shall be immediately notified in writing.
  - 8.2 Vical Representations and Warranties. Vical represents, warrants and covenants to Astellas as of the Effective Date that:
- (a) Control. Except for those rights in-licensed by Vical under the CytRx Agreement, Vical is the sole owner of all of the Vical Technology existing as of the Effective Date, free and clear of all liens.
  - (b) Right to Grant License. Vical has the right to grant the license and sublicenses it grants to Astellas under Section 3.1 of this Agreement.

- (c) No Conflicting Grant of Rights. Vical and its Affiliates have not, and will not during the Term, grant any right to any Third Party that would conflict with the rights granted to Astellas hereunder or, except with Astellas' prior written consent, allow a Third Party to create and maintain any security interest in (i) Vical Patents (excepting Patents licensed to Vical under the CytRx Agreement) or (ii) any rights granted to Astellas hereunder, to secure third-party financing; provided that Vical may allow a Third Party to create and maintain such a security interest without Astellas' prior written consent if such security interest is subject to the rights granted to Astellas under such Vical Patents or other rights as set forth in this Agreement.
- (d) No Infringement. Vical has not received any notice alleging, and is not otherwise actually aware, that the practice of the Vical Patents infringes or may infringe any Patent(s) of any Third Party.
- (e) No Legal Actions. As of the Effective Date, there are no pending legal actions, nor has Vical received any written notice regarding any pending legal actions, with respect to the Vical Technology, and no Vical Patent is the subject of any interference, opposition, cancellation or other protest proceeding.
- (f) Disclosure. Up to and including the Effective Date, Vical has made available to Astellas (i) all material information (including without limitation pre-clinical and clinical data) in its possession or Control relating to the Compound, the Product(s) and Vical Patents in the Field in the Territory, including material information in its possession or Control that is material to the utility or safety of the Compound and/or the Product(s) in the Field in the Territory, and (ii) all safety data in its possession or Control relating to the Compound and Product(s).
- **8.3 Disclaimer.** Except as expressly set forth herein, THE VICAL TECHNOLOGY IS PROVIDED "AS IS," AND EACH PARTY EXPRESSLY DISCLAIMS ANY AND ALL WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION THE WARRANTIES OF DESIGN, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NONINFRINGEMENT OF THE INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES, OR ARISING FROM A COURSE OF DEALING, USAGE OR TRADE PRACTICES.
- **8.4 Limitation of Liability.** NEITHER PARTY SHALL BE ENTITLED TO RECOVER FROM THE OTHER PARTY ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES IN CONNECTION WITH THIS AGREEMENT OR ANY LICENSE GRANTED HEREUNDER; *provided, however*, that this Section 8.4 shall not be construed to limit either party's indemnification obligations under Article 11 or its right to obtain recover damages for breach of Article 9. For clarification, payments under Article 5 shall not be considered special, incidental, consequential or punitive damages.

## 9. CONFIDENTIALITY

9.1 Confidential Information. Except to the extent expressly authorized by this Agreement or otherwise agreed in writing by the parties, the parties agree that, during the Term

and until the [...\*\*\*...] ([...\*\*\*...]) anniversary of the date of expiration or termination of the later to expire or terminate of this Agreement or the U.S. Agreement, each party (in such capacity, the "receiving party") shall keep confidential and shall not publish or otherwise disclose and shall not use for any purpose other than as expressly provided for in this Agreement or the Confidentiality Agreement any Confidential Information of the other party (in such capacity, the "disclosing party"). The receiving party may use Confidential Information of the other party only to the extent required to accomplish the purposes of this Agreement. The receiving party will use at least the same standard of care as it uses to protect proprietary or confidential information of its own (but not less than reasonable care) to ensure that its employees, agents, consultants and other representatives do not disclose or make any unauthorized use of the Confidential Information of the disclosing party. The receiving party will promptly notify the disclosing party upon discovery of any unauthorized use or disclosure of the Confidential Information of the disclosing party. Without limiting the foregoing, the parties acknowledge that Vical Know-How includes valuable trade secrets and that it is in the interests of both parties to protect the confidentiality of the Vical Know-How; provided, that nothing will limit or prevent Vical from using or disclosing the Vical Know-How in connection with its discussions and activities outside the scope of the exclusive license granted to Astellas hereunder with respect to Compounds and Products in the Field in the Territory.

- 9.2 Exceptions. Confidential Information shall not include any information which the receiving party can demonstrate by competent evidence: (a) is now, or hereafter becomes, through no act or failure to act on the part of the receiving party, generally known or available; (b) is known by the receiving party at the time of receiving such information, as evidenced by its records; (c) is hereafter furnished to the receiving party by a Third Party, as a matter of right and without restriction on disclosure; or (d) is independently discovered or developed by the receiving party without the use of Confidential Information of the disclosing party.
- **9.3 Authorized Disclosure.** The receiving party may disclose Confidential Information of the disclosing party as expressly permitted by this Agreement or if and to the extent such disclosure is reasonably necessary in the following instances:
  - (a) prosecuting or defending litigation as permitted by this Agreement;
  - (b) complying with applicable court orders or governmental regulations;
- (c) in the case of Astellas, conducting development manufacturing and/or commercialization activities in accordance with the license granted in Section 3.1, including making regulatory filings with respect to Products;
  - (d) in the case of Vical, as reasonably necessary to fulfill its obligations under the CytRx Agreement; and
- (e) disclosure to Affiliates, sublicensees, subcontractors, employees, consultants, agents or other Third Parties who need to know such information for the development, manufacture and commercialization of Products in accordance with this Agreement or in connection with due diligence or similar investigations by such Third Parties, and disclosure to potential Third Party investors in confidential financing documents, provided,

in each case, that any such Affiliate, sublicensee, subcontractor, employee, consultant, agent or Third Party agrees to be bound by similar terms of confidentiality and non-use at least equivalent in scope to those set forth in this Article 9.

Notwithstanding the foregoing, in the event the receiving party is required to make a disclosure of the disclosing party's Confidential Information pursuant to Section 9.3(a) or (b), it will, except where impracticable, give reasonable advance notice to the disclosing party of such disclosure and use efforts to secure confidential treatment of such information at least as diligent as the receiving party would use to protect its own confidential information, but in no event less than reasonable efforts. In any event, the receiving party agrees to take all reasonable action to avoid disclosure of Confidential Information of the disclosing party.

**9.4 Confidentiality of this Agreement and its Terms.** Except as otherwise provided in this Article 9, each party agrees not to disclose to any Third Party the existence of this Agreement or the terms of this Agreement without the prior written consent of the other party hereto, except that each party may disclose the terms of this Agreement that are not otherwise made public as contemplated by Section 9.5 as permitted under Section 9.3.

### 9.5 Public Announcements.

- (a) Press Releases. As soon as practicable following the date hereof, the parties shall each issue a mutually agreed press release announcing the existence of this Agreement. Except as required by applicable laws and regulations (including disclosure requirements of the U.S. Securities and Exchange Commission ("SEC") or any stock exchange on which securities issued by a party or its Affiliates are traded), neither party shall make any other public announcement concerning this Agreement or the subject matter hereof without the prior written consent of the other, which shall not be unreasonably withheld or delayed; provided that each party may make any public statement, including statements in response to questions by the press, analysts, investors or those attending industry conferences or financial analyst calls, or issue press releases, so long as any such public statement or press release is not inconsistent with prior public disclosures or public statements approved by the other party pursuant to this Section 9.5 and which do not reveal non-public information about the other party. For avoidance of doubt, Vical shall have the right, without the prior written consent of Astellas, to announce events such as achievement of milestones under this Agreement, and other events deemed material by its General Counsel; provided, however, that Vical shall consult with Astellas with regard thereto and provide reasonable opportunity for Astellas to review such announcement in advance. In the event of a required public announcement, to the extent practicable under the circumstances, the party making such announcement shall provide the other party with a copy of the proposed text of such announcement sufficiently in advance of the scheduled release to afford such other party a reasonable opportunity to review and comment upon the proposed text.
- (b) Filing of Agreement. The parties will coordinate in advance with each other in connection with the filing of this Agreement (including redaction of certain provisions of this Agreement) with the SEC or any stock exchange or governmental agency on which securities issued by a party or its Affiliate are traded, and each party will use reasonable efforts to seek confidential treatment for the terms proposed to be redacted; provided that each party will ultimately retain control over what information to disclose to the SEC or any stock exchange

or other governmental agency, as the case may be, and provided further that the parties will use their reasonable efforts to file redacted versions with any governing bodies which are consistent with redacted versions previously filed with any other governing bodies. Other than such obligation, neither party (or its Affiliates) will be obligated to consult with or obtain approval from the other party with respect to any filings to the SEC or any stock exchange or other governmental agency.

### (c) Publications.

- (i) Except as otherwise set forth in Section 9.5(c)(ii) below, at least [...\*\*\*...] ([...\*\*\*...]) days prior to publishing, publicly presenting, and/or submitting for written or oral publication a manuscript, abstract or the like that includes Information relating to any Product in the Field that has not been previously published, each party shall provide to the other party a draft copy thereof for its review (unless such party is required by law to publish such Information sooner, in which case such party shall provide such draft copy to the other party as much in advance of such publication as possible). The publishing party shall consider in good faith any comments provided by the other party during such [...\*\*\*...] ([...\*\*\*...]) day period. In addition, the publishing party shall, at the other party's reasonable request, remove therefrom any Confidential Information of such other party, except each party shall have the right to publicly disclose any information, including Confidential Information, pertaining to safety or efficacy of the Product that such party believes in good faith it is obligated by applicable law or appropriate to conform to applicable regulatory requirements to disclose; provided that it shall delay publication for a period not to exceed [...\*\*\*...] ([...\*\*\*...]) days in order to allow the other party to file for patent protection as permitted by this Agreement in relation to its Confidential Information. The contribution of each party shall be noted in all publications or presentations by acknowledgment or co-authorship, as appropriate.
- (ii) In the event Astellas desires to publish, publicly present, and/or submit for written or oral publication a manuscript, abstract or the like that includes Information relating to any Product in the Field but that does not include any Confidential Information of Vical, Astellas shall provide to Vical a draft copy thereof for its review prior to the date of such publication, presentation or submission, and Astellas shall consider in good faith any comments provided by Vical with respect thereto.
- (iii) Astellas shall, within a reasonable amount of time after the Effective Date and from time to time thereafter, provide to Vical a copy of its plan for publication regarding Compounds and Products in the Field, including all material updates and changes thereto.
- 9.6 Equitable Relief. Given the nature of the Confidential Information and the competitive damage that would result to the disclosing party upon unauthorized disclosure, use or transfer of its Confidential Information to any Third Party, the parties agree that monetary damages may not be a sufficient remedy for any breach of this Article 9. In addition to all other remedies, the disclosing party shall be entitled to seek specific performance and injunctive and other equitable relief as a remedy for any breach or threatened breach of this Article 9.

### 10. TERM AND TERMINATION

10.1 Term. The term of this Agreement shall commence on the Effective Date and continue in each country in the Territory until the expiration of the last Royalty Term in such country, subject, in each case, to earlier termination pursuant to Section 10.2 (the "Term"). On a Product-by-Product and country-by-country basis upon expiration of the Royalty Term with respect to such Product in such country [...\*\*\*...], the license and sublicense granted by Vical to Astellas under Section 3.1 with respect to such Product in such country shall remain in effect on a perpetual, fully paid-up and royalty-free basis, subject to the limits set forth in Article 3.

### 10.2 Early Termination.

### (a) Termination for Cause.

(i) A party shall have the right to terminate this Agreement upon written notice to the other party if such other party is in material breach of this Agreement and has not cured such breach within sixty (60) days (thirty (30) days with respect to any payment breach) after written notice from the terminating party requesting cure of such breach. Any such termination shall become effective at the end of such sixty (60) day (thirty (30) day with respect to any payment breach) period unless the breaching party has cured any such breach prior to the end of such period. [...\*\*\*...].

(ii) A party shall have the right to terminate this Agreement upon written notice to the other party upon the bankruptcy, dissolution or winding up of such other party, or the making or seeking to make or arrange an assignment for the benefit of creditors of such other party, or the initiation of proceedings in voluntary or involuntary bankruptcy, or the appointment of a receiver or trustee of such other party's property that is not discharged within ninety (90) days.

(b) Other Astellas Termination Right. Astellas shall have the right to terminate this Agreement on a country-by-country basis if Astellas reasonably determines that further development and/or commercialization of Products in the Field in such a country in the Territory will not be beneficial for Astellas for scientific, regulatory, commercial, financial, ethical or other fair reasons specified in reasonable detail in writing to Vical: (i) prior to completion of the technology transfer of Vical Know-How relating to the manufacture of Compounds and Products in the Field to Astellas or its designee, upon one hundred eighty (180)

days' prior written notice to Vical, and (ii) thereafter, upon ninety (90) days' prior written notice to Vical.

(c) Other Vical Termination Rights. Vical shall have the right to terminate this Agreement immediately upon written notice to Astellas if Astellas or any of its Affiliates or Sublicensees, directly or indirectly through any Third Party, commences any interference or opposition proceeding with respect to, challenges the validity or enforceability of, or opposes any extension of or the grant of a supplementary protection certificate with respect to, any Vical Patent.

## 10.3 Effect of Termination or Expiration; Surviving Obligations.

- (a) Effect of Any Termination. Upon any termination of this Agreement by either party:
  - (i) all rights and obligations of the parties under this Agreement shall terminate, except as provided in Sections 10.3, 10.4, 10.5 and, as applicable, 10.6;
- (ii) Astellas shall perform its outstanding non-cancellable obligations with respect to Products in the terminated country or in the Territory, as applicable, that existed or accrued prior to the notice date of termination; and
- (iii) Astellas shall cooperate with and provide reasonable assistance to Vical with respect to any applications for Patent Term Extension, including providing such information as may be requested by Vical or any Regulatory Authority in support of such applications.
- (b) Effect of Any Termination Other than Termination by Astellas for Cause. Upon any termination of this Agreement by Astellas under Section 10.2(b) with respect to any country or countries or any termination of this Agreement by Vical under Section 10.2(a) or (c),
- (i) if, at the time of such termination, there are any ongoing clinical trials with respect to Products in the Field in the terminated country or in the Territory, as applicable, the parties shall, at Vical's option, negotiate in good faith and adopt a plan to wind-down the development activities in an orderly fashion or, at Vical's election, promptly transition such development activities to Vical or its designee, with due regard for patient safety and the rights of any subjects that are participants in any clinical trials of the Product and take any actions Vical deems reasonably necessary or appropriate to avoid any human health or safety problems and in compliance with all applicable laws, rules and regulations; and
  - (ii) Astellas shall, and hereby does, grant to Vical:
- (1) the unrestricted right to use and refer to all Information, including all data and regulatory documents, relating to any Compound or Product, in the terminated country or countries and, if this Agreement is terminated in its entirety, in the Territory and also outside the Territory upon any termination of the U.S. Agreement;

(2) an exclusive, royalty-free, perpetual, irrevocable license, with the right to sublicense and further sublicense, under all Patents Controlled by Astellas or its Affiliates that claim or cover a Compound or Product specifically or its manufacture or use in the Territory, solely to research, develop, register, use, make, have made, promote, sell, offer for sale, distribute, import and export Compounds and Products in the Field in the terminated country or countries or, if this Agreement is terminated in its entirety, in the Territory;

(3) a non-exclusive, royalty-free, perpetual, irrevocable license, with the right to sublicense and further sublicense, under all Patents Controlled by Astellas or its Affiliates other than those referenced in subsection (2) above, which Patents would, but for the license granted in this subsection (3), be infringed by the development, use, manufacture, promotion, sale, offer for sale, distribution, import or export of a Compound or Product in the Field in the applicable country or countries, solely to develop, use, make, have made, promote, sell, offer for sale, distribute, import and export Compounds and Products in the Field in the terminated country or countries or, if this Agreement is terminated in its entirety, in the Territory; and

(4) take such other actions and execute such other instruments, assignments and documents as may be necessary to effect the transfers of rights as set forth in subsections (1), (2) and (3) above.

- (c) Surviving Terms. Expiration or termination of this Agreement shall not relieve the parties of any obligation accruing prior to such expiration or termination. Without limiting the foregoing, the obligations and rights of the parties under Sections 6.4 (for the period described therein), 7.1, 8.3, 8.4, 10.3, 10.4 and 10.5 and Articles 1, 9, 11 and 12 shall survive expiration or termination of this Agreement.
- (d) Return of Confidential Information. Within [...\*\*\*...] days following the expiration or termination of this Agreement, each party shall deliver to the other party or destroy any and all Confidential Information of the other party in its possession, as per instruction by the party which owns such Confidential Information. Notwithstanding the foregoing, in case that Astellas grants to Vical right and license pursuant to Section 10.3(b), the party, which is entitled to develop, manufacture and commercialize the Product after expiration or termination of this Agreement, shall not be required to make delivery or destruction pursuant to this Section 10.3(d).
- 10.4 Exercise of Right to Terminate. The use by either party hereto of a termination right provided for under this Agreement shall not give rise to the payment of damages or any other form of compensation or relief to the other party with respect thereto.
- 10.5 Damages; Relief. Subject to Section 10.4 above, termination of this Agreement shall not preclude either party from claiming any other damages, compensation or relief that it may be entitled to upon such termination.
- 10.6 Rights in Bankruptcy. All rights and licenses granted under or pursuant to this Agreement by a party are, and will otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code, licenses of right to "intellectual property" as defined under

Section 101 of the U.S. Bankruptcy Code. The parties agree that a party, as licensee of such rights under this Agreement, will 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 the commencement of a bankruptcy proceeding by or against the licensing party under the U.S. Bankruptcy Code, the licensee will be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property, and same, if not already in its possession, will be promptly delivered to it (a) upon any such commencement of a bankruptcy proceeding upon its written request therefor, unless the licensing party elects to continue to perform all of its obligations under this Agreement, or (b) if not delivered under subsection (a) above, following the rejection of this Agreement by or on behalf of the licensing party upon written request therefor by the licensee.

### 11. INDEMNIFICATION

- 11.1 Indemnification by Vical. Vical hereby agrees to save, defend and hold Astellas and its Affiliates and its and their respective directors, officers, employees and agents (each, a "Astellas Indemnitee") harmless from and against any and all claims, suits, actions, demands, liabilities, expenses and/or loss, including reasonable legal expense and attorneys' fees (collectively, "Losses"), to which any Astellas Indemnitee may become subject as a result of any claim, demand, action or other proceeding by any Third Party to the extent such Losses arise directly or indirectly out of (a) the gross negligence or willful misconduct of any Vical Indemnitee with respect to any obligations or activities contemplated by this Agreement, or (b) the breach by Vical of any warranty, representation, covenant or agreement made by Vical in this Agreement; except, in each case, to the extent such Losses result from the gross negligence or willful misconduct of any Astellas Indemnitee or the breach by Astellas of any warranty, representation, covenant or agreement made by Astellas in this Agreement.
- 11.2 Indemnification by Astellas. Astellas hereby agrees to save, defend and hold Vical and its Affiliates and its and their respective directors, officers, employees and agents (each, a "Vical Indemnitee") harmless from and against any and all Losses to which any Vical Indemnitee may become subject as a result of any claim, demand, action or other proceeding by any Third Party to the extent such Losses arise directly or indirectly out of: (a) the development, manufacture, use, handling, storage, sale or other disposition of any Product in the Territory by Astellas or any of its Sublicensees, (b) the gross negligence or willful misconduct of any Astellas Indemnitee with respect to any obligations or activities contemplated by this Agreement, or (c) the breach by Astellas of any warranty, representation, covenant or agreement made by Astellas in this Agreement; except, in each case, to the extent such Losses result from the gross negligence or willful misconduct of any Vical Indemnitee or the breach by Vical of any warranty, representation, covenant or agreement made by Vical in this Agreement.
- 11.3 Control of Defense. Any person entitled to indemnification under this Article 11 shall give notice to the indemnifying party of any Losses that may be subject to indemnification, promptly after learning of such Losses, and the indemnifying party shall assume the defense of such Losses with counsel reasonably satisfactory to the indemnified party. If such defense is assumed by the indemnifying party with counsel so selected, the indemnifying party will not be subject to any liability for any settlement of such Losses made by the indemnified party without its consent (but such consent will not be unreasonably withheld or delayed), and will not be

obligated to pay the fees and expenses of any separate counsel retained by the indemnified party with respect to such Losses.

11.4 Insurance. Each party shall, at its own expense, procure and maintain during the Term and for a period of three (3) years thereafter, insurance policy/policies, including product liability insurance, adequate to cover its obligations hereunder and which are consistent with normal business practices of prudent companies similarly situated. Such insurance shall not be construed to create a limit of a party's liability with respect to its obligations hereunder including the indemnification obligations under this Article 11. Each party shall provide the other party with written evidence of such insurance or self-insurance upon request. Each party shall provide the other party with written notice at least thirty (30) days prior to the cancellation, non-renewal or material change in such insurance self-insurance which could materially adversely affect the rights of such other party hereunder.

### 12. GENERAL PROVISIONS

- **12.1 Standstill Agreement.** For a period of [...\*\*\*...] ([...\*\*\*...]) years following the Effective Date (the "Standstill Period"), neither Astellas nor any of Astellas' Representatives (as defined below) will, in any manner, directly or indirectly:
- (a) make, effect, initiate, directly participate in or cause (i) any acquisition of beneficial ownership of any securities of Vical or any securities of any subsidiary or other Affiliate of Vical, if, after such acquisition, Astellas would beneficially own more than [...\*\*\*...] percent ([...\*\*\*\*...]%) of the outstanding common stock of Vical, (ii) any acquisition of any assets of Vical or any assets of any subsidiary or other Affiliate of Vical, (iii) any tender offer, exchange offer, merger, business combination, recapitalization, restructuring, liquidation, dissolution or extraordinary transaction involving Vical or any subsidiary or other Affiliate of Vical, or involving any securities or assets of Vical or any securities or assets of any subsidiary or other affiliate of Vical, or (iv) any "solicitation" of "proxies" (as those terms are used in the proxy rules of the Securities and Exchange Commission) or consents with respect to any securities of Vical provided that nothing in this Section 12.1 shall preclude any activities of Astellas or its Representatives with respect to the grant by Vical or any Affiliate of Vical of any license, or the supply by Vical or any subsidiary or other Affiliate of Vical of any products, in each case to Astellas or any of its Affiliates as contemplated by this Agreement;
- (b) form, join or participate in a group (within the meaning of Section 13(d)(3) of the Securities Exchange Act of 1934, as amended) with respect to the beneficial ownership of any securities of Vical;
  - (c) act, alone or in concert with others, to seek to control the management, board of directors or policies of Vical;
  - (d) take any action that might require Vical to make a public announcement regarding any of the types of matters set forth in Section 12.1(a);
  - (e) agree or offer to take, or encourage or propose (publicly or otherwise) the taking of, any action referred to in Section 12.1(a), (b), (c) or (d);

- (f) assist, induce or encourage any Third Party to take any action of the type referred to in Section 12.1(a), (b), (c), (d) or (e);
- (g) enter into any discussions, negotiations, arrangement or agreement with any Third Party relating to any of the foregoing; or
- (h) request or propose that Vical or any of Vical's Representatives amend, waive or consider the amendment or waiver of any provision set forth in this Section 12.1.

For purposes of this Agreement, a party's "Representatives" will be deemed to include each person or entity that is or becomes (i) an Affiliate of such party, or (ii) an officer, director, employee, partner, attorney, advisor, accountant, agent or representative of such party or of any of such party's Affiliates, providing such person is acting on behalf of such party.

Notwithstanding the foregoing, Section 12.1 shall no longer apply (i) during a period commencing with Vical's announcement in a filing with the Securities and Exchange Commission or a press release that (a) it is seeking purchaser for itself or (b) is otherwise exploring strategic options in this regard, and ending with Vical's announcement in a filing with the Securities and Exchange Commission or a press release that is terminating such search or exploration; (ii) during the period beginning with the commencement by a Third Party of a publicly-announced tender or exchange offer for more than [...\*\*\*...] percent ([...\*\*\*...]%) of voting power of the outstanding voting securities of Vical, and ending with the termination by such Third Party of such tender or exchange offer; or (iii) if Vical announces in a filing with the Securities and Exchange Commission or a press release a transaction, or an intention to effect any transaction, which would result in (a) the sale by Vical or one or more Affiliate(s) of assets representing [...\*\*\*...] percent ([...\*\*\*...]%) or more of the consolidated assets of Vical; or (b) the common shareholders of Vical immediately prior to such transaction owning less than [...\*\*\*...] percent ([...\*\*\*...]%) of the outstanding common stock of the acquiring entity or, in case of a merger transaction, the surviving corporation (or, if the surviving corporation is an Affiliate of a parent company), the parent company); provide that, in the case of clause (ii) Astellas has not directly or indirectly taken any action prohibited under this Section 12.1.

The expiration of the Standstill Period will not terminate or otherwise affect any of the other provisions of this Agreement.

12.2 Governing Law. This Agreement shall be governed by, and construed and enforced in accordance with, the laws of the State of New York, excluding its conflicts of laws principles with the exception of sections 5-1401 and 5-1402 of New York General Obligations Law.

### 12.3 Dispute Resolution.

(a) Objective. The parties recognize that disputes as to matters arising under or relating to this Agreement or either party's rights and/or obligations hereunder may arise from time to time. It is the objective of the parties to establish procedures to facilitate the resolution of such disputes in an expedient manner by mutual cooperation and without resort to litigation. To

accomplish this objective, the parties agree to follow the procedures set forth in this Section 12.3 to resolve any such dispute if and when it arises.

(b) Resolution by Executives. Except as otherwise provided in Section 2.1, if an unresolved dispute as to matters arising under or relating to this Agreement or either party's rights and/or obligations hereunder arises, either party may refer such dispute to the Executives, who shall meet in person or by telephone within ten (10) days after such referral to attempt in good faith to resolve such dispute. If such matter cannot be resolved by discussion of the Executives within ten (10) days following such meeting (as may be extended by mutual written agreement), such dispute shall be resolved in accordance with Section 12.3(c). For avoidance of doubt, any disputes, controversies or differences arising from the JSC pursuant to Article 2 shall be resolved solely in accordance with Section 2.1.

### (c) Arbitration.

(i) If the parties do not resolve a dispute as provided in Section 12.3(b), and a party wishes to pursue the matter, each such dispute that is not an "Excluded Claim" shall be resolved by binding arbitration in accordance with the Rules of Arbitration of the International Chamber of Commerce ("ICC") as then in effect (the "ICC Rules"), and judgment on the arbitration award may be entered in any court having jurisdiction thereof. The decision rendered in any such arbitration will be final and not appealable. If either party intends to commence binding arbitration of such dispute, such party will provide written notice to the other party informing the other party of such intention and the issues to be resolved. Within thirty (30) days after the receipt of such notice, the other party may by written notice to the party initiating binding arbitration, add additional issues to be resolved.

(ii) The arbitration shall be conducted by a panel of three (3) arbitrators experienced in the pharmaceutical business, none of whom shall be a current or former employee or director, or a then-current stockholder, of either party, their respective Affiliates or any Sublicensee. Within thirty (30) days after receipt of the original notice of binding arbitration, each party shall select one person to act as arbitrator and the two party-selected arbitrators shall select a third arbitrator within ten (10) days of their appointment. If the arbitrators selected by the parties are unable or fail to agree upon the third arbitrator, the third arbitrator shall be appointed by the ICC in accordance with the ICC Rules. The place of arbitration shall be New York, New York, and all proceedings and communications shall be in English.

(iii) It is the intention of the parties that discovery, although permitted as described herein, will be limited except in exceptional circumstances. The arbitrators will permit such limited discovery necessary for an understanding of any legitimate issue raised in the arbitration, including the production of documents. No later than thirty (30) days after selection of the arbitrators, the parties and their representatives shall hold a preliminary meeting with the arbitrators, to mutually agree upon and thereafter follow procedures seeking to assure that the arbitration will be concluded within six (6) months from such meeting. Failing any such mutual agreement, the arbitrators will design and the parties shall follow procedures to such effect.

- (iv) Either party may apply to the arbitrators for interim injunctive relief until the arbitration award is rendered or the controversy is otherwise resolved. Either party also may, without waiving any remedy under this Agreement, seek from any court having jurisdiction any injunctive or provisional relief necessary to protect the rights or property of that party pending the arbitration award. The arbitrators shall have no authority to award punitive or any other non-compensatory damages. The arbitrators shall have the power to order that all or part of the legal or other costs incurred by a party in connection with the arbitration be paid by the other party. Subject to the preceding sentence, each party shall bear an equal share of the arbitrators' and any administrative fees of arbitration.
- (v) Except to the extent necessary to confirm or enforce an award or as may be required by applicable law, neither a party nor an arbitrator may disclose the existence, content, or results of an arbitration without the prior written consent of both parties. In no event shall an arbitration be initiated after the date when commencement of a legal or equitable proceeding based on the dispute, controversy or claim would be barred by the applicable New York statute of limitations.
- (vi) As used in this Section, the term "Excluded Claim" shall mean a dispute, controversy or claim that concerns (A) the validity, enforceability or infringement of a patent, trademark, copyright or regulatory data exclusivity; or (B) any antitrust, anti-monopoly or competition law or regulation, whether or not statutory.
- 12.4 Entire Agreement; Modification. This Agreement, including the Exhibits hereto, is both a final expression of the parties' agreement and a complete and exclusive statement with respect to all of its terms. Except for the U.S. Agreement, the Services Agreement and the separate letter agreement between the parties, this Agreement supersedes all prior and contemporaneous agreements and communications, whether oral, written or otherwise, concerning any and all matters contained herein and therein, including the Confidentiality Agreement. This Agreement may only be modified or supplemented in a writing expressly stated for such purpose and signed by the parties to this Agreement.
- 12.5 Relationship Between the Parties. The parties' relationship, as established by this Agreement, is solely that of independent contractors. This Agreement does not create any partnership, joint venture or similar business relationship between the parties. Neither party is a legal representative of the other party, and neither party can assume or create any obligation, representation, warranty or guarantee, express or implied, on behalf of the other party for any purpose whatsoever.
- 12.6 Non-Waiver. The failure of a party to insist upon strict performance of any provision of this Agreement or to exercise any right arising out of this Agreement shall neither impair that provision or right nor constitute a waiver of that provision or right, in whole or in part, in that instance or in any other instance. Any waiver by a party of a particular provision or right shall be in writing, shall be as to a particular matter and, if applicable, for a particular period of time and shall be signed by such party.
- 12.7 Assignment. Except as expressly provided hereunder, neither this Agreement nor any rights or obligations hereunder may be assigned or otherwise transferred by either party

without the prior written consent of the other party (which consent shall not be unreasonably withheld); provided, however, that either party may assign or otherwise transfer this Agreement and its rights and obligations hereunder without the other party's consent:

- (a) in connection with the transfer or sale of all or substantially all of the business or assets of such party relating to products for control or prevention of CMV infection to a Third Party, whether by merger, sale of stock, sale of assets or otherwise (a "Sale"), provided that in the event of a Sale (whether this Agreement is actually assigned or is assumed by the acquiring party by operation of law (e.g., in the context of a reverse triangular merger)), intellectual property rights of the acquiring party to such transaction (if other than one of the parties to this Agreement) shall not be included in the technology licensed hereunder; or
- (b) to an Affiliate, provided that the assigning party shall remain liable and responsible to the non-assigning party hereto for the performance and observance of all such duties and obligations by such Affiliate.

The rights and obligations of the parties under this Agreement shall be binding upon and inure to the benefit of the successors and permitted assigns of the parties. Any assignment not in accordance with this Agreement shall be void.

- 12.8 No Third Party Beneficiaries. This Agreement is neither expressly nor impliedly made for the benefit of any party other than those executing it, except as otherwise provided in this Agreement with respect to Astellas Indemnitees under Section 11.1 and Vical Indemnitees under Section 11.2.
- 12.9 Severability. If, for any reason, any part of this Agreement is adjudicated invalid, unenforceable or illegal by a court of competent jurisdiction, such adjudication shall not affect or impair, in whole or in part, the validity, enforceability or legality of any remaining portions of this Agreement. All remaining portions shall remain in full force and effect as if the original Agreement had been executed without the invalidated, unenforceable or illegal part.
- 12.10 Cumulative Remedies. No remedy referred to in this Agreement is intended to be exclusive, but each shall be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under law.
- 12.11 Notices. Any notice to be given under this Agreement must be in writing and delivered either in person, by any method of mail (postage prepaid) requiring return receipt, or by overnight courier or facsimile or electronic mail (email) transmission confirmed thereafter by any of the foregoing, to the party to be notified at its address(es) given below, or at any address such party has previously designated by prior written notice to the other. Notice shall be deemed sufficiently given for all purposes upon the earliest of: (a) the date of actual receipt; (b) if mailed, five days after the date of postmark; or (c) if delivered by overnight courier, the next business day the overnight courier regularly makes deliveries.

If to Astellas, notices must be addressed to:

Astellas Pharma Inc. 3-11, Nihonbashi-Honcho 2-chome Chuo-Ku, Tokyo 103-8411 Japan Attention: Vice President, Legal

Facsimile: [...\*\*\*...]

With a copy to:

Astellas Pharma Inc. 3-11, Nihonbashi-Honcho 2-chome

Chuo-Ku, Tokyo 103-8411

Japan

Attention: Vice President, Licensing and Alliances

Facsimile: [...\*\*\*...]

If to Vical, notices must be addressed to:

Vical Incorporated 10390 Pacific Center Court San Diego, California 92121 USA

Attention: Business Development Facsimile: (858) 646-1150 Email: licensing@vical.com

With a copy to:

Cooley LLP 4401 Eastgate Mall San Diego, California 92121 USA

Attention: [...\*\*\*...]
Telephone: (858) 550-6000
Facsimile: (858) 550-6420
Email: [...\*\*\*...]

12.12 Force Majeure. Except for the obligation to make payment when due, each party shall be excused from liability for the failure or delay in performance of any obligation under this Agreement by reason of any event beyond such party's reasonable control including but not limited to Acts of God, fire, flood, explosion, earthquake, or other natural forces, war, civil unrest, accident, destruction or other casualty, any lack or failure of transportation facilities, any lack or failure of supply of raw materials, any strike or labor disturbance, or any other event

similar to those enumerated above. Such excuse from liability shall be effective only to the extent and duration of the event(s) causing the failure or delay in performance and provided that the party has not caused such event(s) to occur. Notice of a party's failure or delay in performance due to force majeure must be given to the other party within ten (10) days after its occurrence. All delivery dates under this Agreement that have been affected by force majeure shall be tolled for the duration of such force majeure. In no event shall any party be required to prevent or settle any labor disturbance or dispute.

### 12.13 Interpretation.

- (a) Captions & Headings. The captions and headings of clauses contained in this Agreement preceding the text of the articles, sections, subsections and paragraphs hereof are inserted solely for convenience and ease of reference only and shall not constitute any part of this Agreement, or have any effect on its interpretation or construction.
- **(b)** Interpretation. All references in this Agreement to the word "including" shall be deemed to be followed by the phrase "without limitation" or like expression. All references in this Agreement to the singular shall include the plural where applicable, and all references to gender shall include both genders and the neuter.
- (c) Articles, Sections & Subsections. Unless otherwise specified, references in this Agreement to any article shall include all sections, subsections, and paragraphs in such article; references in this Agreement to any section shall include all subsections and paragraphs in such sections; and references in this Agreement to any subsection shall include all paragraphs in such subsection.
  - (d) Days. All references to days in this Agreement shall mean calendar days, unless otherwise specified.
- (e) Ambiguities. Ambiguities and uncertainties in this Agreement, if any, shall not be interpreted against either party, irrespective of which party may be deemed to have caused the ambiguity or uncertainty to exist.
- (f) English Language. This Agreement has been prepared in the English language and the English language shall control its interpretation. In addition, all notices required or permitted to be given hereunder, and all written, electronic, oral or other communications between the parties regarding this Agreement shall be in the English language.
- 12.14 Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original document, and all of which, together with this writing, shall be deemed one instrument. Signatures provided by facsimile transmission or in Adobe™ Portable Document Format (PDF) sent by electronic mail shall be deemed to be original signatures.
- 12.15 HSR Filing. Each of Vical and Astellas agrees to prepare and make appropriate filings under the Hart-Scott-Rodino Anti-Trust Improvements Act of 1976, as amended (the "HSR Act") and any analogous foreign laws and regulations, relating to this Agreement and the

transactions contemplated hereby as soon as reasonably practicable, but in any event within ten (10) days after the date of execution of this Agreement (the "HSR Filing Date"). The parties agree to cooperate in the antitrust clearance process and to furnish promptly to the Federal Trade Commission, the Antitrust Division of the Department of Justice and any other agency or authority, any information reasonably requested by them in connection with such filings. Other than the provisions of this Section 12.15, the rights and obligations of the parties under this Agreement shall not become effective until the waiting period provided by the HSR Act shall have terminated or expired without any action by any governmental agency or challenge to the transaction (the date of such termination or expiration shall be the "Effective Date" of this Agreement). Upon the occurrence of the Effective Date, all provisions of this Agreement shall become effective automatically without the need for further action by the parties. In the event that antitrust clearance from the Federal Trade Commission and Antitrust Division of the Department of Justice is not obtained within ninety (90) days after the date of execution of this Agreement (or such later date as agreed in writing by the parties), this Agreement may be terminated by either party.

[Remainder of this page intentionally left blank.]

IN WITNESS WHEREOF, the parties hereto have duly executed this Ex-U.S. LICENSE AGREEMENT as of the date set forth below.	
VICAL INCORPORATED	ASTELLAS PHARMA INC.
By:	By:
Name: Vijay B. Samant	Name: Yoshihiko Hatanaka
Title: President and CEO	Title: President and CEO
Date: July , 2011	Date: July , 2011

SIGNATURE PAGE TO U.S. LICENSE AGREEMENT

# EXHIBIT A

# Vical Patents in the Territory

# **Vical Primary Patents**

- 1. [...\*\*\*...]
  - [...\*\*\*...]
  - [...\*\*\*...] b.
  - [...\*\*\*...]
- [...\*\*\*...]
- 3. [...\*\*\*...]
- 4. [...\*\*\*...]
  - [...\*\*\*...] a.
  - [...\*\*\*...]

  - [...\*\*\*...] c.
  - [...\*\*\*...] d. [...\*\*\*...] e.
  - f. [...\*\*\*...]
  - [...\*\*\*...] g.
  - h. [...\*\*\*...]
  - i. [...\*\*\*...]
  - [...\*\*\*...] j.

  - k. [...\*\*\*...] 1. [...\*\*\*...]
  - [...\*\*\*...] m.
  - [...\*\*\*...] n.
  - [...\*\*\*...]
  - [...\*\*\*...] p.
- 5. [...\*\*\*...]

# **Vical Patents**

- [...\*\*\*...] 1.
  - [...\*\*\*...] a.
  - [...\*\*\*...] b.
  - [...\*\*\*...]
- [...\*\*\*...]
- [...\*\*\*...] 3.
- 4. [...\*\*\*...]
  - a. [...\*\*\*...]
  - [...\*\*\*...] b.
  - [...\*\*\*...] c.
  - [...\*\*\*...] d.

  - [...\*\*\*...] e.
  - f. [...\*\*\*...]
  - [...\*\*\*...] g.
  - h. [...\*\*\*...]
  - i. [...\*\*\*...]
  - [...\*\*\*...] j.
  - [...\*\*\*...] k.
  - 1. [...\*\*\*...]
  - m. [...\*\*\*...]
  - [...\*\*\*...] n.
  - [...\*\*\*...] o.
  - [...\*\*\*...]
- [...\*\*\*...] 5.
- [...\*\*\*...]
- 7. [...\*\*\*...]
  - a. [...\*\*\*...] [...\*\*\*...]

[...\*\*\*...] c. d. [...\*\*\*...] [...\*\*\*...] e. f. [...\*\*\*...] [...\*\*\*...] g. [...\*\*\*...] h. i. [...\*\*\*...] [...\*\*\*...] j. [...\*\*\*...] k.

[...\*\*\*...] [...\*\*\*...]

m. [... 8. [...\*\*\*...]

\*\*\* Text Omitted and Filed Separately Pursuant to a Confidential Treatment Request under 17 C.F.R. §§ 200.80(b)(4) and 240.24b-2(b)(1)

### SUPPLY AND SERVICES AGREEMENT

THIS SUPPLY AND SERVICES AGREEMENT (the "Agreement") is entered into as of the Effective Date (as defined below) by and between VICAL INCORPORATED, a Delaware corporation ("Vical"), having an address of 10390 Pacific Center Court, San Diego, California, 92121, USA, and ASTELLAS PHARMA INC., a company organized under the laws of Japan ("Astellas"), having an address of 3-11, Nihonbashi-Honcho 2-Chome, Chuo-Ku, Tokyo 103-8411, Japan.

#### RECITALS

WHEREAS, Vical has developed expertise and owns or controls proprietary rights related to Compounds and Products in the Field (each as defined below);

WHEREAS, Astellas is engaged in the research, development and commercialization of pharmaceutical products;

WHEREAS, Astellas and Vical are entering into agreements of even date herewith granting Astellas exclusive rights to develop and commercialize Products in the Field (the "License Agreements"); and

WHEREAS, Astellas wishes to engage Vical to perform certain development and manufacturing services with respect to Compounds and Products on the terms and conditions set forth herein.

#### AGREEMENT

**Now, THEREFORE,** in consideration of the foregoing premises and the mutual covenants contained herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties agree as follows:

## 1. DEFINITIONS

- 1.1 "Affiliate" shall mean, with respect to a particular party, a person, corporation, partnership, or other entity that controls, is controlled by or is under common control with such party. For the purposes of this definition, 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 or cause the direction of the management and policies of such entity, whether by the ownership of more than fifty percent (50%) of the voting stock of such entity, or by contract or otherwise.
- 1.2 "Applicable Laws" shall mean (a) applicable U.S. laws, rules and regulations, (b) if requested by Astellas, applicable European and Japanese laws, rules and regulations, and (c) such other applicable laws, rules and regulations as agreed in writing by the parties (such agreement not to be unreasonably withheld by Vical); provided, that, the laws, rules and regulations described in (b) and (c) shall be only be included in Applicable Laws if and to the extent Astellas provides guidance to Vical regarding such laws, rules and regulations.

- 1.3 "Astellas Indemnitee" shall have the meaning provided in Section 12.1.
- 1.4 "Calendar Quarter" shall mean each respective period of three consecutive months ending on March 31, June 30, September 30 and December 31.
- 1.5 "Calendar Year" shall mean each respective period of twelve (12) consecutive months beginning on January 1.
- 1.6 "Certificate of Analysis" shall have the meaning provided in Section 6.2(b).
- 1.7 "cGMP" shall mean those current Good Manufacturing Practice regulations relating to the production of pharmaceutical products for human use in effect at the time in question for the Manufacture of a Product in the country or jurisdiction in which the Product is Manufactured and certified by the relevant Regulatory Authority in such country including, if applicable, the Code of Federal Regulations, Part 21, Sections 210 and 211 and such other sections thereof as are designated by the title "Current Good Manufacturing Practices" and promulgated under the United States Federal Food, Drug and Cosmetic Act, as are in effect from time to time.
  - 1.8 "CMC" shall mean chemistry, manufacturing and controls.
  - 1.9 "CMV" shall mean cytomegalovirus.
  - 1.10 "Commercial Products" shall have the meaning set forth in Section 3.1.
  - **1.11 "Commercial Supply Agreement"** shall have the meaning provided in Section 3.1.
- 1.12 "Commercially Reasonable Efforts" shall mean that level of efforts and resources consistent with commercially reasonable practices of a company in the pharmaceutical industry with respect to the research, development or supply of a pharmaceutical product at a similar stage of research, development or commercialization, taking into account relevant factors including, without limitation, measures of patent coverage, relative safety and efficacy, product profile, the competitiveness of the marketplace, the proprietary position of such product, the regulatory structure involved, the market potential of such product and other relevant factors, including comparative technical, legal, scientific and/or medical factors, all as measured by the facts and circumstances in effect at the time the carrying out of such obligations is due.
  - 1.13 "Compound" shall mean [...\*\*\*...] plasmid that encodes [...\*\*\*...] of glycoprotein B and/or phosphoprotein 65 [...\*\*\*...]
- 1.14 "Confidential Information" shall mean all Information and other proprietary scientific marketing, financial or commercial information or data, which is generated by or on behalf of a party or its Affiliates or which one party or any of its Affiliates has furnished or otherwise made available to the other party or its Affiliates, whether made available orally, in writing, or in electronic form. Confidential Information shall include all such information

provided or made available pursuant to the Confidentiality Agreement. All Vical Technology (including, without limitation, all Vical Manufacturing Information) shall be Confidential Information of Vical. All Confidential Information shall be subject to the Article 10.

- 1.15 "Confidentiality Agreement" shall mean that certain Confidentiality Agreement [...\*\*\*...].
- 1.16 "Control" shall mean, with respect to any Information, Patent or other intellectual property right, possession by a party of the ability (whether by ownership, license or otherwise, but without taking into account any rights granted by one party to the other party under the terms of this Agreement) to grant access, a right to use, a license or a sublicense (as applicable) to such Information, Patent or other intellectual property right without violating the terms of any agreement or other arrangement with any Third Party.
  - 1.17 "Cost of Goods" shall have the meaning provided in Section 5.2(b).
- 1.18 "Development Expenses" shall mean those costs and expenses incurred by Vical or for its account after the Effective Date in performing the activities described in Sections 2.1 and 2.2 of this Agreement, including, in each case, as applicable, (a) FTE costs at the FTE Rate, (b) the Transfer Price for Products used in performing such activities, including Products used for analytical, release and stability testing, and (c) costs and expenses paid or payable by Vical or for its account to a Third Party with respect to such activities.
- 1.19 "Development Plan" shall mean the annual plan for preclinical and clinical development of Products in the Field, including the budget for such activities to be performed by Vical, and any amendment or modification to such plan, which plan (other than such plan agreed as of the Effective Date) is drafted by the JDC and approved by the JSC under the License Agreements.
  - **1.20** "Effective Date" shall mean the Effective Date of the License Agreements.
- 1.21 "EMA" shall mean the European Medicines Agency or any successor agency thereto having the administrative authority to regulate the marketing of human pharmaceutical products or biological therapeutic products in the European Union.
  - **1.22 "Excluded Claim"** shall have the meaning provided in Section 13.2(c)(vi).
  - 1.23 "Executives" shall have the meaning provided in Section 13.2(b).
- 1.24 "Existing IND" shall mean the existing Investigational New Drug Application (including any amendments thereto) for Product in the Field, as filed by Vical with the FDA pursuant to 21 C.F.R. §312 and Controlled by Vical on the Effective Date.
- 1.25 "FDA" shall mean the United States Food and Drug Administration, or any successor agency thereto having the administrative authority to regulate the marketing of human pharmaceutical products or biological therapeutic products in the United States.

- 1.26 "Field" shall mean all therapeutic and prophylactic use to control or prevent CMV infection in (a) Immunocompromised Patients, including HSCT Recipients and SOT Recipients, and (b) human transplant donors, but excluding, in each case, any therapeutic or prophylactic use to control or prevent CMV infection other than as expressly described in clauses (a) and (b).
- 1.27 "First Commercial Sale" shall mean, with respect to a Product, the first sale for end use to a Third Party in a country or jurisdiction after the applicable Regulatory Authority has granted Regulatory Approval in such country or jurisdiction.
- 1.28 "Forecast" shall mean a written [...\*\*\*...] ([...\*\*\*...])-month rolling quarterly forecast of estimated orders for Compounds and Non-Commercial Products, which shall include estimated orders for Compounds and Non-Commercial Products by Astellas and its Sublicensees, as well as Compounds and Non-Commercial Products necessary for development and regulatory work to be performed pursuant to Section 2.1 or 2.2 and other activities agreed in writing by the parties.
- 1.29 "FTE" shall mean the equivalent of the work time of a full-time employee or contractor of Vical or its Affiliate for a twelve (12) month period [...\*\*\*...]) based on [...\*\*\*...] ([...\*\*\*...]) hours worked per twelve (12) month period.
- 1.30 "FTE Rate" shall mean the rate per FTE per twelve (12) month period, which rate shall be equal to [...\*\*\*...], as such rate may be adjusted by Vical annually, beginning after the first anniversary of the Effective Date, to correspond with increases in the Consumer Price Index of the United States Department of Labor for San Diego County, California.
  - 1.31 "HSCT" shall mean transplantation of hematopoietic stem cells, including peripheral blood stem cells, cord blood stem cells and bone marrow.
  - 1.32 "HSCT Recipient" shall mean a human recipient in a HSCT.
  - 1.33 "HSCT Study" shall mean a Phase 3 Clinical Trial of a Product for use in HSCT Recipients in the Field.
  - 1.34 "ICC" shall have the meaning set forth in Section 13.2(c)(i).
  - 1.35 "ICC Rules" shall have the meaning set forth in Section 13.2(c)(i).
- 1.36 "Immunocompromised Patients" shall mean human patients whose immune system is not functioning normally because of an immunodeficiency disorder or other disease, or as the result of the administration of immunosuppressive drugs or other drugs that may indirectly cause a reduction of the immune system function. For the avoidance of doubt, elderly patients and pregnant women shall not be deemed Immunocompromised Patients solely because such patients are elderly or pregnant, respectively.
- 1.37 "Information" shall mean all tangible and intangible (a) techniques, technology, practices, trade secrets, inventions (whether patentable or not), methods, protocols, processes,

knowledge, know-how, skill, experience, information, data and results (including pharmacological, toxicological, clinical, analytical and quality control data and results), regulatory filings, marketing reports, software and algorithms and (b) compositions of matter, cells, cell lines, assays, animal models and physical, biological or chemical material.

- 1.38 "JDC" shall mean the Joint Development Committee formed by the parties under the License Agreements.
- 1.39 "JSC" shall mean the Joint Steering Committee formed by the parties under the License Agreements.
- 1.40 "Label" shall refer to such labels and other written, printed or graphic matter, (a) upon the applicable product or any container or wrapper utilized with a Product, or (b) accompanying a Product, including, package inserts. "Labeled" or "Labeling" shall have correlative meaning.
  - 1.41 "License Agreements" shall have the meaning provided in the Recitals.
  - 1.42 "Losses" shall have the meaning provided in Section 12.1.
- 1.43 "Manufacture" shall mean all activities related to the manufacturing of a Compound or Product, or any ingredient thereof, whether in bulk, filled, finished or any other form, including manufacturing such Compound or Product for clinical or non-clinical use or for commercial sale, Packaging, Labeling, in-process and finished Product testing, release of such Product or any component or ingredient thereof, quality assurance activities related to manufacturing and release of such Product, ongoing stability tests and regulatory activities related to any of the foregoing. "Manufactured" or "Manufacturing" shall have correlative meaning.
  - 1.44 "Manufacturing Coordinators" shall mean the manufacturing coordinators designated by the parties under the License Agreements.
- 1.45 "Manufacturing Plan" shall mean (a) the annual plan for (i) CMC activities (including, without limitation, formulation, analytical and process development, and scale-up, stability, packaging and shipping studies) with respect to Compound and Product in the Field, including the budget for such activities to be performed by Vical and (ii) the Manufacture of Compound and Products in the Field, and (b) any amendment or modification to such plan, which plan (other than such plan agreed as of the Effective Date) is drafted by the Manufacturing Coordinators and approved by the JSC under the License Agreements.
  - **1.46 "Manufacturing Process"** shall have the meaning provided in Section 7.2.
  - 1.47 "Non-Commercial Products" shall have the meaning set forth in Section 3.1.
  - 1.48 "Objection Notice" shall have the meaning provided in Section 6.3(b).

- 1.49 "Package" shall mean all containers, including bottles, cartons, shipping cases or any other like matter used in packaging or accompanying a Product. "Packaged" or "Packaging" shall have correlative meaning.
- 1.50 "Patents" shall mean (a) all patents, including design patents, certificates of invention, applications for certificates of invention, priority patent filings and patent applications, including provisional patent applications and design patent applications, and (b) any renewal, divisional, continuation, continuation-in-part, or request for continued examination of any of such patents, certificates of invention and patent applications, and any and all patents or certificates of invention issuing thereon, and any and all reissues, reexaminations, extensions, certificates of correction, divisions, renewals, substitutions, confirmations, registrations, revalidations, revisions, and additions of or to any of the foregoing.
- 1.51 "Phase 3 Clinical Trial" shall mean a pivotal clinical trial of a Product conducted in human patients in any country designed to ascertain efficacy and safety of such Product for the purpose of submitting an application for Regulatory Approval to the competent Regulatory Authority, including any human clinical trial that would satisfy the requirements for a Phase 3 study as defined in 21 C.F.R. 312.21(c) or its successor regulation.
- 1.52 "Product" shall mean any pharmaceutical product that contains one or more Compound(s), alone or as a Combination Product, including, in each case, all formulations, line extensions and modes of administration, including any pharmaceutical product containing any formulation of one or more Compound(s) with poloxamer CRL1005, but excluding, in each case, any formulation with the Vaxfectin Adjuvant. "Combination Product" shall mean any pharmaceutical product that contains one or more Compound(s) in combination with one or more other therapeutically and/or prophylactically active ingredient(s), whether packaged together or included in a prime-boost regimen or in the same therapeutic formulation, including, in each case, all formulations, line extensions and modes of administration, but excluding, in each case, any formulation with the Vaxfectin Adjuvant. For clarification, poloxamers, other delivery systems and adjuvants shall not be considered therapeutically and/or prophylactically active ingredients.
  - 1.53 "Quality Agreement" shall have the meaning provided in Section 6.4.
  - 1.54 "Raw Materials" shall have the meaning provided in Section 7.1.
- 1.55 "Regulatory Approval" shall mean any and all approvals (including individual and national price and reimbursement approvals, as applicable), licenses, registrations, or authorizations of any country, federal, supranational, state or local regulatory agency, department, bureau or other governmental entity that are necessary to market and sell a Product in the Field in any country or regulatory jurisdiction.
- 1.56 "Regulatory Authority" shall mean any national, federal, supra-national, regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity whose review and/or approval is necessary for the manufacture, packaging, use, storage, import, export, distribution, promotion, marketing, offer for sale and sale of a Product in the Field in any country or regulatory jurisdiction.

- 1.57 "Sale" shall have the meaning provided in Section 13.6(a).
- 1.58 "SOT" shall mean solid organ transplantation.
- 1.59 "SOT Recipient" shall mean a human recipient in a SOT.
- 1.60 "Specifications" shall mean the specifications for a Compound or Product mutually agreed to by the parties and changes to such specifications made at the request of a Regulatory Authority in the applicable country or jurisdiction or by mutual agreement of the parties from time to time. The Specifications for VCL-6365, VCL-6368 and Product as of the Effective Date have been agreed by the parties and provided under separate letter agreement.
- 1.61 "Sublicensee" shall mean a Third Party or Affiliate to whom Astellas has granted a sublicense of the right to research, develop, make, have made, use, sell, offer for sale, have sold or import a Product in the Field, beyond the mere right to purchase such Product.
  - **1.62** "Term" shall have the meanings provided in Section 11.1.
  - 1.63 "Third Party" shall mean any entity other than Vical or Astellas or an Affiliate of Vical or Astellas.
  - 1.64 "Transfer Price" shall have the meaning provided in Section 5.2(a).
  - 1.65 "U.S." shall mean the United States of America and its territories and possessions, including Puerto Rico and the District of Columbia.
- 1.66 "Vaxfectin Adjuvant" shall mean Vical's proprietary cationic lipid-based system known as Vaxfectin® comprising (±)-N-(3-aminopropyl)-N,N-dimethyl-2,3-bis(syn-9-tetradeceneyloxy)-1-propanaminium bromide (GAP-DMORIE) or derivatives thereof and one or more co-lipid(s), including 1,2-diphytanoyl-sn-glycero-3-phosphoethanolamine (DPyPE), which is claimed or disclosed in a Patent Controlled by Vical.
  - 1.67 "VCL-6365" shall mean Vical's proprietary compound known as VCL-6365.
  - 1.68 "VCL-6368" shall mean Vical's proprietary compound known as VCL-6368.
  - **1.69** "Vical Indemnitee" shall have the meaning provided in Section 12.2.
  - 1.70 "Vical Manufacturing Information" shall have the meaning provided in Section 3.2.
  - 1.71 "Vical Technology" shall have the meaning provided in each of the License Agreements, as applicable.

### 2. DEVELOPMENT AND REGULATORY ACTIVITIES

2.1 Development Activities. Subject to the terms and conditions of this Agreement, Vical shall use Commercially Reasonable Efforts to perform (a) CMC activities (including, without limitation, formulation, analytical and process development, and scale-up, stability,

packaging and shipping studies) with respect to Compound or Product in the Field as agreed in writing by the parties and set forth in the Manufacturing Plan, including CMC-related development with respect to Products in the Field as necessary for obtaining Regulatory Approval for Products in the Field in each of [...\*\*\*...] and (b) development and other activities, including clinical and non-clinical activities, with respect to Compound or Product in the Field as agreed in writing by the parties and set forth in the Development Plan. All Information generated by or on behalf of Vical in performing its obligations under this Section 2.1 relating to Compound or Product, together with all intellectual property rights (including, but not limited to, Patents) therein, shall be owned by Vical and shall be included in the Vical Technology under the applicable License Agreement, as appropriate, and pursuant to Section 13.8. Each of the Development Plan and the Manufacturing Plan as of the Effective Date for the first year after the Effective Date, and a summary of the Development Plan and the Manufacturing Plan for the second and third years after the Effective Date, including the number of FTEs to be used by Vical in performing development activities and CMC activities, respectively, relating to Products in the Field during such years, has been agreed to by the parties and provided under separate letter agreement.

- 2.2 Regulatory Activities. Subject to the terms and conditions of this Agreement, Vical shall use Commercially Reasonable Efforts to provide Astellas with reasonable assistance as provided in the Development Plan or otherwise agreed in writing by the parties in connection with Astellas' preparation of such portions of filings with Regulatory Authorities for Products in the Field that relate to HSCT Study or other clinical study (including any study of a Product for use in SOT Recipients) design or CMC matters, and responses to questions from the applicable Regulatory Authorities with respect thereto.
- 2.3 Compliance with Laws; Disclosure Regarding Vical's Efforts. Vical shall perform its obligations under Sections 2.1 and 2.2 in accordance with Applicable Laws. Vical shall keep Astellas informed as to the progress of the development and regulatory activities performed by Vical pursuant to Sections 2.1 and 2.2, including by providing updates through the JDC.

### 3. SUPPLY OF PRODUCTS

3.1 Supply Obligations. During the Term, Vical will Manufacture or have Manufactured and supply or have supplied, and Astellas shall purchase from Vical, (a) Compounds and Products (including placebo) for CMC, development and regulatory activities with respect to Compounds and Products in the Field (including activities performed by Vical pursuant to Sections 2.1 and 2.2) (such Products, the "Non-Commercial Products"), and (b) following execution of, and subject to, the Commercial Supply Agreement (as defined below), Products for commercial requirements of Astellas and its Sublicensees, including Products to be marketed, sold, offered for sale or distributed by or on behalf of Astellas or its Sublicensees to customers in the Field pursuant to the License Agreements (such Products, the "Commercial Products"). Vical and Astellas shall negotiate in good faith and execute an amendment to this Agreement to include terms and conditions applicable to the supply by Vical of Commercial Products in addition to those terms and conditions applicable to Products contained herein including, but not limited to, (i) the form of Commercial Product to be Manufactured and supplied by Vical (i.e., finished form of Products or bulk form of Products) and (ii) the timing

and content of forecasts and purchase orders to be submitted by Astellas to Vical for Commercial Products (such agreement, the "Commercial Supply Agreement"). The Commercial Supply Agreement shall be subject to this Agreement and will be executed by the parties no later than [...\*\*\*...] for Regulatory Approval of a Product in the Field. In case that Vical entrusts with a Third Party Manufacture of the Compound, Non-Commercial Product and/or the Commercial Product, such Third Party shall be approved in writing by Astellas prior to commencement of such entrustment, which approval shall not be unreasonably withheld or delayed.

3.2 Transfer of Vical Manufacturing Information. Starting no later than six (6) months after first Regulatory Approval of the first Product in the Field or such earlier date as requested in writing by Astellas, the parties shall work together to agree to a plan for transitioning responsibility for the Manufacture and supply of Compounds and Products in the Field to Astellas or its designated contract manufacturer, and the parties shall use Commercially Reasonable Efforts to implement such plan and complete such transfer as promptly as possible, but [...\*\*\*...] or such earlier date as agreed in writing by the parties. Such plan shall provide for the transfer by Vical to Astellas or its designated contract manufacturer of all Vical Manufacturing Information and for Vical to provide reasonable assistance to enable Astellas or its designated contract manufacturer and supply Compounds and Products in the Field in accordance with the licenses and sublicenses granted under the applicable License Agreements. Such transfer and assistance will be provided at Astellas' sole expense according to a budget included in such plan (including, without limitation, any expense to perform any necessary clinical studies required in connection with the transfer of the Manufacture and supply of Compounds and Products in the Field to Astellas or its designated contract manufacturer). "Vical Manufacturing Information" shall mean all Vical Technology necessary or useful for the Manufacture and supply of Compounds and Products in the Field, including all necessary quality control Information, plasmid hosts and master cell banks in Vical's possession.

### 4. FORECASTS AND PURCHASE ORDERS FOR COMPOUNDS AND NON-COMMERCIAL PRODUCTS

4.1 Forecasts. Astellas shall provide Vical with an initial Forecast for Compounds and Non-Commercial Products promptly following finalization of the protocol for the HSCT Study. Thereafter, no later than [...\*\*\*...] ([...\*\*\*...]) days prior to each Calendar Quarter (or such other times as agreed by the parties in writing with respect to clinical supply of Products), Astellas shall provide Vical with Forecasts for Compounds and Non-Commercial Products, with such Forecasts including a breakdown of orders on a study-by-study basis and the type and form of Compounds and Non-Commercial Products required (i.e., Compounds, formulated bulk Non-Commercial Products and/or finished Non-Commercial Products). Following receipt of a Forecast, Vical shall add to such Forecast amounts of Compounds and Non-Commercial Products necessary for analytical, release and stability testing, CMC, development and regulatory work to be performed pursuant to Section 2.1 or 2.2 and other activities agreed in writing by the parties (to the extent not already included in the Forecast provided by Astellas), which amounts of Products shall be automatically deemed included in such Forecast, and Vical shall provide Astellas such updated Forecast. The parties agree that, unless otherwise agreed in writing by the parties, with respect to any Forecast, Astellas shall order and purchase one hundred percent

(100%) of the volume of Compounds and Non-Commercial Products set forth in each Forecast for the first [...\*\*\*...] ([...\*\*\*...]) months of such Forecast; provided that, Astellas may request that Vical supply more than one hundred percent (100%) of the volume of Compounds and Non-Commercial Products set forth in each Forecast for the first [...\*\*\*...] ([...\*\*\*...]) months of such Forecast, and Vical shall not be obligated to Manufacture or supply Astellas with such additional quantities of Compounds and Non-Commercial Products but shall use Commercially Reasonable Efforts to do so.

- 4.2 Purchase Orders. Astellas shall order Compounds and Non-Commercial Products by submitting written purchase orders, in such form as the parties shall agree from time to time, to Vical specifying the quantities of Compounds and Non-Commercial Products ordered (which shall be consistent with the requirements in Section 4.1), the type and form of Compounds and Non-Commercial Products ordered (i.e., Compounds, formulated bulk Non-Commercial Products and/or finished Non-Commercial Product), the desired shipment date for such Compounds and Non-Commercial Products and any special shipping instructions. Astellas shall order Compounds and Non-Commercial Products in lots of a defined number of units/lot pursuant to each purchase order as reasonably specified by Vical. Astellas shall submit each purchase order to Vical at least [... \*\*\*\*...] ([...\*\*\*\*...]) days in advance of the desired shipment date specified in such purchase order. Vical shall use Commercially Reasonable Efforts to make each shipment of Compounds and Non-Commercial Products in the quantity and on the shipment date specified for it on Astellas' purchase order, via the mode(s) of transportation and to the party and destination specified on such purchase order. Any purchase orders for Compounds and Non-Commercial Products submitted by Astellas to Vical shall reference this Agreement and shall be governed exclusively by the terms contained herein. The parties hereby agree that, with respect to supply of Compounds and Non-Commercial Products, the terms and conditions of this Agreement shall supersede any term or condition in any order, confirmation or other document furnished by Astellas or Vical that is in any way inconsistent with these terms and conditions.
- 4.3 Quantity of Orders. The parties will discuss and agree on the configuration of Compounds and Non-Commercial Products (e.g., in boxes, bottles, etc.) for purposes of Forecasts and purchase orders of Compounds and Non-Commercial Products pursuant to this Article 4.

### 5. PAYMENTS

**5.1 Development Expenses.** Astellas shall reimburse Vical for all Development Expenses (excluding the Transfer Price for Compounds and Products included in such Development Expenses to the extent Astellas has already paid the Transfer Price for such Compound and Products pursuant to Section 5.2) that do not exceed the total budget for such Development Expenses as set forth in the Development Plan or the Manufacturing Plan, as the case may be (or as otherwise agreed in writing by the parties with respect to activities that are not set forth in the Development Plan or Manufacturing Plan) by more than [...\*\*\*...] percent ([...\*\*\*...]%) of the total budget for such Development Expenses, on an annual basis, unless otherwise approved by the JSC. If Vical reasonably anticipates that actual Development Expenses for a given year will exceed the budget for such Development Expenses as set forth in the Development Plan, Manufacturing Plan or other budget agreed in writing by the parties by more than [...\*\*\*...] percent ([...\*\*\*...]%), the JDC and/or Manufacturing Coordinators, as appropriate, shall promptly prepare and

submit to the JSC proposed changes to the Development Plan, Manufacturing Plan, or other budget, as the case may be, to reflect an appropriate increase in the budget for such Development Expenses, together with a reasonable explanation, for review and approval by the JSC. The JSC shall promptly, and in any event within [...\*\*\*...] ([...\*\*\*...]) days of submission of such changes by the JDC or Manufacturing Coordinators, review and use good faith efforts to promptly agree to amend the Development Plan, Manufacturing Plan, or such other budget, as the case maybe, to reflect such changes, or keep them as they are (including, if applicable, an agreement that such amendment shall apply retroactively to actual Development Expenses that exceeded the applicable budget by more than [...\*\*\*...] percent ([...\*\*\*...]%) prior to such amendment). The parties agree that, for purposes of expediting such review and approval, the JSC shall be permitted to review and approve such amendments via email. For Astellas' due budget control, Vical agrees to submit to Astellas (a) a monthly report of the Development Expenses incurred by Vical for each calendar month during the Term, within [...\*\*\*...] ([...\*\*\*...]) days following the end of such calendar month, and (b) a [...\*\*\*...] report of the Development Expenses incurred by Vical as compared against the budget for such Development Expenses for each [...\*\*\*...] during the Term, within [...\*\*\*...] ([...\*\*\*...]) days following the end of such [...\*\*\*...]

## 5.2 Supply of Products.

(a) Transfer Price. Astellas shall pay Vical a transfer price for Compounds and Products as follows: (i) for Compounds supplied by Vical under this Agreement to be used (whether by or for Astellas or Vical) in CMC, development and regulatory activities, Cost of Goods for such Compound; provided, however, that in no event shall such transfer price exceed US\$[...\*\*\*...] per milligram for VCL-6365 and US\$[...\*\*\*...] per milligram for VCL-6368, (ii) for Non-Commercial Products (including placebo) supplied by Vical under this Agreement, including reference standard and Products for validation runs and analytical, release and stability testing, Cost of Goods for such Non-Commercial Product; provided, however, that in no event shall such transfer price exceed (A) for finished Non-Commercial Product, US\$[...\*\*\*...] per one vial of the finished Non-Commercial Product, US\$[...\*\*\*...] per milligrams of Compound per one milliliter of the finished Non-Commercial Product; and (iii) for Commercial Products to be supplied by Vical under this Agreement following execution of the Commercial Supply Agreement, including Products for analytical, release and stability testing, an amount equal to the Cost of Goods for such Commercial Products plus [...\*\*\*...] percent ([...\*\*\*...]%); provided, however, that, if Astellas purchases at least [...\*\*\*...] vials of Commercial Products (or, if applicable, at least such amount of Compound contained in [...\*\*\*...] vials of Commercial Products) in a given Calendar Year, then in no event shall the transfer price for such Commercial Products purchased in such Calendar Year exceed (A) for finished Commercial Product, US\$[...\*\*\*...] per one vial of the finished Commercial Product containing one dose of five milligrams of Compound per one milliliter of the finished Commercial Product, US\$[...\*\*\*...] per one vial of the finished Commercial Product containing one dose of five milligrams of Compound per one milliliter of the finished Commercial Product, US\$[...\*\*\*...] per one vial of the finished Comme

Products (or, if applicable, at least such amount of Compound contained in [...\*\*\*...] vials of Commercial Products) in a given Calendar Year, then in no event shall the transfer price for such Compounds purchased in such Calendar Year exceed US\$[...\*\*\*...] per milligram for VCL-6365 and US\$[...\*\*\*...] per milligram for VCL-6368 (in each case, the "*Transfer Price*").

(b) Cost of Goods. "Cost of Goods" means the actual fully-burdened cost of Compound, Non-Commercial Product (including placebo) and/or Commercial Product shipped. As used herein, the cost of Compound, Non-Commercial Product (including placebo) and/or Commercial Product means (i) in the case of products, materials (including, but not limited to, poloxamer CRL1005), reagents and services acquired from Third Parties for use in connection with Manufacturing and/or supplying Compound, Non-Commercial Product and/or Commercial Product, payments made to such Third Parties, and (ii) in the case of Manufacturing and supply services performed by Vical or its Affiliate, the actual unit costs of Manufacture in bulk form or final Manufacturing (including the costs of any Packaging purchased by Vical, but excluding any costs of Packaging and Labeling purchased and provided by Astellas pursuant to Section 7.3, if any, and any costs for which Vical is reimbursed pursuant to Section 5.2(c)), as the case may be, plus the variances and other costs specifically provided for herein. Actual unit costs shall consist of direct material and direct labor costs, plus manufacturing overhead reasonably allocable to such Manufacturing and supply services, of Vical or its Affiliate, in each case in accordance with reasonable cost accounting methods, consistently applied. Direct material costs shall include the costs incurred in purchasing materials, including sales and excise taxes imposed thereon and customs duty and charges levied by Regulatory Authorities, and all costs of packaging components. Direct labor shall include all actual FTE costs of employees and contractors engaged in direct Manufacturing or supply activities and direct quality control and quality assurance activities who are directly employed in Manufacturing and supply services. Manufacturing overhead allocable to Manufacturing and supply services may include indirect labor, facilities' start-up costs, unsuccessful or low yielding production runs, excess or idle capacity, th

(c) Shipping Materials. Astellas shall reimburse Vical for all costs incurred by Vical in purchasing, at the request of Astellas, shipping materials (including shipping containers and packaging) for Products and/or Compounds.

#### 5.3 Invoices; Method of Payments.

(a) Invoices. Vical shall invoice Astellas for Development Expenses and, if applicable, any costs incurred by Vical in purchasing shipping materials for Compounds and Products, on a monthly basis within [...\*\*\*...] ([...\*\*\*...]) days following the end of each month. Vical shall invoice Astellas for the aggregate Transfer Price of Compounds and Products at the time of shipment of such Compounds and Products. For purposes of this Section, the style and content of the invoice issued by Vical pursuant to this Section shall be agreed in advance by Vical and Astellas. Vical also agrees to notify Astellas by e-mail of the amount to be invoiced under this Section 5.3(a) for the last month of each Calendar Quarter within [...\*\*\*...] ([...\*\*\*...]) business days following the end of such Calendar Quarter on a best estimate basis.

- (b) Method of Payments. All payments due hereunder to Vical shall be paid to Vical in U.S. Dollars not later than [...\*\*\*...] ([...\*\*\*...]) days following the date of the applicable invoice, unless, in the case of payment for Compounds and Products, such shipment of Compounds or Products is rejected in accordance with the provisions of Section 6.3. All payments owed under this Agreement shall be made by wire transfer in immediately available funds to a bank and account designated in writing by Vical, unless otherwise specified in writing by Vical.
- (c) Late Payments. In the event that any payment due under this Agreement is not made when due, the payment shall accrue interest from the date due at the rate of [...\*\*\*...] percent ([...\*\*\*...]%) above the U.S. Prime Rate (as set forth by Bloomberg (Ticker symbol PRIME index)); provided, however, that in no event shall such rate exceed the maximum legal annual interest rate. The payment of such interest shall not limit Vical from exercising any other rights it may have as a consequence of the lateness of any payment.
- 5.4 Records; Audits. Vical shall keep complete, fair and true books of accounts and records for the purpose of determining the amounts payable to Vical pursuant to this Agreement, including Development Expenses and Cost of Goods. Such books and records shall be kept for [...\*\*\*...] ([...\*\*\*...]) years following the end of the Calendar Quarter to which they pertain. Astellas shall have the right to cause an independent, certified public accountant, reasonably acceptable to Vical, to audit such records to confirm Development Expenses and Cost of Goods for a period covering not more than the preceding [...\*\*\*...] ([...\*\*\*...]) years. Such audits may be exercised during normal business hours upon reasonable prior written notice to Vical. Prompt adjustments shall be made by the parties to reflect the results of such audit. Astellas shall bear the full cost of such audit discloses an overpayment by Astellas of more than five percent (5%) of the amount of payments due under this Agreement, in which case, Vical shall bear the full cost of such audit and shall promptly remit to Astellas the amount of any overpayment.

### 6. DELIVERY; QUALITY ASSURANCE; ACCEPTANCE

**6.1 Delivery Terms.** Vical will deliver Compounds and/or Products to Astellas in such quantities and on the delivery dates as are specified in purchase orders. Deliveries shall be made [...\*\*\*...] (Incoterms 2010) Vical's or its Third Party manufacturer's designated facility. For clarification, Astellas shall be responsible for the costs of shipping materials for Products as set forth in Section 5.2(c).

## 6.2 Testing; Certificate of Analysis.

- (a) Batch Testing. Vical will perform standard analytical testing of each Manufactured batch of Compounds and/or Products to be delivered to Astellas to verify that each of them meets the Specifications according to the procedure described in the corresponding documentation and that Compounds and/or Products were Manufactured in accordance with Applicable Laws.
- (b) Certificate of Analysis. Vical shall provide a certificate of analysis (the "Certificate of Analysis"), and any other documentation necessary for Astellas to release into commerce and sell Products under all Regulatory Approvals, to Astellas with each shipment of

Compounds and/or Products supplied hereunder. Such Certificate of Analysis shall certify with respect to each shipment and batch (identified by batch number) (i) the quantity of the shipment, and (ii) that delivered Compounds and/or delivered Products conforms to the Specifications, respectively, as well as any further information required by the relevant Regulatory Authorities that Astellas may have previously notified Vical is necessary. Astellas shall be under no obligation to accept any shipment of Compounds and/or Products without an accompanying Certificate of Analysis.

## 6.3 Acceptance and Rejection.

- (a) Rejection. Astellas may reject any shipment (or portion thereof) of Compounds and/or Products if such shipment fails to conform to any warranty set forth in Section 9.1 of this Agreement by providing to Vical written notice of such rejection and the reasons therefor within [...\*\*\*...] ([...\*\*\*...]) days after delivery of such shipment; otherwise, Astellas shall be deemed to have accepted such shipment of Compounds and/or Products.
- (b) Dispute Procedure. Astellas' basis for rejection shall be conclusive unless Vical notifies Astellas in writing, within [...\*\*\*...] ([...\*\*\*...]) days of Vical's receipt of notice that Astellas is rejecting the Compounds and/or the Products, that Vical disagrees with such basis for rejection (an "Objection Notice"). If Astellas and Vical fail within ten (10) days after delivery of the Objection Notice to agree as to whether the Compounds and/or the Products are defective, representative samples of the batch of the Compounds in question and/or the Products in question shall be submitted to a mutually-acceptable independent laboratory or consultant for analysis or review. The results of such evaluation shall be binding upon the parties. The parties shall share equally the cost of such evaluation except that the party that is determined to have been incorrect in its determination of whether the Compounds and/or the Products should be rejected shall assume the responsibility for, and pay, the costs of any such evaluation and reimburse the other for any amounts previously paid to the independent laboratory or consultant in connection with that determination.
- (c) Payment for Rejected Compounds and/or Rejected Products. If any shipment of Compounds and/or Products is rejected by Astellas, Astellas' obligation to pay all amounts payable to Vical in respect of the rejected shipment shall be suspended unless and until there is a determination by the independent laboratory or consultant in support of Vical's Objection Notice in accordance with Section 6.3(b). If only a portion of a shipment is rejected, Astellas' duty to pay the amount allocable to the defective portion only shall be suspended.
- (d) Remedy for Rejected Compounds and/or Rejected Products. If a shipment or partial shipment is rejected by Astellas pursuant to the provisions of this Section 6.3 and there is not a determination by the independent laboratory or consultant in support of Vical's Objection Notice in accordance with Section 6.3(b), Astellas shall return to Vical at Vical's request and expense (or, at the election of Vical, destroy at Vical's expenses and provide evidence of such destruction to Vical) any such rejected Compounds and/or any such rejected Products. Vical shall (i) credit the original invoice in respect of the rejected Compounds and/or the rejected Products, and (ii) adjust the invoice to Astellas for any Compounds that were not rejected and/or any Products that were not rejected, payment of which is due in accordance with the terms of the original invoice. The foregoing sentence sets forth the sole and exclusive

remedy of Astellas for any rejection of Compounds and/or Products pursuant to this Section 6.3 and any breach by Vical of Section 9.1 of this Agreement other than a breach of the warranty set forth in Section 9.1(a) that cannot be discovered in the course of inspection or testing conducted by Astellas upon receipt of Compounds or Products, as applicable.

- (e) Replacement Compounds and/or Products. During the pendency of any rejection discussions Vical shall use Commercially Reasonable Efforts to supply Astellas with replacement Compounds and/or replacement Products which Astellas shall purchase on the same terms as the Compounds and/or the Products that are the subject of the rejection discussions.
- **6.4 Quality Agreement.** Within [...\*\*\*...] ([...\*\*\*...]) days from the Effective Date, the parties will enter into an agreement that details the quality assurance obligations of each party ("Quality Agreement") with respect to the Manufacture and supply of the Compounds and Non-Commercial Products pursuant to this Agreement. The Quality Agreement with respect to the Manufacture and supply of the Commercial Products will be executed within [...\*\*\*...] ([...\*\*\*...]) days from the date of execution of the Commercial Supply Agreement.

#### 7. MANUFACTURE OF NON-COMMERCIAL PRODUCTS AND COMPOUNDS

- 7.1 Raw Materials. Vical shall be responsible for obtaining, and shall store at no cost to Astellas, any raw materials, components and other ingredients (excluding Packaging and Labeling materials to be provided by Astellas) ("Raw Materials") required for the Manufacture and supply of Compounds and/or Non-Commercial Products pursuant to this Agreement, in reasonable quantities consistent with Astellas' Forecasts and purchase orders.
- 7.2 Manufacture of Compound and Non-Commercial Product; Changes to Specifications or to the Manufacturing Process. Vical will Manufacture Non-Commercial Products in accordance with the Specifications, cGMPs and Applicable Laws, including, as applicable, any laws, rules, guidelines, regulations, guidance, points to consider documents and standards of the Environmental Protection Agency, the Occupational Safety and Health Administration and state and local authorities that apply to the Manufacture of Compounds and Non-Commercial Products. The parties shall notify each other within [...\*\*\*...] ([...\*\*\*...]) hours of any new instructions or specifications required by Regulatory Authorities with jurisdiction over the Manufacture, import, export, use or sale of Products in the Field, and the parties shall confer with respect to any response regarding such instruction or specification and the best means to comply with such requirements. If Vical intends to make any changes to the Specifications, or in the Raw Materials, equipment, process or procedures used to Manufacture, the Compounds and Non-Commercial Products (the "Manufacturing Process"), (a) which would require an amendment of the Existing IND or (b) which the Manufacturing Coordinators have agreed in writing should be changed only with Astellas' prior written consent, Vical shall obtain the prior written consent of Astellas through the Manufacturing Coordinators with respect to any such proposed changes to the Specifications or the Manufacturing Process. Further, Vical shall promptly notify Astellas in writing through the Manufacturing Coordinators of any and all changes to the Specifications or the Manufacturing Process actually implemented. Any changes to the Specifications or to the Manufacturing Process (including any

capital expenditures), unless such changes were requested by Vical and were not required by applicable laws, rules or regulations, in which case Vical shall be responsible for the costs of implementing such changes.

- 7.3 Labeling and Packaging. With respect to Compounds and Non-Commercial Products, Astellas shall provide to Vical or Vical's designee its instruction for any Labels and Packaging therefor or, if agreed by the parties, Astellas may provide to Vical or Vical's designee any or all Labels and Packaging for Compounds and Non-Commercial Products, at Astellas' sole costs and expenses. All Product Labels and Packaging or trade dress shall comply with applicable laws, rules and regulations. Astellas shall be solely responsible for ensuring the accuracy of all information contained on all Labels and Packaging for Compounds and Non-Commercial Products and for the compliance of all such Labels and Packaging with applicable laws, rules and regulations. Should Astellas desire or Astellas or Vical be required pursuant to applicable laws, rules and regulations to make any change in any such Labels or Packaging, Astellas shall be responsible for procuring the updating of all artwork and text associated with such change and providing such changes and, if the parties have agreed that Astellas will supply such Labels and Packaging, corresponding changed Labels and Packaging to Vical or Vical's designee. Vical's obligations to supply Astellas and its Sublicensees with Compounds and Non-Commercial Products shall be contingent upon Vical's or Vical's designee's timely receipt of Labels and Packaging, or instructions for Labels and Packaging, as appropriate, and other necessary items from Astellas, if applicable.
- 7.4 Product Shortfall. Vical shall use Commercially Reasonable Efforts to avoid shortfalls in supply of Compounds and/or Non-Commercial Products based on the Forecasts provided by Astellas. In the event Vical is unable to supply to Astellas, in whole or in part, Compounds and/or Non-Commercial Products requested for any reason (except to the extent caused by Astellas), then, in addition to other rights or remedies available, Vical shall promptly notify Astellas, in writing, of such shortage, or potential shortage, or inability to timely supply Compounds and/or Non-Commercial Products and, if possible, the date when Vical will again be able to supply Compounds and/or Non-Commercial Products. Vical will use Commercially Reasonable Efforts to remedy any shortfall of Compounds and/or Non-Commercial Products as soon as practicable and Vical will allocate its available production capacity for the production of Compounds and/or Non-Commercial Products in a manner proportional to the utilization of all customers (including Vical) of such capacity in the prior [...\*\*\*...] ([...\*\*\*...]) month period.
- 7.5 Maintenance of Inventory. Astellas shall maintain an inventory of Compounds and Non-Commercial Products at a level sufficient to enable Astellas to meet reasonable demands for Non-Commercial Products in the Field.

# 8. REGULATORY

**8.1 Regulatory Compliance.** Vical shall comply with all regulatory requirements with respect to Compounds and Products imposed by Applicable Laws upon Vical as the manufacturer of Compound and Product. Vical shall, on a timely basis, provide Astellas with such information in Vical's possession as the manufacturer of Compound and Product as reasonably required by Astellas. For Vical's compliance with all regulatory requirements mentioned above, if required by the Regulatory Authority directly or through Astellas, Vical

shall, and shall cause its Third Party manufacturer to, allow a Regulatory Authority to conduct inspection of the facilities at which Compound and/or Product are Manufactured. In case that Vical or its Third Party manufacturer receives request or notice of inspection by a Regulatory Authority of the facilities at which Compound and/or Product are Manufactured, Vical shall promptly so notify Astellas. Upon request by Astellas, Vical shall, and shall cause its Third Party manufacturer to, permit Astellas' representative to be present in such inspection by the Regulatory Authority; provided, however that, for clarification, all information made available to Astellas or its representative during such meeting shall be considered Vical Manufacturing Information.

- 8.2 cGMP Compliance and QA Audits. Upon written request to Vical, once per Calendar Year, Astellas shall have the right to have representatives visit Vical's and/or its Third Party manufacturer's Manufacturing facilities during normal business hours to discuss any related issues with Vical's and/or its Third Party manufacturer's Manufacturing and management personnel and to review and inspect (a) Vical's and/or its Third Party manufacturing and storage facilities, (b) the quality control procedures, and/or (c) any records and reports pertinent to the Manufacture, disposition or transport of Products as may be necessary to evidence Vical's and/or its Third Party manufacturer's compliance with all applicable laws, rules and regulations relating to the Manufacture of Product, including compliance with cGMP; provided, however, that with respect to for-cause inspections, Astellas shall be permitted to conduct such for-cause inspections more than once per Calendar Year. Astellas shall have the right to conduct QM/QP inspection for Manufacture at Vical of Products for use in a HSCT Study no later than [...\*\*\*...] prior to such Manufacture (it being understood that certain amount of bulk Compound in total quantities thereof that would be used in such Manufacture has been manufactured prior to the Effective Date and provided that this Agreement has been signed with sufficient time to allow inspection within such a timeframe for finished Non-Commercial Product for such HSCT Study).
- 8.3 Recall of Products. For any Product, in the event that: (a) any Regulatory Authority issues a request, directive or order that such Product be recalled or retrieved; (b) a court of competent jurisdiction orders that such Product be recalled or retrieved; or (c) Astellas reasonably determines, after reasonable, good faith discussion with Vical if time permits, that such Product should be recalled or retrieved, Astellas shall promptly notify Vical of such event and shall conduct such activity and take appropriate corrective actions, and Vical shall provide such assistance to Astellas as is reasonably necessary to carry out such activities. All costs and expenses of such recall and corrective actions shall be the responsibility of Astellas, provided however, to the extent the recall can be attributed to the negligence or willful misconduct of Vical or Vical's breach of this Agreement, Vical shall be responsible for such cost and expense to the extent of such negligence, willful misconduct or breach. For purposes hereof, such cost and expenses shall be limited to reasonable, actual and documented costs incurred by the parties for such recall, withdrawal or correction, and replacement of Products to be recalled.
- **8.4 Permits.** Vical represents and warrants to Astellas that it has and will maintain during the Term all government permits, including, health, safety and environmental permits, necessary for the conduct of the actions and procedures that it undertakes pursuant to this Agreement.

8.5 Documentation. Vical shall keep complete, accurate and authentic accounts, notes, data and records of the work performed by Vical under this Agreement (including all manufacturing master production and control records, batch production and control records, production procedures, testing documentation, and shipping records) and shall maintain complete and adequate records pertaining to the methods and facilities used for the Manufacture, processing, testing, packing, labeling, holding and distribution of Compounds and Products in accordance with Applicable Laws. Vical agrees that, in response to any complaint, or in the defense by Astellas of any litigation, hearing, regulatory proceeding or investigation relating to the Products, Vical shall use Commercially Reasonable Effort to make available to Astellas during normal business hours and upon reasonable prior written notice, such Vical employees and records reasonably necessary to permit the effective response to, defense of, or investigation of such matters, subject to appropriate confidentiality protections. Except the case that such complaint or the litigation, hearing, regulatory proceeding or investigation relating to the Products is caused due to Vical's gross negligence, willful misconduct or breach of this Agreement, Astellas shall reimburse Vical for all reasonable costs and expenses incurred by Vical in connection with the performance of Vical's obligations under the immediately preceding sentence.

**8.6 Samples.** Vical shall retain samples of Compounds and Non-Commercial Products for a period requested by Astellas after Astellas' acceptance of such batch, which period shall in no event exceed the longer of [...\*\*\*...] ([...\*\*\*...]) years or the minimum period required by applicable law.

### 9. REPRESENTATIONS AND WARRANTIES

- 9.1 Product Warranty. Vical represents and warrants that Compounds and Products delivered hereunder will (a) be Manufactured by Vical in accordance with all applicable Regulatory Approvals, cGMPs and Applicable Laws, (b) conform to the Specifications at the time of delivery, (c) not be adulterated under Applicable Laws at the time of delivery, and (d) be supplied in accordance with the Quality Agreement.
- **9.2 No Debarred or Disqualified Persons.** Vical represents and warrants that is not debarred under the United States Federal Food, Drug and Cosmetic Act or comparable laws in any other country or jurisdiction, and it does not, and will not during the Term, employ or use the services of any person or entity who is debarred, in connection with the performance of activities pursuant to this Agreement. In the event that Vical becomes aware of the debarment or threatened debarment of any person or entity providing services to Vical which directly or indirectly relate to activities under this Agreement, Astellas shall be immediately notified in writing.
- 9.3 Mutual Representations and Warranties. Each party represents and warrants to the other that: (a) it is duly organized and validly existing under the laws of its jurisdiction of incorporation or formation, and has full corporate or other power and authority to enter into this Agreement and to carry out the provisions hereof; (b) it is duly authorized to execute and deliver this Agreement and to perform its obligations hereunder, and the person or persons executing this Agreement on its behalf has been duly authorized to do so by all requisite corporate or partnership action; and (c) this Agreement is legally binding upon it, enforceable in accordance

with its terms, and does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound, nor violate any material law or regulation of any court, governmental body or administrative or other agency having jurisdiction over it.

- 9.4 Disclaimer. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, OR ANY OTHER WRITTEN AGREEMENT BETWEEN THE PARTIES, NEITHER PARTY MAKES ANY REPRESENTATIONS OR EXTENDS ANY WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, AND EACH PARTY EXPRESSLY DISCLAIMS ALL IMPLIED WARRANTIES OF MERCHANTABILITY AND OF FITNESS FOR A PARTICULAR PURPOSE OR USE, NON-INFRINGEMENT, VALIDITY AND ENFORCEABILITY OF PATENTS, OR THE PROSPECTS OR LIKELIHOOD OF DEVELOPMENT OR COMMERCIAL SUCCESS OF PRODUCTS.
- 9.5 Limitation of Liability. NEITHER PARTY SHALL BE ENTITLED TO RECOVER FROM THE OTHER PARTY ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES IN CONNECTION WITH THIS AGREEMENT OR ANY LICENSE GRANTED HEREUNDER; provided however, that this Section 9.5 shall not be construed to limit either party's indemnification obligations under Article 12 or its right to obtain recover damages for breach of Article 10. For clarification, payments under Article 5 shall not be considered special, incidental, consequential or punitive damages.

#### 10. CONFIDENTIALITY

10.1 Confidential Information. Except to the extent expressly authorized by this Agreement or otherwise agreed in writing by the parties, the parties agree that, during the Term and continuing until [...\*\*\*...] ([...\*\*\*...]) years after expiration or termination of the later to expire or terminate of the License Agreements, each party (in such capacity, the "receiving party") shall keep confidential and shall not publish or otherwise disclose and shall not use for any purpose other than as expressly provided for in this Agreement or the Confidentiality Agreement any Confidential Information of the other party (in such capacity, the "disclosing party"). The receiving party may use Confidential Information of the other party only to the extent required to accomplish the purposes of this Agreement. The receiving party will use at least the same standard of care as it uses to protect proprietary or confidential information of its own (but not less than reasonable care) to ensure that its employees, agents, consultants and other representatives do not disclose or make any unauthorized use of the Confidential Information of the disclosing party. The receiving party will promptly notify the disclosing party upon discovery of any unauthorized use or disclosure of the Confidential Information of the disclosing party. Without limiting the foregoing, the parties acknowledge that Information relating to Compound or Product that is generated by or on behalf of Vical in performing its obligations under Section 2.1 of this Agreement includes valuable trade secrets and that it is in the interests of both parties to protect the confidentiality of such Information; provided, that nothing will limit or prevent Vical from using or disclosing such Information in connection with its discussions and activities outside the scope of the exclusive licenses granted to Astellas under the License Agreements with respect to Compounds and Products in the Field.

- 10.2 Treatment of Vical Manufacturing Information. In addition to the other provisions herein, both parties recognize that maintaining the confidentiality and trade secret nature of the Vical Manufacturing Information requires a higher level of vigilance than other Confidential Information, and Astellas agrees to: (a) maintain in confidence Vical Manufacturing Information with the same degree of care that Astellas uses to protect its own like information (but no less than reasonable care); (b) strictly limit access to and use of Vical Manufacturing Information to employees, agents, consultants and other representatives of Astellas with a need to know such information; and (c) use Vical Manufacturing Information only for Manufacturing and supplying Products in the Field. Astellas shall ensure that any person having access to the Vical Manufacturing Information will be made aware of its highly confidential nature and will agree to be bound by confidentiality terms no less stringent than those in this Agreement. The obligations under this Section 10.2 shall survive and continue in effect for a period of [...\*\*\*...] ([...\*\*\*...]) years after expiration or termination of the later to expire or terminate of the License Agreements; provided, however, that such obligations with respect to trade secrets included in the Confidential Information and identified and maintained as trade secrets by Vical will continue for so long as such trade secrets retain their legal status as trade secrets. Each of Vical and Astellas acknowledge and agree that Sections 10.3 and 10.4 shall apply to Vical Manufacturing Information; provided, that (i) Confidential Information of Vical disclosed to any contract manufacturer used by either party pursuant to this Agreement; and (ii) any Confidential Information set forth in Section 10.3 or otherwise cease to be Confidential Information of Vical for any reason.
- 10.3 Exceptions. Confidential Information shall not include any information which the receiving party can demonstrate by competent evidence: (a) is now, or hereafter becomes, through no act or failure to act on the part of the receiving party, generally known or available; (b) is known by the receiving party at the time of receiving such information, as evidenced by its records; (c) is hereafter furnished to the receiving party by a Third Party, as a matter of right and without restriction on disclosure; or (d) is independently discovered or developed by the receiving party without the use of Confidential Information of the disclosing party.
- 10.4 Authorized Disclosure. The receiving party may disclose Confidential Information of the other party as expressly permitted by this Agreement or if and to the extent such disclosure is reasonably necessary in the following instances:
  - (a) defending litigation as permitted by this Agreement;
  - **(b)** complying with applicable court orders or governmental regulations;
- (c) in the case of Astellas, conducting development, manufacturing and/or commercialization activities in accordance with the license granted in the License Agreements, including making regulatory filings with respect to Products;
  - (d) in the case of Vical, as otherwise permitted in the License Agreements; and
- (e) disclosure to Affiliates, sublicensees, subcontractors, employees, consultants, agents or other Third Parties who need to know such information for the development,

manufacture and commercialization of Products in accordance with this Agreement or in connection with due diligence or similar investigations by such Third Parties, and disclosure to potential Third Party investors in confidential financing documents, provided, in each case, that any such Affiliate, sublicensee, subcontractor, employee, consultant, agent or Third Party agrees to be bound by similar terms of confidentiality and non-use at least equivalent in scope to those set forth in this Article 10.

Notwithstanding the foregoing, in the event the receiving party is required to make a disclosure of the disclosing party's Confidential Information pursuant to Section 10.4(a) or (b), it will, except where impracticable, give reasonable advance notice to the disclosing party of such disclosure and use efforts to secure confidential treatment of such information at least as diligent as the receiving party would use to protect its own confidential information, but in no event less than reasonable efforts. In any event, the receiving party agrees to take all reasonable action to avoid disclosure of Confidential Information of the disclosing party.

10.5 Confidentiality of this Agreement and its Terms. Except as otherwise provided in this Article 10, each party agrees not to disclose to any Third Party the existence of this Agreement or the terms of this Agreement without the prior written consent of the other party hereto, except that each party may disclose the terms of this Agreement that are not otherwise made public as contemplated by Section 10.6 as permitted under Section 10.4.

#### 10.6 Public Announcements.

(a) Press Releases. As soon as practicable following the date hereof, the parties shall each issue a mutually agreed to press release announcing the existence of this Agreement. Except as required by applicable laws and regulations (including disclosure requirements of the U.S. Securities and Exchange Commission ("SEC") or any stock exchange on which securities issued by a party or its Affiliates are traded), neither party shall make any other public announcement concerning this Agreement or the subject matter hereof without the prior written consent of the other, which shall not be unreasonably withheld or delayed; provided that each party may make any public statement, including statements in response to questions by the press, analysts, investors or those attending industry conferences or financial analyst calls, or issue press releases, so long as any such public statement or press release is not inconsistent with prior public disclosures or public statements approved by the other party pursuant to this Section 10.6 and which do not reveal non-public information about the other party. For avoidance of doubt, Vical shall have the right, without the prior written consent of Astellas, to announce events deemed material by its General Counsel; provided, however, that Vical shall consult with Astellas with regard thereto and provide reasonable opportunity for Astellas to review such announcement in advance. In the event of a required public announcement, to the extent practicable under the circumstances, the party making such announcement shall provide the other party with a copy of the proposed text of such announcement sufficiently in advance of the scheduled release to afford such other party a reasonable opportunity to review and comment upon the proposed text.

**(b) Filing of Agreement.** The parties will coordinate in advance with each other in connection with the filing of this Agreement (including redaction of certain provisions of this Agreement) with the SEC or any stock exchange or governmental agency on which securities

issued by a party or its Affiliate are traded, and each party will use reasonable efforts to seek confidential treatment for the terms proposed to be redacted; provided that each party will ultimately retain control over what information to disclose to the SEC or any stock exchange or other governmental agency, as the case may be, and provided further that the parties will use their reasonable efforts to file redacted versions with any governing bodies which are consistent with redacted versions previously filed with any other governing bodies. Other than such obligation, neither party (or its Affiliates) will be obligated to consult with or obtain approval from the other party with respect to any filings to the SEC or any stock exchange or other governmental agency.

10.7 Equitable Relief. Given the nature of the Confidential Information and the competitive damage that would result to the disclosing party upon unauthorized disclosure, use or transfer of its Confidential Information to any Third Party, the parties agree that monetary damages may not be a sufficient remedy for any breach of this Article 10. In addition to all other remedies, the disclosing party shall be entitled to seek specific performance and injunctive and other equitable relief as a remedy for any breach or threatened breach of this Article 10.

#### 11. TERM AND TERMINATION

11.1 Term. The term of this Agreement shall commence on the Effective Date and continue until the earliest to occur of (a) the third anniversary of the First Commercial Sale of the first Product in the Field, (b) the date when Astellas notify Vical in writing that it will take over all the responsibility of Vical for the Manufacture and supply of Products in the Field after completion of the transitioning of responsibility for Manufacture and supply of Products in the Field to Astellas or its designated contract manufacturer pursuant to Section 3.2, and (c) the date of expiration or termination of the later to expire or terminate of the License Agreements, in each case unless terminated earlier pursuant to Section 11.2 (the "Term"). In the event a License Agreement terminates or expires (or terminates or expires with respect to any country or countries to the extent provided therein) prior to the end of the Term, then thereafter during the Term, subject to Section 11.3(b), all obligations of Vical under this Agreement with respect to the applicable country or countries shall terminate unless otherwise agreed by the parties.

#### 11.2 Early Termination.

- (a) A party shall have the right to terminate this Agreement upon written notice to the other party if such other party is in material breach of this Agreement and has not cured such breach within sixty (60) days (thirty (30) days with respect to any payment breach) after written notice from the terminating party requesting cure of such breach. Any such termination shall become effective at the end of such sixty (60) day (thirty (30) day with respect to any payment breach) period unless the breaching party has cured any such breach prior to the end of such period.
- (b) A party shall have the right to terminate this Agreement upon written notice to the other party upon the bankruptcy, dissolution or winding up of such other party, or the making or seeking to make or arrange an assignment for the benefit of creditors of such other party, or the initiation of proceedings in voluntary or involuntary bankruptcy, or the appointment

of a receiver or trustee of such other party's property that is not discharged within ninety (90) days.

#### 11.3 Effect of Expiration or Termination; Surviving Obligations.

- (a) Transfer of Vical Manufacturing Information. In the event this Agreement is terminated prior to agreement to a plan regarding the transitioning of responsibility for Manufacture and supply of Products in the Field to Astellas or its designated contract manufacturer pursuant to Section 3.2, and one or both of the License Agreement(s) remain(s) in effect after such termination of this Agreement, the parties shall work together to agree to a plan for transitioning responsibility for the Manufacture and supply of Products to Astellas or its designated contract manufacturer promptly after such termination, and shall use Commercially Reasonable Efforts to implement such plan and complete such transfer as promptly as possible, but in any event within twenty four (24) months after such termination. Such plan shall provide for the transfer by Vical to Astellas or its designated contract manufacturer of all Vical Manufacturing Information and for Vical to provide reasonable assistance to enable Astellas or its designated contract manufacture and supply Products in the Field in accordance with the licenses and sublicenses granted under the applicable License Agreements, such transfer and assistance to be provided at Astellas' sole expense according to a budget included in such plan (including, without limitation, any expense to perform any necessary clinical studies required in connection with the transfer of the Manufacture and supply of Products in the Field to Astellas or its designated contract manufacturer). In the event this Agreement is terminated after the parties have agreed to a plan for transitioning responsibility for the Manufacture and supply of Products to Astellas or its designated contract manufacturer pursuant to Section 3.2, but prior to completion of such transition, and one or both of the License Agreement(s) remain(s) in effect after such termination of this Agreement, the parties shall work together to implement such plan and complete such transition, in accordance with the timelines set forth t
- **(b) Surviving Terms.** Expiration or termination of this Agreement shall not relieve the parties of any obligation accruing prior to such expiration or termination including, without limitation, all obligations of Astellas to purchase any Compounds and Products ordered by it (or which Astellas is obligated to order pursuant to Section 4.2) prior to such termination. Without limiting the foregoing, the obligations and rights of the parties under Sections 5.4, 9.4, 9.5, 11.3, 11.4 and 11.5 and Articles 1, 10, 12 and 13 shall survive expiration or termination of this Agreement.
- (c) Return of Confidential Information. Within [...\*\*\*...] days following the expiration or termination of this Agreement, each party shall deliver to the other party or destroy any and all Confidential Information of the other party in its possession, as per instruction by the party which owns such Confidential Information. Notwithstanding the foregoing, in case that either party has a license (or sublicense, as applicable) under any Confidential Information of the other party pursuant to either of the License Agreements following such expiration or termination of this Agreement, such party shall not be required to make delivery or destruction of such Confidential Information pursuant to this Section 11.3(c).

- 11.4 Exercise of Right to Terminate. The use by either party hereto of a termination right provided for under this Agreement shall not give rise to the payment of damages or any other form of compensation or relief to the other party with respect thereto.
- 11.5 Damages; Relief. Subject to Section 11.4 above, termination of this Agreement shall not preclude either party from claiming any other damages, compensation or relief that it may be entitled to upon such termination.

#### 12. INDEMNIFICATION

- 12.1 Indemnification by Vical. Vical hereby agrees to save, defend and hold Astellas, and its Affiliates and their respective directors, officers, employees and agents (each, a "Astellas Indemnitee") harmless from and against any and all claims, suits, actions, demands, liabilities, expenses and/or loss, including reasonable legal expense and attorneys' fees (collectively, "Losses"), to which any Astellas Indemnitee may become subject as a result of any claim, demand, action or other proceeding by any Third Party to the extent such Losses arise directly or indirectly out of (a) the gross negligence or willful misconduct of any Vical Indemnitee with respect to any obligations or activities contemplated by this Agreement, or (b) the breach by Vical of any warranty, representation, covenant or agreement made by Vical in this Agreement (except for breach by Vical of the warranty set forth in Section 9.1, other than a breach of the warranty set forth in Section 9.1(a) that cannot be discovered in the course of inspection or testing conducted by Astellas upon receipt of Compounds or Products, as applicable); except, in each case, to the extent such Losses result from the gross negligence or willful misconduct of any Astellas Indemnitee or the breach by Astellas of any warranty, representation, covenant or agreement made by Astellas in this Agreement.
- 12.2 Indemnification by Astellas. Astellas hereby agrees to save, defend and hold Vical and its Affiliates and their respective directors, officers, employees and agents (each, a "Vical Indemnitee") harmless from and against any and all Losses to which any Vical Indemnitee may become subject as a result of any claim, demand, action or other proceeding by any Third Party to the extent such Losses arise directly or indirectly out of: (a) the gross negligence or willful misconduct of any Astellas Indemnitee with respect to any obligations or activities contemplated by this Agreement, or (b) the breach by Astellas of any warranty, representation, covenant or agreement made by Astellas in this Agreement; except, in each case, to the extent such Losses result from the gross negligence or willful misconduct of any Vical Indemnitee or the breach by Vical of any warranty, representation, covenant or agreement made by Vical in this Agreement.
- 12.3 Control of Defense. Any person entitled to indemnification under this Article 12 shall give notice to the indemnifying party of any Losses that may be subject to indemnification, promptly after learning of such Losses, and the indemnifying party shall assume the defense of such Losses with counsel reasonably satisfactory to the indemnified party. If such defense is assumed by the indemnifying party with counsel so selected, the indemnifying party will not be subject to any liability for any settlement of such Losses made by the indemnified party without its consent (but such consent will not be unreasonably withheld or delayed), and will not be obligated to pay the fees and expenses of any separate counsel retained by the indemnified party with respect to such Losses.

#### 13. GENERAL PROVISIONS

13.1 Governing Law. This Agreement shall be governed by, and construed and enforced in accordance with, the laws of the State of New York, excluding its conflicts of laws principles with the exception of sections 5-1401 and 5-1402 of New York General Obligations Law.

#### 13.2 Dispute Resolution.

- (a) Objective. The parties recognize that disputes as to matters arising under or relating to this Agreement or either party's rights and/or obligations hereunder may arise from time to time. It is the objective of the parties to establish procedures to facilitate the resolution of such disputes in an expedient manner by mutual cooperation and without resort to litigation. To accomplish this objective, the parties agree to follow the procedures set forth in this Section 13.2 to resolve any such dispute if and when it arises.
- **(b) Resolution by Executives.** If an unresolved dispute as to matters arising under or relating to this Agreement or either party's rights and/or obligations hereunder arises, either party may refer such dispute to the Chief Executive Officer of Vical and a senior executive of Astellas who reports directly to the Chief Executive Officer of Astellas (the Chief Executive Officer of Vical and such senior executive of Astellas, collectively, the "*Executives*"), who shall meet in person or by telephone within ten (10) days after such referral to attempt in good faith to resolve such dispute. If such matter cannot be resolved by discussion of the Executives within ten (10) days following such meeting (as may be extended by mutual written agreement), such dispute shall be resolved in accordance with Section 13.2(c).

#### (c) Arbitration.

(i) If the parties do not resolve a dispute as provided in Section 13.2(b), and a party wishes to pursue the matter, each such dispute that is not an "Excluded Claim" shall be resolved by binding arbitration in accordance with the Rules of Arbitration of the International Chamber of Commerce ("ICC") as then in effect (the "ICC Rules"), and judgment on the arbitration award may be entered in any court having jurisdiction thereof. The decision rendered in any such arbitration will be final and not appealable. If either party intends to commence binding arbitration of such dispute, such party will provide written notice to the other party informing the other party of such intention and the issues to be resolved. Within 30 days after the receipt of such notice, the other party may by written notice to the party initiating binding arbitration, add additional issues to be resolved.

(ii) The arbitration shall be conducted by a panel of three (3) arbitrators experienced in the pharmaceutical business, none of whom shall be a current or former employee or director, or a then-current stockholder, of either party, their respective Affiliates or any Sublicensee. Within thirty (30) days after receipt of the original notice of binding arbitration, each party shall select one person to act as arbitrator and the two party-selected arbitrators shall select a third arbitrator within ten (10) days of their appointment. If the arbitrators selected by the parties are unable or fail to agree upon the third arbitrator, the third arbitrator shall be appointed by the ICC in accordance with the ICC Rules. The place of

arbitration shall be New York, New York, and all proceedings and communications shall be in English.

- (iii) It is the intention of the parties that discovery, although permitted as described herein, will be limited except in exceptional circumstances. The arbitrators will permit such limited discovery necessary for an understanding of any legitimate issue raised in the arbitration, including the production of documents. No later than thirty (30) days after selection of the arbitrators, the parties and their representatives shall hold a preliminary meeting with the arbitrators, to mutually agree upon and thereafter follow procedures seeking to assure that the arbitration will be concluded within six (6) months from such meeting. Failing any such mutual agreement, the arbitrators will design and the parties shall follow procedures to such effect.
- (iv) Either party may apply to the arbitrators for interim injunctive relief until the arbitration award is rendered or the controversy is otherwise resolved. Either party also may, without waiving any remedy under this Agreement, seek from any court having jurisdiction any injunctive or provisional relief necessary to protect the rights or property of that party pending the arbitration award. The arbitrators shall have no authority to award punitive or any other non-compensatory damages. The arbitrators shall have the power to order that all or part of the legal or other costs incurred by a party in connection with the arbitration be paid by the other party. Subject to the preceding sentence, each party shall bear an equal share of the arbitrators' and any administrative fees of arbitration.
- (v) Except to the extent necessary to confirm or enforce an award or as may be required by applicable law, neither a party nor an arbitrator may disclose the existence, content, or results of an arbitration without the prior written consent of both parties. In no event shall an arbitration be initiated after the date when commencement of a legal or equitable proceeding based on the dispute, controversy or claim would be barred by the applicable New York statute of limitations.
- (vi) As used in this Section, the term "Excluded Claim" shall mean a dispute, controversy or claim that concerns (A) the validity, enforceability or infringement of a patent, trademark or copyright or regulatory data exclusivity; or (B) any antitrust, anti-monopoly or competition law or regulation, whether or not statutory.
- 13.3 Entire Agreement; Modification. This Agreement, including the Exhibits hereto, is both a final expression of the parties' agreement and a complete and exclusive statement with respect to all of its terms. Except for the License Agreements and the side letter agreement between the parties, this Agreement supersedes all prior and contemporaneous agreements and communications, whether oral, written or otherwise, concerning any and all matters contained herein and therein, including the Confidentiality Agreement. This Agreement may only be modified or supplemented in a writing expressly stated for such purpose and signed by the parties to this Agreement.
- 13.4 Relationship Between the Parties. The parties' relationship, as established by this Agreement, is solely that of independent contractors. This Agreement does not create any partnership, joint venture or similar business relationship between the parties. Neither party is a legal representative of the other party, and neither party can assume or create any obligation,

representation, warranty or guarantee, express or implied, on behalf of the other party for any purpose whatsoever.

- 13.5 Non-Waiver. The failure of a party to insist upon strict performance of any provision of this Agreement or to exercise any right arising out of this Agreement shall neither impair that provision or right nor constitute a waiver of that provision or right, in whole or in part, in that instance or in any other instance. Any waiver by a party of a particular provision or right shall be in writing, shall be as to a particular matter and, if applicable, for a particular period of time and shall be signed by such party.
- 13.6 Assignment. Except as expressly provided hereunder, neither this Agreement nor any rights or obligations hereunder may be assigned or otherwise transferred by either party without the prior written consent of the other party (which consent shall not be unreasonably withheld); provided, however, that either party may assign or otherwise transfer this Agreement and its rights and obligations hereunder without the other party's consent:
- (a) in connection with the transfer or sale of all or substantially all of the business or assets of such party relating to products for control or prevention of CMV infection to a Third Party, whether by merger, sale of stock, sale of assets or otherwise (a "Sale"), provided that in the event of a Sale (whether this Agreement is actually assigned or is assumed by the acquiring party by operation of law (e.g., in the context of a reverse triangular merger)), intellectual property rights of the acquiring party to such transaction (if other than one of the parties to this Agreement) shall not be included in the technology licensed hereunder; or
- (b) to an Affiliate, provided that the assigning party shall remain liable and responsible to the non-assigning party hereto for the performance and observance of all such duties and obligations by such Affiliate.

The rights and obligations of the parties under this Agreement shall be binding upon and inure to the benefit of the successors and permitted assigns of the parties. Any assignment not in accordance with this Agreement shall be void.

- 13.7 Vical Third Party Contractors. The parties acknowledge and agree that Vical may use a Third Party contractor to perform development and regulatory activities and/or Manufacture and supply Compounds and Products under this Agreement and that the terms "Vical shall" or "Vical will" or the like, shall be deemed to be followed by the words "or Vical's designated Third Party contractor will" or "Vical's designated Third Party contractor shall" or "Vical shall require that its designated Third Party contractor shall" or the like, with respect to Vical's development, regulatory, Manufacturing and supply obligations herein.
- 13.8 Non-Exclusive License. Vical shall, and hereby does, grant to Astellas a non-exclusive, [...\*\*\*...] worldwide license, with the right to sublicense and further sublicense, under Vical Technology which is made or developed by or on behalf of Vical in performing its obligations under this Agreement and funded by Astellas under this Agreement, for all uses.

- 13.9 No Third Party Beneficiaries. This Agreement is neither expressly nor impliedly made for the benefit of any party other than those executing it, except as otherwise provided in this Agreement with respect to Astellas Indemnitees under Section 12.2 and Vical Indemnitees under Section 12.1.
- 13.10 Severability. If, for any reason, any part of this Agreement is adjudicated invalid, unenforceable or illegal by a court of competent jurisdiction, such adjudication shall not affect or impair, in whole or in part, the validity, enforceability or legality of any remaining portions of this Agreement. All remaining portions shall remain in full force and effect as if the original Agreement had been executed without the invalidated, unenforceable or illegal part.
- 13.11 Cumulative Remedies. No remedy referred to in this Agreement is intended to be exclusive, but each shall be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under law.
- 13.12 Notices. Any notice to be given under this Agreement must be in writing and delivered either in person, by any method of mail (postage prepaid) requiring return receipt, or by overnight courier or facsimile or electronic mail (email) transmission confirmed thereafter by any of the foregoing, to the party to be notified at its address(es) given below, or at any address such party has previously designated by prior written notice to the other. Notice shall be deemed sufficiently given for all purposes upon the earliest of: (a) the date of actual receipt; (b) if mailed, five days after the date of postmark; or (c) if delivered by overnight courier, the next business day the overnight courier regularly makes deliveries.

If to Astellas, notices must be addressed to:

Astellas Pharma Inc.
3-11, Nihonbashi-Honcho 2-chome
Chuo-Ku, Tokyo 103-8411
Japan
Attention: Vice President, Legal
Facsimile: [...\*\*\*...]

With a copy to:

Astellas Pharma Inc.
3-11, Nihonbashi-Honcho 2-chome
Chuo-Ku, Tokyo 103-8411
Japan
Attention: Vice President, Licensing and Alliances
Facsimile: [...\*\*\*...]

If to Vical, notices must be addressed to:

Vical Incorporated 10390 Pacific Center Court San Diego, California 92121 USA

Attention: Business Development Facsimile: (858) 646-1150 Email: licensing@vical.com

With a copy to:

Cooley LLP 4401 Eastgate Mall San Diego, California 92121 USA Attention: [...\*\*\*...] Telephone: (858) 550-6000

Telephone: (858) 550-6000 Facsimile: (858) 550-6420 Email: [...\*\*\*...]

13.13 Force Majeure. Except for the obligation to make payment when due, each party shall be excused from liability for the failure or delay in performance of any obligation under this Agreement by reason of any event beyond such party's reasonable control including but not limited to Acts of God, fire, flood, explosion, earthquake, or other natural forces, war, civil unrest, accident, destruction or other casualty, any lack or failure of transportation facilities, any lack or failure of supply of raw materials, any strike or labor disturbance, or any other event similar to those enumerated above. Such excuse from liability shall be effective only to the extent and duration of the event(s) causing the failure or delay in performance and provided that the party has not caused such event(s) to occur. Notice of a party's failure or delay in performance due to force majeure must be given to the other party within 10 days after its occurrence. All delivery dates under this Agreement that have been affected by force majeure shall be tolled for the duration of such force majeure. In no event shall any party be required to prevent or settle any labor disturbance or dispute.

### 13.14 Interpretation.

- (a) Captions & Headings. The captions and headings of clauses contained in this Agreement preceding the text of the articles, sections, subsections and paragraphs hereof are inserted solely for convenience and ease of reference only and shall not constitute any part of this Agreement, or have any effect on its interpretation or construction.
- (b) Interpretation. All references in this Agreement to the word "including" shall be deemed to be followed by the phrase "without limitation" or like expression. All references in this Agreement to the singular shall include the plural where applicable, and all references to gender shall include both genders and the neuter.

- (c) Articles, Sections & Subsections. Unless otherwise specified, references in this Agreement to any article shall include all sections, subsections, and paragraphs in such article; references in this Agreement to any section shall include all subsections and paragraphs in such sections; and references in this Agreement to any subsection shall include all paragraphs in such subsection.
  - (d) Days. All references to days in this Agreement shall mean calendar days, unless otherwise specified.
- (e) Ambiguities. Ambiguities and uncertainties in this Agreement, if any, shall not be interpreted against either party, irrespective of which party may be deemed to have caused the ambiguity or uncertainty to exist.
- (f) English Language. This Agreement has been prepared in the English language and the English language shall control its interpretation. In addition, all notices required or permitted to be given hereunder, and all written, electronic, oral or other communications between the parties regarding this Agreement shall be in the English language.
- 13.15 Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original document, and all of which, together with this writing, shall be deemed one instrument. Signatures provided by facsimile transmission or in Adobe™ Portable Document Format (PDF) sent by electronic mail shall be deemed to be original signatures.

[Remainder of this page intentionally left blank.]

IN WITNESS WHEREOF, the parties hereto have duly executed this Supply and Services Agreement as of the date set forth below.		
ASTELLAS PHARMA INC.	VICAL INCORPORATED	
By:	By:	
Name: Yoshihiko Hatanaka	Name: Vijay B. Samant	
Title: President and CEO	Title: President and CEO	
Date: July , 2011	Date: July , 2011	

SIGNATURE PAGE TO SUPPLY AND SERVICES AGREEMENT

\*\*\* Text Omitted and Filed Separately Pursuant to a Confidential Treatment Request under 17 C.F.R. §§ 200.80(b)(4) and 240.24b-2(b)(1)

#### EXCLUSIVE LICENSE AGREEMENT

THIS LICENSE AGREEMENT (the "Agreement") is made by and between City of Hope, a California nonprofit public benefit corporation located at 1500 East Duarte Road, Duarte, California 91010 ("COH") and Vical Incorporated, a Delaware corporation, located at 9373 Towne Centre Drive, Suite 100, San Diego, California 92121-3088 ("VICAL").

A. COH operates an academic research and medical center that encourages the use of its inventions, discoveries and intellectual property for the best interests of the public. COH has developed, and subject to the rights reserved by the United States Government, owns right, title, and interest in United States Patents No. 6,242,567 entitled "Method for detection and prevention of human cytomegalovirus infection," and 6,133,433 entitled "Method for detection and prevention of human cytomegalovirus infection," and certain other "Patent Rights" defined below. COH desires to have VICAL develop, market and exploit the Patent Rights into commercial products for the benefit of the public.

B. VICAL desires to acquire from COH certain licenses under the Patent Rights subject to the terms and conditions set forth below.

THEREFORE, for good and valuable consideration the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

#### 1. DEFINITIONS

- 1.1 <u>Affiliated Companies</u>. "Affiliated Companies" or "Affiliates" means each and any subsidiary, parent, closely-held or other corporation, partnership, limited liability company, or other legal entity in which a Patty owns or controls fifty percent (50%) or more of any such entity's stock, voting securities or other right to elect or control management, or where any such entity owns or controls, fifty percent (50%) or more of a Party's stock, voting securities or other right to elect or control management.
- 1.2 <u>Confidential Information</u>. "Confidential Information" means all terms in this Agreement, including royalty and other payments, sales information, annual reports provided under this Agreement,

materials relating to pending patent applications, and any business or technical information disclosed by one of the Parties to the other Party in writing and marked "confidential," whether or not patentable, copyrightable, or otherwise protected by law. Notwithstanding the foregoing, Confidential Information will not include, and nothing in Section 17 will in any way restrict the rights of either COH or VICAL to use, disclose, or otherwise deal with any information that: (i) was in the public domain as of the Effective Date or comes into the public domain during the term of this Agreement through no act of the receiving Party; (ii) was independently known to the receiving Party prior to receipt from the disclosing Party, or made available to the receiving Party as a matter of lawful right by a third party; (iii) is independently conceived, invented, or acquired by the receiving Party by persons who were not exposed to the information; or (iv) information that is required to be disclosed by law, court order, or other legal process.

- 1.3 <u>Designee</u>. "Designee" means any corporation or other entity that is employed by VICAL or otherwise under contract with VICAL to make, use, sell, promote, distribute, market, import, or export Licensed Products on behalf of or in partnership or other association with VICAL.
- 1.4 Effective Date. "Effective Date" means February 3, 2003.
- 1.5 Field. "Field" means all recombinant CMV vaccines containing or encoding molecules larger than fifty (50) amino acids, including DNA-based, viral-based and recombinant protein-based vaccines, and excludes diagnostics.
- 1.6 Improvement. "Improvement" means an improvement to an invention claimed in the Patent Rights that, absent a license, cannot be practiced without infringing a Valid Claim. For avoidance of doubt, Improvement does not mean or include developments that are useful in practicing the Patent Rights, but which may be practiced, absent a license, without infringing a Valid Claim.
- 1.7 <u>License Year</u>. "License Year" means the period from the Effective Date through December 31, 2003 (the "First License Year") and each twelve-month period thereafter from January 1st through December 31st.
- 1.8 <u>Licensed Products</u>. "Licensed Products" means vaccines, the manufacture, development, use,

offering to sell, sale, or import of which, but for the license granted herein, would infringe a Valid Claim. Licensed Products do not include diagnostics.

- 1.9 Net Invoice Price. "Net Invoice Price" means the amount invoiced, billed, or received by or on behalf of VICAL, its Affiliated Companies, or their Designees on account of the sale, transfer or other disposition of Licensed Products to Third Parties in any arms-length transaction, less reasonable, customary and documented deductions applicable to the Licensed Products for any of the following:
  - (a) trade, quantity and cash discounts actually granted to customers, not in excess of the selling price of the Licensed Product;
  - (b) discounts, refunds, rebates, charge backs, and retroactive price adjustments;
  - (c) actual product returns and allowances; and
  - (d) any tax imposed on the production, sale, delivery or use of the product actually paid.

If VICAL combines with a Licensed Product one or more vaccines (a "Combination Product") and these vaccines, if sold separately, would not be a Licensed Product, the Net Invoice Price of the Licensed Product shall be calculated on a country-by-country basis using the following formula: the Net Invoice Price of the Combination Product shall be multiplied by the fraction A/(A+B) where A is the average sales price of the Licensed Product charged in the country of the sale during the preceding three-months when sold separately and B is the average sales price charged for all other vaccines included in the Combination Product for which the Combination Product is marketed and sold in that same country during the same period when sold separately. In the event that the Licensed Product or other vaccines are not sold separately, Net Invoice Price of the Licensed Product to the selling party during the quarter of sale and D is the average cost of the other vaccines to the selling party during the same quarter. For purposes of this calculation, "cost" shall mean the cost of acquisition, if purchased, or the cost of manufacture, the latter being the sum of direct manufacturing costs

determined in accordance with generally accepted accounting principles. If this latter formula (C/C+D) is used to calculate Net Invoice Price, the Net Invoice Price of the Licensed Product shall be no less than the Net Invoice Price of the Combination product multiplied by the fraction having a numerator of 1 and a denominator equal to the total number of vaccines for which the Combination Product is marketed and sold. For example, if the Combination Product contains three such vaccines, the Net Invoice Price of the Licensed Product shall be no less than 1/3 of the Net Invoice Price of the Combination Product.

- 1.10 Party. "Party" means COH or VICAL.
- 1.11 Patent Rights. "Patent Rights" means, collectively, all right, title and interest of COH in, to and under (i) United States Patents Nos. 6,242,567, entitled "Method for detection and prevention of human cytomegalovirus infection," (ii) all foreign counterparts of United States Patents Nos. 6,242,567 and 6,133,433; and (iii) any continuations-in-part, continuations, continued prosecution applications, divisionals, reexaminations reissues, or patent term extension patents claiming substantially the same technology as United States Patents Nos. 6,242,567 and 6,133,433.
- 1.12 Quarter. "Quarter" means each calendar quarter (i.e., ending March 31, June 30, September 30, and December 31), or portion thereof, during the term of this Agreement.
- 1.13 Territory. "Territory" means the entire world.
- 1.14 Third Parties. "Third Parties" means a third party that is not COH, VICAL, any of their Affiliated Companies, or Designees.
- 1.15 <u>Valid Claim.</u> "Valid Claim" means an unexpired claim of an issued patent of the Patent Rights which has not been held unenforceable, unpatentable, or invalid by a decision of a court or other governmental agency of competent jurisdiction, unappealed within the time allowed for appeal or unappealable.

## 2. LICENSE OF PATENT RIGHTS

2.1 <u>License Grant</u>. Subject to the rights retained by COH in Sections 2.2 and 2.3, below, COH hereby grants to VICAL and VICAL hereby accepts from COH, to the extent that each lawfully may do so, an exclusive, royalty-bearing right and license under the Patent Rights to make, have made, offer to sell, sell, use and import Licensed Products in the Field. No other license or rights under the Patent Rights or any other intellectual property of COH is granted or intended to be granted under this Agreement, either expressly, by implication, estoppel, or otherwise.

## 2.2 Ownership of Intellectual Property; Rights Retained by COH

- (a) COH shall retain all right, title, and interest in, to and under the Patent Rights except for the rights explicitly granted to VICAL in accordance with this Agreement.
- (b) Except for the rights explicitly granted to COH in accordance with this Agreement, including Section 2.2 (c) and (e), and 2.3 below, COH shall have no right (i) to make, have made, use, sell, offer for sale, or import Licensed Products or (ii) to grant others any right or license to do the same; provided, however, that nothing in this Agreement shall prohibit COH from making, having made, or using Licensed Products, in connection with its internal, non-commercial research, clinical, and teaching programs. Nothing in this Section 2.2(b) is intended to grant to COH any right to vaccines manufactured by or on behalf of Vical.
- (c) COH shall retain the exclusive right during the term of this Agreement (i) to make, have made, use, sell, offer for sale, import and otherwise exploit any products or methods covered by the Patent Rights (including but not limited to products identical to Licensed Products) outside the Field; and (ii) to license or otherwise exploit any and/or all of those retained Patent Rights.
- (d) Upon termination of this Agreement, all rights granted under this Agreement shall revert to COH.
- (e) The rights granted by COH to VICAL under Section 2.1 shall become non-exclusive, at the option of COH, if: (i) VICAL fails to perform in any material respect a material term,

condition or obligation required under this Agreement, and VICAL does not cure that failure to perform within thirty (30) days after written notice by COH to VICAL; or (ii) VICAL makes any material misrepresentation during the negotiations of this agreement or in any document or other disclosure or representation required under the Agreement. Each and every Section of this Agreement shall be considered a material provision unless the Parties agree otherwise in writing signed by authorized representatives of both Parties. COH's rights under this Section 2.2(e) shall be in addition to any other rights and remedies it may have under this Agreement or at law or equity.

#### 2.3 Sublicenses

- (a) VICAL shall have the right to sublicense non-exclusively the rights and/or licenses granted by COH to VICAL under Section 2.1; provided, however, that: (i) the sublicensee shall have no further right to grant sublicenses; (ii) the terms of any sublicense shall not be inconsistent with the terms of this Agreement; and (iii) VICAL promptly shall provide COH with a copy of each final sublicense agreement within ten (10) days after execution. VICAL shall remain liable to COH for all obligations under this Agreement, including, without limitation, payment to COH of any amounts due on account of sales, transfers or other dispositions of Licensed Products by sublicensees. In addition, COH shall be deemed a third-party beneficiary of any sublicense agreement with the right to enforce the same. VICAL shall have the right to sublicense only while it is the exclusive licensee of the Patent Rights, and any sublicense shall be subject to the termination and assignment rights of COH under Section 2.3(b) below.
- (b) VICAL shall have the right to enter into an exclusive agreement with a Third Party with which VICAL collaborates in the normal course of business for the manufacture, marketing, and sale of Licensed Products in the Field (a "Collaboration Agreement"); provided, however, that: (i) the Third Party shall have no right to grant licenses; (ii) the terms of any Collaboration Agreement shall not be inconsistent with the terms of this Agreement; (iii) VICAL shall provide COH with a copy of each final Collaboration Agreement within ten (10) days following execution; and (iv) the Third Party shall not be authorized to manufacture, market, or sell Licensed Products or practice any of the Patent

- Rights independent of the Collaboration Agreement.
- (c) If COH exercises its rights under Sections 2.2(e) or 4.2, all rights of VI CAL under this Section 2.3 shall terminate. Any sublicense shall, at COH's option, terminate or shall be assigned to COH; provided, however, that COH shall not assume any obligations or liabilities owed by VICAL prior to any such assignment.

## 2.4 <u>Commercial Efforts</u>

- (a) VICAL shall use diligent efforts to effect introduction of Licensed Products into the commercial market as soon as practicable, consistent with sound and reasonable business practice and judgment; thereafter, until the expiration of this Agreement, VICAL, consistent with sound and reasonable business practice and judgment, shall use diligent efforts to keep Licensed Products reasonably available to the public.
- (b) COH may terminate or render this license non-exclusive if VICAL fails materially to meet its obligations under Section 2.4(a), above.
- 2.5 Progress Reports. Commencing with the end of the First License Year, and at the end of each License Year thereafter, VICAL shall deliver to COH within fifteen (15) days of the end of the License Year, a written report setting forth a summary of the activities undertaken by VICAL in connection with the research, development, regulatory approval, manufacturing, testing, promotion, sale, and distribution of the Licensed Products during the preceding License Year and activities which VICAL proposes to undertake during the subsequent License Year. The report will include the date of first sale of each Licensed Product.
- 2.6 Rights of the United States Government. VICAL hereby acknowledges that the research which resulted in the Patent Rights was funded in part by the government of the United States of America, and accordingly, the rights and license granted by COH to VICAL are subject to certain statutes and the rights, claims, and limitations granted to the government of the United States of America as set forth at 35 U.S.C. § 200 et seq., and 37 C.F.R. Section 401 et seq., or similar regulations of any competent governmental authority. This Agreement shall be subject to modifications to conform to

the requirements of those statutes and regulations.

## 3. COMPENSATION

## 3.1 Amount

- (a) VICAL shall pay to COH within five (5) business days of the Effective Date a one-time up front license fee in the amount of [...\*\*\*...]. This payment is nonrefundable and separate from and not an advance or credit against any other amount payable by VICAL to COH under this Agreement.
- (b) VICAL shall pay to COH [...\*\*\*...] of the Net Invoice Price of all Licensed Products sold, transferred or otherwise disposed of by or on behalf of VICAL, Affiliated Companies, or their Designees.
- (c) In the event that VICAL grants a sublicense that includes rights under any of the Patent Rights or enters into a Collaboration Agreement, in addition to any royalties or other amounts payable to COH pursuant to (b) above, COH shall be entitled to [...\*\*\*...] of any royalties, fees, milestone payments, or other consideration (including non-cash consideration) VICAL receives under the sublicense or Collaboration Agreement. Provided, however, in no event shall COH receive less than the amount that would be due COH under Section 3.1 (b) had the sale of products by the sublicensee under the sublicense, or by a Third Party under the Collaboration Agreement, been a sale by VICAL of a Licensed Product (i.e., [...\*\*\*...]). The obligations in this section apply regardless of whether a sublicense or Collaboration Agreement includes a license to rights in addition to the Patent Rights.
- (d) No royalty shall be paid on sales or other transfers of Licensed Products to or between VICAL, Affiliated Companies, and Designees intended for further sale or transfer. Royalties on these sales or transfers shall become due upon the further sale or transfer to Third Parties.

- (e) Amounts due COH under Sections 3. 1 (b)-(d) accrue as follows: for sale, transfer or other disposition of Licensed Products under Section 3. 1 (b), upon the date of invoice or other transfer; for all other amounts due COH, sixty (60) days after the fee, royalty, or other consideration described above is due and payable to VICAL or its Affiliates. For each unit of Licensed Product, the royalty shall be payable only once regardless of the number of claims contained in the Patent Rights which apply to that Licensed Product.
- (f) License maintenance fees in the amounts set forth below will be due under this Section 3.1(f) within thirty (30) days of the end of the relevant License Year, as follows:

For the License Years prior to VICAL's first commercial sale of a licensed product in which VICAL is actively conducting a clinical trial, License maintenance fees shall be:

First License Year	\$[***]
Year 1	\$[***]
Year 2	\$[***]
Year 3	\$[***]
Year 5 and thereafter	\$[***]

The following additional fees shall be added to the amounts set forth above for the License Years prior to VICAL's first commercial sale of a Licensed Product in which VICAL is not actively conducting a clinical trial:

First License Year	\$[***]
Year 1	\$[***]
Year 2	\$[***]
Year 3	\$[***]

For the License Year in which the first commercial sale occurs and the License Years thereafter, License maintenance fees shall be:

Year of first commercial sale	[***]
License Years following License	
Year of first commercial sale	\$[***]

The License maintenance fees set forth in this Section 3.1 (e) may be credited against the royalties described under Section 3.1(b), above. For each License Year, the License maintenance fee due for that License Year shall be credited only against royalties earned and payable during the immediately following License Year. No payment shall be carried forward or credited against royalties earned or payable in any other period or credited against any other amounts due.

#### 3.2 Adjustment to Royalties

In the event that VICAL is required to pay royalties in order to obtain licenses to patents other than the Patent Rights without which VICAL could not lawfully make, use, sell, offer to sell or import Licensed Products as contemplated in this Agreement ("Required Other Royalties"), then the following provisions shall apply:

- (a) Subject to the requirements of (c)-(e) below, COH, on request by VICAL will reduce the royalty rate under Sections 3.1(b) by a maximum reduction [...\*\*\*...] (i.e., to a rate not lower than [...\*\*\*...]);
- (b) The reduction authorized by (a), above, shall apply only to the extent that the royalties payable to COH under Section 3.1 (b), combined with all Required Other Royalties in the aggregate, both before and after the application of (a), exceed [...\*\*\*...] of the average Net Invoice Price of Licensed Product;

- (c) The reductions authorized by (a), above, shall apply only if all other parties to which VICAL pays Required Other Royalties have agreed to reduce their royalty payments from VICAL by a percentage amount that is equal to or greater than the reduction COH makes to its royalty payment under (a), above. By way of example, if COH's royalty rate is reduced by [...\*\*\*...], the royalty VICAL pays COH will be reduced by [...\*\*\*...]. Before a [...\*\*\*...] reduction in the royalty rate can be applied to COH, all other parties first must agree to reduce the royalty they are to be paid by at least the same [...\*\*\*...]. This subsection (c) shall exclude Vical's existing license with the Wisconsin Alumni Research Foundation for United States patent applications or original and any reexaminations, reissues, and extensions thereof, and any equivalents thereto (including foreign equivalents), and any United States or foreign patents which may issue from such patent applications and continuations, CIP applications or divisionals thereof, and any reexaminations, reissues, and extensions thereof including any foreign equivalents thereto.
- (d) In no case shall the operative royalty rate payable to COH under Section 3.1(b), after all reductions permitted by (a), above, be less than the largest percentage royalty paid by VICAL to any Third Party on account of sale, transfer or other disposition of Licensed Products; and
- (e) If VICAL wishes to exercise its right to reduce royalty rates under this Section 3.2, it must provide COH with advance written notice and provide COH, along with each Quarterly statement required under Section 3.3(a), a written certification of the amount of royalties actually paid to Third Parties in that Quarter, the amount of any reduction in royalty rates claimed by VICAL for that Quarter, and the basis for VICAL's calculation thereof.

#### 3.3 Payment

a) Within thirty (30) days of the end of each License Year until the total, cumulative Net Invoice Price exceeds \$[...\*\*\*...], VICAL shall deliver to COH payment of all royalties, fees or other amounts due COH that accrued during that License Year, together with a written statement setting forth the following information:

(i) the number and price of

Licensed Products sold, transferred or otherwise disposed of by or on behalf of VICAL by product and country of sale, specifically identifying any sales to Affiliates; (ii) the applicable Net Invoice Price(s); (iii) all amounts received from sublicensees, including those which would give rise to royalties under 3.1 (c) above; (iv) an itemization and calculation of the amount of royalties and other fees and consideration due COH, including any deductions from gross sales or other adjustments; (v) the application of any credit for License maintenance fees paid pursuant to Section 3.1 (e); and (vi) any additional information reasonably necessary to enable COH to understand the basis of and confirm these calculations, including without limitation, the status of any clinical trial including Licensed Product. Once the total, cumulative Net Invoice Price exceeds \$[...\*\*\*...], VICAL's obligations under this Section 3.3 shall be performed within thirty (30) days of the end of each Quarter for the duration of this Agreement.

- (b) All royalties, fees or other payments due COH under Section 3.1 shall be paid in United States dollars. If the amount of any royalty, fee or payment is calculated, in whole or in part, based on amounts stated in a currency other than United States dollars, prior to making the royalty calculation the foreign currency shall be converted into United States dollars using the foreign exchange rate published by The Wall Street Journal on the last business day of the Quarter during which the royalty, fee or other payment accrued.
- (c) Unless otherwise specified, all payments due under this Agreement will be due thirty (30) days following the end of the relevant License Year or Quarter, as provided in 3.3.(a), above. If any payment required under this Agreement is not paid when due, it shall bear interest from the due date until paid at the lesser of twelve percent (12%) per annum or the maximum rate allowable by law.
- 3.4 <u>Books and Records.</u> VICAL shall make available at its principal place of business in California or another mutually agreeable location in California true and complete books of account, records, royalty statements, invoices, and other data containing all particulars reasonably necessary for an independent determination of the royalties, fees and other amounts payable by VICAL to COH under this Agreement ("Records"). The Records for each License Year shall be maintained for a period of five (5) years after the end of that License Year or five (5) years after the information

contained in those Records first was provided to COH, whichever is later. COH's accountants, financial officers, technology development and transfer officers, attorneys, and outside Certified Public Accountants as chosen by COH, shall have the right to audit, inspect, copy, and make extracts from all Records to the extent necessary to verify the accuracy of any payments made and statements furnished to COH. COH may exercise this right during normal business hours on three (3) business days prior written notice once per License Year. If any Records requested by COH are not immediately available, VICAL shall make them available within five (5) business days of the request. In the event any examination by COH discloses an underpayment to COH, VICAL shall pay to COH the amount of any underpayment together with interest as set forth at Section 3.3(c) within ten (10) days of VICAL's receipt of a written notice describing the findings. In the event the examination reveals that the amount of any underpayment for any Quarter exceeds five percent (5%) of the royalties and fees actually paid by VICAL to COH, VICAL shall also reimburse COH, in addition to the royalties, fees and applicable interest, all of COH's reasonable and documented costs and expenses, including, but not limited to, all professional fees directly related to any such examination or subsequent resolution. All information obtained by COH as a result of auditing activities performed under this Section 3.3 will be considered VICAL's Confidential Information.

## 4. <u>TERM AND TERMINATION</u>

- 4.1 <u>Term.</u> The term of this Agreement shall commence on the Effective Date and expire upon the expiration date of the last to expire of the Patent Rights, unless otherwise terminated pursuant to Section 4.2.
- 4.2 <u>Termination</u>. This Agreement may be terminated prior to its expiration in accordance with Section 4.1 upon the happening of any of the following events:
  - (a) At the option of either Party, if the other Party shall fail to perform in any material respect a material term, condition or obligation under this Agreement and that failure is not cured within thirty (30) days after written notice of the failure by the terminating Party is received by the other Party;
  - (b) At the option of either Party, if the other Patty made any material misrepresentation during

- the negotiation of this Agreement, or in any document or other disclosure or representation required under this Agreement;
- (c) At the option of VICAL, after the end of the third License Year, upon ninety (90) days prior written notice. The License maintenance fee due for the License Year in which the Agreement is terminated under this Section 4.2(c) is non-refundable, and all other payments shall be due and payable on the thirtieth (30) day after termination (120 days following the written notice), if not otherwise due earlier pursuant to the terms of this Agreement;
- (d) Immediately and without any notice or other act by COH, if VICAL seeks to dissolve, liquidate its assets, or windup its business; or if VICAL ceases to do business in the ordinary course;
- (e) Immediately and without any notice or other act by COH, if VICAL shall commence a voluntary case or other proceeding seeking liquidation, reorganization or other relief with respect to itself or its debts under any bankruptcy, insolvency or other similar law now in effect, or seeking the appointment of a trustee, receiver, liquidator, custodian or other similar official of it or any substantial part of its property;
- (f) Immediately and without any notice or other act by COH, if an involuntary case or other proceeding shall be commenced against VICAL seeking liquidation, reorganization or other relief with respect to it or its debts under any bankruptcy, insolvency or other similar law in effect or seeking the appointment of a trustee, receiver, liquidator, custodian or other similar official of it or any substantial part of its property, and such involuntary case remains unstayed and in effect for more than sixty (60) days; or
- (g) Immediately and without any notice or other act by COH, if VICAL has not yet provided COH with written notice by the end of the fourth License Year that VICAL is actively engaged in a clinical trial involving a Licensed Product.
- 4.3 <u>Duties Upon Termination</u>. Upon the termination of this Agreement, VICAL shall immediately

cease to make, have made, offer to sell, sell, use, or import Licensed Products. VICAL shall pay to COH, within thirty (30) days of termination, all royalties, fees, and other payments accrued under this Agreement. Any cause of action, claim or liability of COH or VICAL accrued or to accrue due to any breach, omission, obligation or other duty owed to the other Party shall survive termination.

## 5. <u>REPRESENTATIONS AND WARRANTIES</u>

COH and VICAL each hereby represents and warrants to the other Party that: (1) it is a corporation duly organized, validly existing and in good standing under the laws of its state of incorporation; (2) it has the right and authority to execute and deliver this Agreement and to consummate the transactions contemplated hereunder; (3) this Agreement is a legal, valid and binding agreement of the Party and enforceable against it; (4) the execution and delivery of this Agreement will not breach any governing instrument or agreement of the Party or, to each Party's knowledge, any statute, regulation or any other restriction upon the Party; and, (5) it has secured all requisite authorizations and approvals necessary to the execution, delivery and performance of this Agreement.

VICAL further represents that it has the ability, desire and intent to exploit the Patent Rights into commercial products consistent with sound and reasonable business practices and judgment.

## 6. <u>LIMITATIONS ON WARRANTIES AND REMEDIES</u>

- 6.1 EXCEPT AS EXPRESSLY SET FORTH IN RECITAL A AND SECTION 5, COH MAKES NO REPRESENTATIONS OR WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO: (i) ANY IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, OR (ii) ANY REPRESENTATION OR WARRANTY WITH RESPECT TO THE VALIDITY, SCOPE, OR OWNERSHIP OF THE PATENT RIGHTS.
- 6.2 COH MAKES NO REPRESENTATION OR WARRANTY WITH RESPECT TO THE LICENSED PRODUCTS OR THE INFRINGEMENT BY THE SAME OF ANY PATENT, COPYRIGHT, OR OTHER PROPRIETARY RIGHT, OR ANY REPRESENTATION OR WARRANTY WITH RESPECT TO THE ABSENCE OF ANY DEFECT IN THE LICENSED

- PRODUCTS OR PATENT RIGHTS. VICAL IS AWARE THAT IN ORDER TO PRACTICE ANY OR ALL OF THE PATENT RIGHTS, IT MAY BE NECESSARY TO OBTAIN ADDITIONAL LICENSES TO OTHER PATENTS OR INTELLECTUAL PROPERTY.
- 6.3 VICAL SHALL NOT MAKE ANY REPRESENTATION OR WARRANTY TO THIRD PARTIES CONTRARY TO THE LIMITATIONS ON WARRANTIES AND REPRESENTATIONS GIVEN BY COH.
- 6.4 VICAL HAS HAD THE OPPORTUNITY TO REVIEW OR HAS REVIEWED THE PATENT RIGHTS TO VERIFY THE SUITABILITY OF THE PATENT RIGHTS FOR VICAL'S INTENDED PURPOSE AND IS NOT RELYING ON ANY STATEMENTS OF COH WITH RESPECT TO THE FOREGOING.
- 6.5 IN NO EVENT SHALL COH BE LIABLE FOR ANY INCIDENTAL, CONSEQUENTIAL, OR PUNITIVE DAMAGES, INCLUDING, BUT NOT LIMITED TO, ANY LOST PROFITS OR OPPORTUNITES, ARISING OUT OF, RELATING TO, OR IN CONNECTION WITH THE SUBJECT MATTER OF THIS AGREEMENT, EVEN IF COH HAS BEEN ADVISED OF THE POSSIBLITY OF SUCH DAMAGES. IN NO EVENT SHALL COH'S LIABILITY TO VICAL UNDER OR RELATING TO THIS AGREEMENT (WHETHER IN TORT, CONTRACT, QUANTUM MERUIT, OR OTHERWISE) EXCEED THE AMOUNT ACTUALLY RECEIVED BY COH FROM VICAL PURSUANT TO THIS AGREEMENT. IN NO EVENT SHALL COH BE LIABLE TO VICAL FOR ANY DAMAGES ARISING OUT OF, RELATED TO, OR IN CONNECTION WITH THE MANUFACTURE, SALE, USE, OFFER FOR SALE, OR IMPORTATION OF LICENSED PRODUCTS OR EXPLOITATION OF THE PATENT RIGHTS.
- 6.6 THE LIMITATIONS SET FORTH ABOVE IN THIS SECTION 6 SHALL SURVIVE ANY EXPIRATION OR TERMINATION OF THIS AGREEMENT FOR ANY REASON.

## 7. PATENT PROSECUTION

7.1 Patent Prosecution. COH and VICAL shall cooperate to determine which additional patent

applications should be filed and/or prosecuted to protect and exploit the Patent Rights (the "Agreed Patents/Applications"). COH shall, at VICAL's expense, file, prosecute and maintain the Agreed Patents/Applications that include claims in the Field, including arranging for payment of renewal and maintenance fees. COH also shall, at VICAL's expense, defend or prosecute any reexamination, protest, interference, opposition or other proceedings in the United States Patent and Trademark Office or foreign patent offices regarding any Agreed Patents/Applications or any patents issuing therefrom. COH shall be entitled to use counsel of its choice for the above activities subject to the approval of VICAL, which will not be unreasonably withheld. COH shall consult with VICAL regarding major decisions in the course of any of the above activities (e.g., election to abandon an application, take an appeal, copy claims to initiate an interference). In furtherance of such consultation COH will provide VICAL with copies of relevant documentation for review by VICAL in a reasonable time after COH's receipt of those documents. Notwithstanding such consultation, COH shall have sole and final discretion with respect to the activities provided for in this section.

- 7.2 Reimbursement of Future Expense. COH shall invoice VICAL for COH's reasonable and documented expenses, including attorneys' fees, incurred after the Effective Date in connection with any of the activities specified in Section 7.1, above. VICAL shall pay all such invoices within thirty (30) days of receipt thereof.
- 7.3 Surrender of Patent Rights. VICAL may elect to surrender its license under the Patent Rights with respect to any foreign country or countries upon sixty (60) days written notice to COH. If VICAL makes such an election, then VICAL's license under Section 2.1 shall terminate with respect to those countries, the definitions of Patent Rights in Section 1.10 and Territory in Section 1.12 shall be deemed to exclude those countries, and VICAL shall have no further obligation to reimburse COH for any activities under Section 7.1 related solely to patents or patent applications in those countries; provided, however, that VICAL shall not be relieved from responsibility to reimburse COH for any expenses incurred prior to the expiration of the sixty (60)-day notice period (or such longer period specified in VICAL's notice).
- 7.4 <u>Cooperation</u>. VICAL shall cooperate fully in the activities described in Section 7.1, above, and shall execute and deliver such documents and take such other actions as COH reasonably may

request in connection therewith. VICAL shall provide COH prompt notice of all matters that come to its attention that may affect these activities.

#### 8. DEFENSE OF TECHNOLOGY

- 8.1 Notice of Suspected Infringement. In the event either Party discovers or becomes aware of any suspected infringement of the Patent Rights in the Field in the Territory, that Party promptly shall notify the other Party in writing of the details of the suspected infringement, including the identity of the suspected infringing party. For so long as VICAL's right and license pursuant to Section 2.1 is exclusive, VICAL shall offer the suspected infringing party a sublicense in accordance with Section 2.3 or otherwise seek to abate the suspected infringement.
- 8.2 Abatement of Suspected Infringement by VICAL. If the suspected infringing party does not accept the sublicense offered in accordance with Section 8.1 or does not otherwise cease the suspected infringement, VICAL and COH shall confer to determine whether the suspected infringement is substantial and the potential cost and predicted outcome of an infringement action against the suspected infringing party would be favorable to COH and VICAL. If COH and VICAL agree that it would be favorable, then VICAL, at its sole cost and expense and with jointly agreed-to counsel, may commence an infringement action against the suspected infringing party. COH shall cooperate reasonably in any such infringement action, including, if requested by VICAL, joining the action, all at VICAL's expense. COH shall have the right at all times to participate fully in any such action, including through use of its own independent counsel, provided that COH shall be responsible for the expense of its independent counsel. Any judgment, damages, settlement or award that results from any such action shall be allocated first to VICAL to the extent of actual documented unreimbursed costs incurred in connection with the action, then to COH to the extent of actual documented unreimbursed costs incurred (including costs for independent counsel, if any), and the remainder to be allocated [...\*\*\*...] to COH and [...\*\*\*...] to VICAL.
- 8.3 Action by COH. If VICAL fails within six (6) months following the initial discovery of a suspected infringement to grant a sublicense, initiate an infringement action, or otherwise abate the suspected infringement, and COH continues to believe in its reasonable business judgment that the

suspected infringement is substantial and the potential cost and predicted outcome of an infringement action against the suspected infringing party would be favorable, then: (i) the rights granted by COH to VICAL under Section 2.1 shall, at COH's option, become non-exclusive in the manner provided in Section 2.2(e) above; and (ii) COH may, at its sole option, commence an infringement action against the suspected infringing party in COH's name and at COH's expense, and VICAL shall cooperate reasonably in any such action (at VICAL's expense). Any judgment, damages, settlement or award which results from any such action shall be allocated first to COH to the extent of the actual documented unreimbursed costs incurred in connection with the action, then to VICAL to the extent of actual documented unreimbursed costs incurred, and the remainder to be allocated one hundred percent (100%) to COH. The right granted to COH under (i), above, to make the license grant hereunder non-exclusive, shall apply only if either (a) Vical is commercially manufacturing, commercially marketing, commercially exporting, or offering for sale commercially a Licensed Product or (b) the suspected infringer is commercially manufacturing, commercially marketing, commercially exporting, or offering for sale commercially a commercial product that COH believes infringes the Patent Rights.

8.4 <u>Common Interest Privilege</u>. Any communications between or among COH, VICAL and their respective counsel concerning any of the matters provided for in this Section 8 or Section 7, above, shall be treated as Confidential Information and shall not be deemed a waiver of any applicable privilege or immunity. These communications shall, to the fullest extent permitted by law, be deemed privileged communications made in furtherance of a joint prosecution or defense, or among parties having common legal interests.

## 9. <u>INDEMNIFICATION</u>

9.1 VICAL shall at all times during the term of this Agreement and thereafter, indemnity, defend, and hold COH, its Affiliated Companies, and their trustees, directors, officers, employees and agents ("Indemnities"), harmless from and against all claims, suits, liabilities, losses, damages, proceedings, demands, expenses (including reasonable legal expenses and reasonable attorneys' fees) and costs ("Claims"), related in any way to the exercise by VICAL of any rights granted under this Agreement, including but not limited to the production, manufacture, sales, use, consumption, importation, promotion, distribution, advertisement or other application of a

Licensed Product by VICAL, an Affiliated Company, a sublicensee, or a customer of any of them. VICAL shall not be obligated, however, to indemnify Indemnitees for that portion of any Claim determined to arise directly from the gross negligence or a willful act or omission by COH, or a breach of any warranty set forth in Section 5 by COH.

9.2 COH shall notify VI CAL promptly of any Claim for which indemnification is sought, and cooperate reasonably with VICAL, at the expense of VICAL, in the defense and settlement of that Claim. VICAL, in settling any Claim, shall not make any admission of fault or impose any obligation on COH, without the prior written consent of COH.

## 10. INSURANCE

VICAL shall obtain and maintain, during the term of this Agreement (and covering claims made for a period of three (3) years thereafter), Comprehensive General Liability Insurance, including Products Liability Insurance, with a reputable, secure insurance carrier(s) in the amount of at least [...\*\*\*...] per occurrence to cover acts or omissions concerning the production, manufacture, sale, use, importation, consumption, promotion, distribution, advertisement or other application of Licensed Products by VICAL or anyone acting under its permission, and to cover VICAL's indemnification obligations set forth in Section 9, above.

## 11. NOTICE

Any notice or other communication required or permitted shall be in writing and shall be deemed to have been received on the delivery date if personally delivered, sent by overnight courier, or sent by facsimile; or, if mailed, seventy-two (72) hours after having been placed in the United States mail, registered or certified, postage prepaid, addressed to the Party to whom it is directed at the address set forth below:

If to COH:

City of Hope 1500 East Duarte Road Duarte, CA 91010-3000

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Attention: Sr. Vice President for Technology Development
      Facsimile: [...***...]
      With a copy to:
      City of Hope
      Office of General Counsel
      1500 East Duarte Road
      Duarte, CA 91010-3000
      Facsimile: [...***...]
If to VICAL:
      Vical, Incorporated
      9373 Towne Centre Drive,
      Suite 100 San Diego, CA 92121-3088
      Attention: Executive Director, Business Development &
                 Technology Assessment
      Facsimile: [...***...]
      With a copy to:
      [...***...]
Cooley Godward, LLP 4401
      Eastgate Mall San Diego, CA 92121-1909
      Tel: [...***...]
      Facsimile: [...***...]
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Either Party may change the address to which notices are to be addressed by giving the other Party written notice in the manner described in this Section 11.

## 12. GOVERNING LAW AND JURISDICTION

The validity, construction, and interpretation of this Agreement shall be governed in all respects by, and the Agreement shall be construed in accordance with, the laws of the State of California, exclusive of choice of law principles. Each party consents to service of process in any action or

proceeding by mailing a copy of such process by United States mail, registered or certified, postage prepaid, return receipt requested, to the addresses listed in Section 11. Unless otherwise agreed to by the Parties, all disputes, claims or proceedings between the Parties arising under this Agreement shall be brought to trial or other adjudication in the state or federal courts sitting in Los Angeles County, California, except for disputes, claims or proceedings that are within the exclusive jurisdiction of the Federal Circuit. Subject to any right of appeal, both Parties agree that any judgement rendered shall be conclusive, binding, and enforceable by any court of competent jurisdiction. In the event of litigation or other proceedings arising out of or relating to this Agreement (including proceedings in bankruptcy), the prevailing Party shall be entitled to recover its reasonable attorneys' fees and expenses of litigation.

## 13. FORCE MAJEURE

Except for the obligation to pay royalties and other sums under this Agreement, neither VICAL nor COH shall be liable for non-performance caused by any circumstance beyond its reasonable control, including, without limitation, the following: war, floods, earthquakes, other acts of God, industrial disputes, civil disobedience, strikes, fire, mobilization, changes in governmental regulation or interpretation, requisition, embargo, restriction and shortage of transport facilities, fuel, energy or supplies. Each party claiming the benefit of such an excuse agrees to notify the other Party promptly in writing of any such delay or failure in performance, and to resume performance as soon as is reasonably practicable.

#### 14. PUBLICATION

Neither Party shall use the name of the other Party or of any staff member or employee of the other Party in any publication or presentation which relates to the subject matter of this Agreement without the prior written consent of the other Party in each instance.

#### 15. RELATIONSHIP OF THE PARTIES

The relationship between the Parties under this Agreement is that of licensee and licensor. Neither Party shall have any right or authority whatsoever to assume or to create any obligation or

responsibility of the other Party or to bind the other Party in any manner.

#### 16. SEVERABLE PROVISIONS

The provisions of this Agreement are severable and if anyone or more provisions may be determined to be illegal or otherwise unenforceable, in whole or in part, the remaining provisions, and any partially unenforceable provisions to the extent enforceable, shall nevertheless be binding and enforceable.

#### 17. CONFIDENTIAL INFORMATION

The Parties agree to hold in confidence any Confidential Information disclosed by the other Party hereunder, and not to disclose any Confidential Information to any third party without the express written consent of the other Party, provided that either Party may disclose such information, in confidence, to its attorneys, auditors and professional advisors with a need to know, or to a court or tribunal as necessary to enforce this Agreement. The Parties shall use the same degree of care in protecting Confidential Information as each uses for its own information of like importance, but not less than a reasonable degree of care. Each Party will use Confidential Information only for purposes of furthering the purposes of this Agreement. With respect to any Confidential Information that is revealed by a Party to the other Party, this confidentially requirement will remain in force for a period of five (5) years following the date the Confidential Information is revealed, except that the terms of this Agreement and the amount of any payments hereunder shall remain confidential throughout the Term of this Agreement, except as expressly provided herein.

#### 18. ASSIGNMENT

VICAL shall not assign or transfer in any manner (including operation or law) this Agreement, nor any of its rights, obligations, or duties, without the prior written consent of COH, which consent COH may withhold in its sole discretion. Provided, however, VICAL may assign its rights under this agreement to a party that acquires all or substantially all of the assets of VICAL.

## 19. HEADINGS

Section and subsection headings are not to be considered part of this Agreement and are included solely for convenience and reference and in no way define, limit, or describe the scope of this Agreement or the intent of any provision.

## 20. NO CONSTRUCTION AGAINST DRAFTER

No provision of the Agreement, or any document delivered pursuant to the Agreement, shall be construed against any party, merely because that party drafted that provision or document.

## 21. PATENT MARKING

VICAL shall mark all Licensed Products, or their containers or manuals, in accordance with all applicable United States patent marking laws and laws of any foreign country where Licensed Products are sold.

## 22. EXPORT

VICAL shall be responsible for compliance with all export control regulations and obtaining any necessary licenses prior to the exportation of Licensed Products or technical information relating to Licensed Products.

## 23. ENTIRE AGREEMENT

This Agreement embodies and sets forth the entire agreement and understanding of the Parties and supersedes all prior oral and written agreements, understandings or arrangements relating to the subject matter of this Agreement. Neither Patty shall be entitled to rely on any agreement, understanding or arrangement that is not expressly set forth in this Agreement. This Agreement shall not be amended, modified, varied or supplemented except in writing signed by duly authorized representatives of the Parties.

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be executed as of the date and year first set forth above.

## VICAL, INCORPORATED

By: /s/ VIJAY B. SAMANT

Vijay B. Samant President and CEO Date: February 3, 2003

## CITY OF HOPE

By: /s/ LARRY A. COUTURE, PH.D.

Larry A. Couture, Ph.D. Sr. Vice President for Technology Development Date: February 3, 2003

## CERTIFICATION

#### I, Vijay B. Samant, certify that:

- 1. I have reviewed this quarterly report on Form 10-Q of Vical Incorporated;
- 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:
  - 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 4, 2011

By: /s/ VIJAY B. SAMANT

Vijay B. Samant Chief Executive Officer

## CERTIFICATION

#### I, Jill M. Broadfoot, certify that:

- 1. I have reviewed this quarterly report on Form 10-Q of Vical Incorporated;
- 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 4, 2011

By: /s/ JILL M. BROADFOOT

Jill M. Broadfoot 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

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. § 1350, as adopted), Vijay B. Samant, the Chief Executive Officer of Vical Incorporated (the "Company"), hereby certifies that, to the best of his knowledge:

- 1. The Company's Quarterly Report on Form 10-Q for the period ended September 30, 2011, to which this Certification is attached as Exhibit 32.1 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended; and
- 2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition of the Company at the end of the period covered by the Periodic Report and results of operations of the Company for the period covered by the Periodic Report.

Dated: November 4, 2011	
/s/ VIJAY B. SAMANT	
Vijay B. Samant Chief Executive Officer	

THIS CERTIFICATION "ACCOMPANIES" THE FORM 10-Q TO WHICH IT RELATES, IS NOT DEEMED FILED WITH THE SEC AND IS NOT TO BE INCORPORATED BY REFERENCE INTO ANY FILING OF THE COMPANY UNDER THE SECURITIES ACT OF 1933, AS AMENDED, OR THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED (WHETHER MADE BEFORE OR AFTER THE DATE OF THE FORM 10-Q), IRRESPECTIVE OF ANY GENERAL INCORPORATION LANGUAGE CONTAINED IN SUCH FILING. A SIGNED ORIGINAL OF THIS CERTIFICATION HAS BEEN PROVIDED TO THE COMPANY AND WILL BE RETAINED BY THE COMPANY AND FURNISHED TO THE SECURITIES AND EXCHANGE COMMISSION OR ITS STAFF UPON REQUEST.

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

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. § 1350, as adopted), Jill M. Broadfoot, the Chief Financial Officer of Vical Incorporated (the "Company"), hereby certifies that, to the best of her knowledge:

- 1. The Company's Quarterly Report on Form 10-Q for the period ended September 30, 2011, to which this Certification is attached as Exhibit 32.2 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended; and
- 2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition of the Company at the end of the period covered by the Periodic Report and results of operations of the Company for the period covered by the Periodic Report.

Dated: November 4, 2011
/s/ JILL M. BROADFOOT

Jill M. Broadfoot Chief Financial Officer

THIS CERTIFICATION "ACCOMPANIES" THE FORM 10-Q TO WHICH IT RELATES, IS NOT DEEMED FILED WITH THE SEC AND IS NOT TO BE INCORPORATED BY REFERENCE INTO ANY FILING OF THE COMPANY UNDER THE SECURITIES ACT OF 1933, AS AMENDED, OR THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED (WHETHER MADE BEFORE OR AFTER THE DATE OF THE FORM 10-Q), IRRESPECTIVE OF ANY GENERAL INCORPORATION LANGUAGE CONTAINED IN SUCH FILING. A SIGNED ORIGINAL OF THIS CERTIFICATION HAS BEEN PROVIDED TO THE COMPANY AND WILL BE RETAINED BY THE COMPANY AND FURNISHED TO THE SECURITIES AND EXCHANGE COMMISSION OR ITS STAFF UPON REQUEST.